REPUBLIC OF KENYA

KENYA LABORATORY BIORISK

MANAGEMENT CURRICULUM

April 2019

REPUBLIC OF KENYA

Kenya Laboratory Biorisk Management

CURRICULUM

2nd Edition

2019

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FOREWORD

This is the second edition of the Kenya National Laboratory Biosafety and Biosecurity Training Curriculum. The first was developed in 2014 and has been improved to embrace Biorisk Management (BRM) on the basis of a one-health approach. It is designed to strategically and professionally address the gaps, identified including biosecurity to generate a harmonized and integrated curriculum based on international best practices that would strengthen BRM systems for the human, animal and plant health sectors as well as other sectors. The Global Health Security Agenda (GHSA) initiative, through the World Health Organization's (WHO) Joint External Evaluation (JEE) exercise for Kenya recommended development of a common curriculum through - a one-health lens for biosafety and biosecurity training and training-of-trainers for the agriculture and health sectors as a priority action. This would not only strengthen national collaboration and coordination efforts among all the key sectors but also other players at regional level.

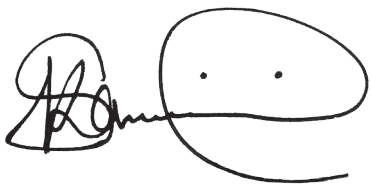
The improved curriculum namely Kenya Laboratory Biorisk Management Curriculum (KLBRMC), consists of eleven modules with a broad applicability to all sectors. These modules mainly emphasizes on bio-threat reduction, a priority activity particularly in the face of continued disease outbreaks, emerging and re-emerging disease pathogens and bioterrorism threats. In addition they support the country's compliance to its national, regional and global obligations.

The harmonized curriculum, which integrates of biosafety and biosecurity management, groups the target audience into three training levels or tracks. This is geared towards benefiting not only hands-on laboratory personnel, managers, supervisors, top management, field workers and support staff, but also other cadres in different sectors that are regularly involved in activities that would expose them to potentially infectious biological material or other hazards.

Proper utilization of this curriculum by all sectors is therefore encouraged in order to protect personnel from potentially harmful pathogens as well as secure infectious agents against accidental release or deliberate misuse to harm people, animals, plants, or the environment. Development of this Kenya Biosafety and Biosecurity Training Curriculum was through an initiative of the Ministry of Health and the Ministry of Agriculture Livestock, Fisheries and Irrigation, made possible through financial and technical support from its strategic development partners on BRM.

Finally both ministries are grateful to their staff, other strategic development partners

and other stakeholders in the area of Biorisk management for their contributions either technically or financially towards the development and roll out of this curriculum.



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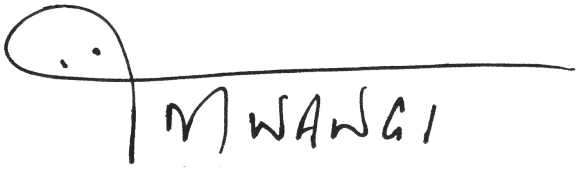

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PREFACE

This multi-sectoral one-health Laboratory Biorisk Management Curriculum has been developed as a result of the need to promote a shared culture of responsibility, reduce dual use risks, mitigate biological proliferation and deliberate use threats, and ensure safe custody of biological agents. It's also a derivative of World Health Organization (WHO) - Joint External Evaluation (JEE) exercise for Kenya through the Global Health Safety Agenda initiative.

Global increase in Biorisk resulting from disease outbreaks, emerging and re-merging disease pathogens and bioterrorism threats have also made the development of curriculum inevitable. Although continued biosciences research and biotechnological advances are important in providing intervention strategies for emerging disease threats to human, animal and plant sectors as well as enhancing food security, these activities are also associated with Biorisk. These could both be accidental, naturally occurring or even intentional, not only to laboratory and field workers but also to the community and the environment at large.

The country's agricultural, veterinary medical personnel working in laboratories as well as in the field, are constantly exposed to infectious agents thus raising concerns regarding the need to ensure proper biosafety and biosecurity standard practices are implemented to protect workers and the community at large. This curriculum therefore will go a long way in equipping these personnel with knowledge, skills and abilities necessary for effective assessment and management of Biorisk to be able to protect themselves, other workers, secure biological materials and also protect environment.

The Kenya Laboratory Biorisk Management Curriculum (KLBRMC) will be available for use within human, animal and plant sectors as well as other relevant sectors. The Ministry of Health and the Ministry of Agriculture, Livestock, Fisheries and Irrigation therefore encourages all partners and stakeholders to support its dissemination and implementation in order to strengthen BRM systems.

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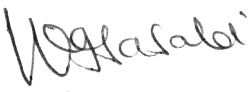
ACKNOWLEDGEMENT

The Kenya Laboratory Biorisk Management Curriculum was developed through a participatory process which involved various individuals, institutions and organizations and a result of efforts from many individuals. We would like to acknowledge with much appreciation the crucial role of the institutions, which contributed to this curriculum by offering technical, logistical and financial support for the formulation of the curriculum.

These include Government of Kenya through the Ministry of Health – National Public Health Laboratory Services (NPHLS) which took a leading role in the entire process, World Bank-East African Public Health Laboratory Network (EAPHLN), Defense Threat Reduction Agency (DTRA, USA), Centers for Disease Control and Prevention (CDC) Kenya, Kenya Medical Research Institute (KEMRI), Kenya Agricultural & Livestock Research Organization (KALRO), Kenya Plant Health Inspectorate Service (KEPHIS), Food and Agricultural Organization (FAO), Kenya, Sandia National Laboratories (SNL-USA) and National Institute for Public Health and the Environment (Ministry of Health, Welfare and Sport), Netherlands.

We would also like to express our gratitude and appreciation to all those individuals who offered technical and professional support and the writers of the modules of the curriculum. We acknowledge all individuals who tirelessly contributed towards the development of this Kenya Laboratory Biorisk Management Curriculum.



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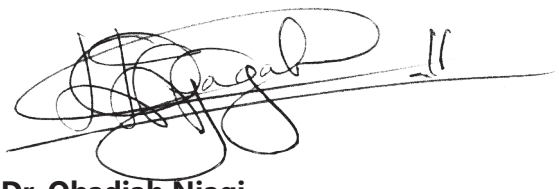

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ABBREVIATIONS AND ACRONYMS

AMP	Assessment, Mitigation and Performance
BRM	Biorisk Management
BSC	Biological Safety Cabinet
BSL	Biosafety Level
BWC	Biological Weapons Convention
BWTC	Biological Weapons and Toxins Convention
CDC	Centers for Disease Control and prevention
DGR	Dangerous Goods Regulations
DURC	Dual Use Research of Concern
EAPHLN	East African Public Health Laboratory Network
EOC	Emergency Operation Control
GBRMC	Global Biorisk Management Curriculum
GCLP	Good Clinical Laboratory Practices
GHSA	Global Health Security Agenda
GLWP	Good Laboratory Work Practices
GMO	Genetically Modified Organisms
HCW	Health Care Waste
IATA	International Air Transport Association
ICS	Incident Command System
IHR	International Health Regulations
IPC	Infection Prevention and Control
ISO	International Standards Organization
JEE	Joint External Evaluation
KALRO	Kenya Agricultural & Livestock Research Organization
KLBRMC	Kenya Laboratory Biorisk Management Curriculum
KEMRI	Kenya Medical Research Institute
KEPHIS	Kenya Plant Health Inspectorate service
LQMS	Laboratory Quality Management Systems
MTA	Material Transfer Agreement
OIE	World Organization for Animal Health
OSH	Occupational Safety and Health
OSHA	Occupational Safety Health Act
PEP	Post Exposure Prophylaxis

PPE	Personal Protective Equipment
SOP	Standard Operating Procedures
UN	United Nations
UNSCR	United Nations Security Council Resolution
VBM	Valuable Biological Material
WHO	World Health Organization
WIBA	Work Injury Benefits Act

1 Definition of Terms

For the purpose of this curriculum, the following biosafety and biosecurity terms are used:

1. Biosafety (GMO-related): Refers to the protection of human health and the environment from the possible adverse effects of the products of modern biotechnology. It focuses on the development of policy and procedures to prevent the trans-boundary movement of Genetically Modified Organisms (GMOs) that may have adverse effects on conservation and the sustainable use of biological diversity. (Cartagena Protocol on Biosafety; Food and Agriculture Organization of the United Nations, Rome 2009).

2. Laboratory biosafety: Refers to the protection of laboratory workers from unintentional exposure to biological agents and toxins in the laboratory, or the accidental release of biological agents and toxins into the environment. It focuses on the containment principles, technologies, and practices implemented in laboratories to prevent unintentional exposures and accidental release. (CWA 15793:2011 adapted from WHO Laboratory biosafety manual, third edition, 2004, WHO/CDS/CSR/LYO/2004.11).

3. Biosecurity (farm-related): Refers to the protection of biological resources from foreign and invasive species. It focuses on the development and implementation of mechanisms for the veterinary and agricultural sectors to prevent the introduction and spread of pests and diseases within a defined territory (www.farmbiosecurity.com.au/).

4. Laboratory biosecurity: Refers to the protection of, control over, and accountability for valuable biological materials within life-science laboratories. It focuses on security principles, technologies, and practices implemented in laboratories to prevent unauthorized access to, and the loss, theft, misuse, diversion, or intentional release of, valuable biological materials. (WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6).

5. Biorisk: Covers both biosafety and biosecurity and refers to the combination of the probability of occurrence of harm, and the severity of that harm, where the source of harm is a biological agent or toxin. Note: The source of harm may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release. (CWA 15793:2011, pending ISO/WD 35001), (adapted from ISO/IEC Guide 51:1999).

2 Introduction to the Curriculum

2.1 Title of the Program

Kenya Laboratory Biorisk (Biosafety and Biosecurity) Management Program.

2.2 Programme Philosophy

Harmonization of biorisk management principles with the aim of enhancing biosafety and biosecurity in the work place, instituting a culture of rigorous assessment of risks posed by infectious agents and toxins, and mitigating those risks for local, national, regional and international health, safety and security.

2.3 Background of the Curriculum

Globally, there are increased biorisks resulting from increased disease outbreaks, emerging diseases and bioterrorism. Biosciences research and biotechnological activities are important in providing intervention strategies for emerging disease outbreaks as well as enhancing food security. However, these activities are also associated with biorisks, which could either be accidental, naturally occurring or even intentional, not only to laboratory and field workers but also to the community at large and the environment. Nevertheless, since the aforementioned research activities foster the long - term health security and wellness of the public, animals, plants and the environment, a biorisk management strategy will ensure that such activities are conducted in a safe and secure manner. This will go a long way to promote both national and global bio - threat reduction Therefore, there is need to provide personnel working in the fields of biosciences and medicine with knowledge, skills and abilities for effective assessment and management of biorisks to protect workers, secure biological materials, and ensure a clean and safe environment.

Currently the public health laboratories utilize the Kenya National Laboratory Biosafety & Biosecurity Training (KNLBBT) Curriculum, consisting of five (5) modules that were developed and launched eight years ago by the Ministry of Health (MoH) with support from US Centers for Disease Control and Prevention (CDC) President's Emergency Plan for AIDS Relief (PEPFAR). The Kenyan veterinary livestock diagnostic and vaccine production laboratories currently use the Global Biorisk Management Curriculum (GBRMC), consisting of 44 course modules available free through Sandia National Laboratories (SNL) and US Department of Defense, Defense Threat Reduction Agency's Biological Threat Reduction Program (DTRA BTRP). Despite the successful implementation of the KNLBBT Curriculum,

gaps were identified which include: lack of adequate biosecurity content in MoH biosafety and biosecurity curriculum, lack of occupational health in veterinarian GBRMC material, lack of waste management for both chemical and electronic, lack of PPE (fit testing), lack of field biosafety and biosecurity module, lack of a module addressing pathogen security and accountability, lack of a module on access control mechanisms in laboratories to prevent release of biological toxins and lack of modules on plant biosafety and biosecurity. Furthermore, there was lack of coordinated and harmonized training for animal (wildlife and livestock), human and plant health sectors.

Additionally, emphasis through World Health Organization (WHO) and Global Health Security Agenda (GHSA) Joint External Evaluation (JEE) Tool, recommended for Kenya, as a priority action, to:

i) Develop a common curriculum for basic biosafety and biosecurity training and training-of-trainers between the human, animal and plant health sectors.
ii) Strengthen collaboration and coordination efforts among key sectors and
iii) Conduct joint biorisk assessments and biorisk management trainings in regions not currently covered by CDC-United States President's Emergency Plan for AIDS Relief funded partners.

In order to address these gaps, there was need to review the KNLBBT Curriculum and develop a harmonized and integrated curriculum for the animal, human and plant health sectors. The revised KNLBBT Curriculum presented below consists of eleven (11) modules with a broad applicability to the three sectors. These modules emphasize bio-threat reduction which is key to our nation and addresses our global obligations as outlined by: Biological Weapons and Toxins Convention (BWTC); United Nations Security Council Resolution (UNSCR) 1540; World Organization for Animal Health (OIE); World Trade Organization Sanitary & Phytosanitary (SPS) Measures and Agreement; Global Health Security Agenda (GHSA); Prevent Action Package - 3 (Biosafety & Biosecurity); World Health Organization (WHO); Kenya National Action Plan as a result of the Joint External Evaluation (JEE) and International Health Regulations (IHR).

2.4 Rationale of the Curriculum

The rationale of the curriculum is based on the need to train management and leadership, technical field workers and support staff in biorisk management within the animal, human and plant sector due to:

i. The ever-present and dynamic threats to exposure of infectious biological materials/agents and dual-use aspects for human, animal and plant health biological laboratories.

ii. Increased bioterrorism threat in case of unauthorized access and misuse of biological agents.
iii. The need to improve knowledge on best practices in biosafety and biosecurity among management, professional and support staff in animal, human and plant sectors.

2.5 Target Audience

This curriculum integrates Biorisk (biosafety and biosecurity) Management (BRM) into a harmonized BRM curriculum to benefit hands-on laboratory technicians, managers and supervisors, top management, field biological workers and support staff. This revised curriculum has grouped the above audiences into three training levels, namely Level I (Management and Leadership), Level II (Professionals and Technical/ Laboratory workers), and Level III (Support staff and Field workers.). The topics are the same but the depth of coverage differs for each level as well as the duration for each module. The three audiences mentioned above, have been grouped into three categories based on their responsibilities and anticipated level of risks associated with their work activities (Appendix I).

However, specific responsibilities or work activities of staff should be assessed and the appropriate Level I, II or III be delivered (such as, a cadre Level III may require additional depth in a specific area that is covered with more depth in Level II). An introduction to each module is provided under level I (Management and Leadership) that informs the module's intent. This introduction is provided only for level I in order to avoid repetition, but is applicable to all levels.

This curriculum will guide training of these audiences across animal, human and plant sectors towards achieving minimum requirements, practices and procedures that will minimize risks to personnel, facilities and the environment resulting from handling of biological agents. The curriculum will be implemented through participant guides and manuals and facilitators guides. For a quality biorisk management (BRM) training for the technical track, four trainers will be utilized to support a maximum class of twenty five participants. This has been informed by intensity of the module content and the practical sessions to be delivered within the 5 day of the training.

2.6 Curriculum Objectives

The curriculum is guided by the following objectives.

2.6.1 Overall Objective

A harmonized Biorisk Management Curriculum that enables workforce development of bioscience practitioners with knowledge and skills in biosafety and biosecurity among the human, animal and plant health sectors to enhance safety and security with working with biological agents.

2.6.2 Specific Objectives

The specific objectives are;

i. To equip the learners with knowledge on the policies and concepts of biosafety and biosecurity.
ii. To provide the learner with knowledge, skills and attitudes required for proper handling of biological agents.
iii. To enable the learner to manage biosafety and biosecurity risks through effective biorisk management actions that supports appropriate mitigation measures, monitors performance, and communicates outcomes of laboratory and field biorisk assessment.

2.7 Overall Expected Learning Outcomes

The expected overall learning outcomes for the three audience levels as appropriate to their roles, responsibilities, and contribution to biorisk management are to:

i. Describe and apply the principles of biosafety and biosecurity.
ii. Conduct biorisk assessments applicable to work activities.
iii. Describe and apply the biorisk mitigation strategies.
iv. Implement biorisk mitigation strategies.
v. Demonstrate positive affective, behavioral, and cognitive attributes to matters of biorisk management.

2.8 Specific Learning Outcomes for the Three Training Tracks

The specific learning outcomes for the three training tracks are as follows;

2.8.1 Leve l: Management and Leadership Track

By the end of the course the learner should be able to exhibit ability to do the following:

i. Describe the purpose of staff health programs; take steps towards establishing, and maintaining such programs.

ii. Recognize the relationship between relevant local and international regulations and legal requirements and biorisk management and take steps towards compliance.
iii. Establish biorisk management goals, objectives, roles and responsibilities.
iv. Support and participate in biorisk management assessment process.
v. Provide an enabling environment for the execution of a biorisk management programme.
vi. Enable staff training in biorisk management.
vii. Mobilize and lead a team to plan, monitor, evaluate and improve implementation of a biorisk management programme.
viii. Describe the human and financial resources needed to implement a biorisk management program at their Institutions.
ix. Integrate aspects of biorisk management into human resource performance.
x. Associate maintenance of facilities and equipment with biorisk management objectives.
xi. Be ready to secure necessary approvals and budgets to support the maintenance of facilities and equipment to implement biorisk management objectives.
xii. Formulate, disseminate and communicate policies and regulations regarding biorisk management.
xiii. Describe biosecurity mitigation strategies including physical security, information security, and transport security, material, control and accountability, and personnel reliability.
xiv. Be ready to secure necessary approvals and budgets to support biosafety and biosecurity mitigation measures such as biosafety and biosecurity equipment, consumables, and physical and information security.
xv. Describe the management's role in incident planning, preparation and response.

2.8.2 Level II: Professionals/Technical track

By the end of the course the learner should be able to exhibit ability to do the following:

i. Describe the meaning of an ethical code of conduct.
ii. Explain the meaning of dual -use equipment and expertise.
iii. Characterize and evaluate biosafety and biosecurity risks given a specific situation and work activity.
iv. Select a range of biosafety mitigation measures, based on biosafety risks, across the hierarchy of controls to support biorisk management objectives.
v. Select a range of biosecurity mitigation measures, based on biosecurity risks, threats and vulnerabilities, across the pillars of biosecurity mitigation strategies

to support biorisk management objectives.

vi. Outline the steps in a biorisk management incident response plan and support the development of a plan.
vii. Explain the roles and responsibilities in a biorisk management incident response plan.
viii. Explain the purpose of biorisk audits, inspection and assessments and contribute to developing of performance indicators specific to a biorisk management objective.
ix. Describe performance monitoring plans in accordance with stated BRM objectives.
x. Implement biorisk management policies and regulations.
xi. Demonstrate practices that adhere to GLWP/GCLP.
xii. Identify decontamination, disinfection, and waste disposal steps and materials to support a waste management plan.
xiii. Differentiate between categories of biological materials and required packaging and labeling.
xiv. Develop, validate and implement biosafety and biosecurity standard operating procedures.
xv. Contribute to training needs assessment on biorisk management.
xvi. Explain and develop appropriate biosecurity mitigation procedures based on risk assessment including physical, information, and transport security, material, control and accountability, and personnel reliability.
xvii. Classify chemicals with regards to chemical safety and compatibility to support the development of a chemical management plan.
xviii. Describe biosafety mitigation measures including how PPE, procedures, training, administrative controls, and engineered controls work to reduce biosafety risks.
xix. Classify and maintain records and documents with proper biosecurity mitigation measures.
xx. Appropriately select and use personal protective equipment for laboratory or field procedures and activities.
xxi. Appropriately manage waste in the laboratory or field.
xxii. Participate in selecting and carrying out decontamination and sterilization.

2.8.3 Level III: Support/Non-Technical track

By the end of the course the learner should be able to exhibit ability to do the following:

i. Define what is meant by an ethical code of conduct.
ii. Define biosafety, biosecurity, hazards, threats, and biorisk management

terminology.

iii. Describe the personal safety and security risks in biohazardous waste disposal.
iv. Describe their role and responsibility to policies and guidelines.
v. Describe their role and responsibility with sanitary and phytosanitary standard operating procedures.
vi. Recognize that those who handle biological materials, including animals, must use proper personal protective equipment as part of biosafety measures.
vii. Recognize packages containing biological materials and recall measures that support biosecurity and biosafety mitigation measures such as proper labels, packaging, chain of custody that together supports safe and secure shipment of biological materials.
viii. Recognize and know how to report incidents (such as accidents, injuries, theft or loss).
ix. Identify key incident command system elements and be ready to follow your institutional incident command structure.
x. Appropriately select and use personal protective equipment for laboratory or field procedures and activities.
xi. Appropriately manage waste in the laboratory or field.
xii. Participate in selecting and carrying out decontamination and sterilization.

2.9 Mode of Delivery

The curriculum will be offered through face-to-face teaching, e-learning, practical demonstrations, and group or individual work assignments. The resources required for effective delivery of the Biorisk Laboratory Management Curriculum include but are not limited to: facilitators, audio-visual equipment (LCD projectors, laptops, CD-ROMs), networked computers, white boards, flip charts, recommended text books, journals, participant guides and manuals, facilitators' guides.

2.10 Assessment

Assessments will be carried out using a variety of tools including but not limited to: pre- and post-tests, follow-up checklists, assignments, case scenarios with questions, questions and answers during the module delivery, and on-site post training evaluations.

2.11 Summary Level Duration

Table 1 shows the duration of the course.

Table 1: Summary Course duration

	Day 1	Day 2	Day 3	Day 4	Day 5
Management and Leadership					
Professionals/Technical staff					
Non - technical/Support staff					

3 Curriculum Course Schedules

3.1 Management and Leadership Track (1 day training)

Table 2 shows the management and Leadership track (1 day training)

Table 2: Management and Leadership track (1 day training)

Day 1	Monday or any appropriate day (1 day training)	Facilitators
8.00 – 8.15am	Registration	Facilitators
8.15 – 8.30am	Introductions and Opening Ceremony	Facilitators
8.30 – 9.00am	Objectives, Outputs and Participant expectations	Name of facilitators
9.00 – 9.30am	Module 1: Introduction to Biosafety and Biosecurity	Name of facilitators
9.30 – 10.00am	Module 2: Policies and Regulations in Biorisk Management	Name of facilitators
10.00 – 10.30am	Module 3: Laboratory Biosecurity	Name of facilitators
10.30 – 11.00am	Health Break	All
11.00 – 11.30am	Module 4: Field Biosafety and Biosecurity	Name of facilitators
11.30 – 12.00pm	Module 5: Biorisk Management	Name of facilitators
12.00 – 12.30pm	Module 6: Bio-containment and Facility Design	Name of facilitators
12.30 – 1.00pm	Module 7: Waste Management	Name of facilitators
1.00 – 2.00pm	Lunch Break	All
2.00 – 3.30pm	Module 8: Shipping and Transport of Biological Materials	Name of facilitators
3.30 – 4.00pm	Module 9: Incident Management & Emergency Response	Name of facilitators
4.00 – 4.30pm	Module 10: Occupational Safety and Health	Name of facilitators

4.30 – 5.00pm	Module 11: Roles and Responsibilities of Key Players in Biorisk Management	Name of facilitators
5.00 – 5.15pm	Closing remarks and award of certificates	Facilitators

3.2 Professional/Laboratory Track (5 day training)

Table 3 shows the professional/laboratory track training

Table 3: Professional/Laboratory track (5 day training)

Day 0	**Sunday Preplanning Meeting**	**Facilitators**
3.00-5.00pm	Verification of training materials, venue arrangement, division of modules/ responsibilities	
Day 1	**Monday:**	**Facilitators**
8.00 – 8.15am	Registration	Facilitators
8.15 – 8.30am	Introductions and Opening Ceremony	Facilitators
8.30 – 9.00am	Objectives, Outputs and Participant expectations	Name of facilitators
9.00 – 9.30am	Pretest	All
9.30 – 10.30am	Module 1: Introduction to Biosafety and Biosecurity	Name of facilitators
10.30 – 11.00am	Health Break	All
11.00 – 1.00pm	Module 1: Introduction to Biosafety and Biosecurity (Cont'd)	Name of facilitators
1.00 – 2.00pm	Lunch Break	All
2.00 – 4.00pm	Module 2: Policies and Regulations in Biorisk Management	Name of facilitators
4.00 – 4.30pm	Health Break	All
4.30 – 5.00pm	Day's Evaluation	Facilitators
Day 2	**Tuesday:**	**Facilitators**
9.00 – 9.30am	Recap of day 1	Facilitators
9.30 – 10.30am	Module 3: Laboratory Biosecurity	Name of facilitators
10.30 – 11.00am	Health Break	All
11.00 – 1.00pm	Module 4: Field Biosafety and Biosecurity	Name of facilitators
1.00 – 2.00pm	Lunch Break	All

2.00 – 4.00pm	Module 5: Biorisk Management	Name of facilitators
4.00 – 4.30pm	Health Break	All
4.30 – 5.00pm	Day's Evaluation	Facilitators
Day 3	**Wednesday:**	**Facilitators**
9.00 – 9.30am	Recap of day 1	Facilitators
9.30 – 10.30am	Module 6: Bio-containment and Facility Design	Name of facilitators
10.30 – 11.00am	Health Break	All
11.00 – 1.00pm	Module 7: Waste Management	Name of facilitators
1.00 – 2.00pm	Lunch Break	All
2.00 – 4.00pm	Module 8: Shipping and Transport of Biological Materials	Name of facilitators
4.00 – 4.30pm	Health Break	All
4.30 – 5.00pm	Day's Evaluation	Facilitators
9.00 - 9.30am	Recap of day 1	Facilitators
Day 4	**Thursday:**	**Facilitators**
9.00-9.30am	Recap of day 1	Facilitators
9.30 – 10.30am	Module 9: Incident Management & Emergency Response	Name of facilitators
10.30-11.00am	Health Break	All
11.00 – 1.00pm	Module 9: Incident Management & Emergency Response (Cont'd)	Name of facilitators
1.00 – 2.00pm	Lunch Break	All
2.00 – 4.00pm	Module 10: Occupational Safety and Health	Name of facilitators
4.00 – 4.30pm	Health Break	All
4.30 – 5.00pm	Day's Evaluation	Facilitators
Day 5	**Friday:**	**Facilitators**
9.00 – 9.30am	Recap of Day 4	Facilitators
9.30 – 10.00am	Post test	All
10.00 – 10.30am	Module 11: Roles and Responsibilities of Key Players in Biorisk Management	Name of facilitators
10.30 – 11.00am	Health Break	All

11.00–12.00pm	Module 11: Roles and Responsibilities of Key Players in Biorisk Management	Name of facilitators
12.00 –12.30pm	Discussions	Name of facilitator
12.30-1.00pm	Site visit to Laboratory	Name of facilitators
1.00 – 2.00pm	**Lunch**	**All**
2.00 – 3.00pm	Site visit to Laboratory (Report preparation)	Facilitators
3.00 – 4.00pm	Facility work plan	Name of facilitators
4.000 – 4.30pm	Course evaluation by participants	Name of facilitators
4.30pm	Official closure and award of certificates	Facilitators

3.3 Field and Support Staff (2 day training)

Table 4 shows field and support staff (2 day training)

Table 4: Field and Support staff (2 day training)

Day 1	Monday:	*Facilitators*
8.00 – 8.15am	Registration	Facilitators
8.15 – 8.30am	Introductions and Opening Ceremony	Facilitators
8.30 – 9.00am	Objectives, Outputs and Participant expectations	Name of facilitators
9.00 – 9.45am	Module 1: Introduction to Biosafety and Biosecurity	Name of facilitators
9.45 – 10.30am	Module 2: Policies and Regulations in Biorisk Management	Name of facilitators
10.30 – 11.00am	Health Break	All
11.00 – 11.45am	Module 3: Laboratory Biosecurity	Name of facilitators
11.45 – 2.30pm	Module 4: Field Biosafety and Biosecurity	Name of facilitators
12.30 –1.00pm	Discussion	Name of facilitators
1.00 – 2.00pm	Lunch Break	All

2.00 – 2.45pm	Module 5: Biorisk Management	Name of facilitators
2.45 – 3.30pm	Module 6: Bio-containment and Facility Design	Name of facilitators
3.30 – 4.00pm	Discussions	Name of facilitators
4.00 – 4.30pm	Day's Evaluation	Facilitators
Day 2	**Tuesday:**	**Facilitator**
9.00 – 9.30am	Recap of Day 1	Facilitators
9.45 –10.30am	Module 7: Waste Management	Name of facilitators
10.30 – 1.00am	Health Break	All
11.00 –11.45am	Module 8: Shipping and Transport of Biological Materials	Name of facilitators
11.45 –12.30pm	Module 9: Incident Management & Emergency Response	Name of facilitators
12.30 –1.00pm	Discussion	Name of facilitators
1.00 – 2.00pm	Lunch Break	All
2.00 – 2.45pm	Module 10: Occupational Safety and Health	Name of facilitators
2.45 – 3.30pm	Module 11: Roles and Responsibilities of Key Players in Biorisk Management	Name of facilitators
3.30 – 4.00pm	Course Evaluation by participants	Name of facilitators
400 – 4.30pm	Official closure and award of certificates	Facilitators

4 Module Content Description

4.1 LEVEL I: MANAGEMENT AND LEADERSHIP TRACK

Module 1: Introduction to Biosafety and Biosecurity

Introduction

This module will introduce the learners to the basic concepts of biosafety and biosecurity as the foundation to the other modules described in this curriculum. The learner will be enabled to understand the definitions of biosafety, biosecurity, and biorisk management (BRM) and the relationship of these concepts to the laboratory- Quality Management System (LQMS), universal standard precautions, good Clinical Laboratory Practices (GCLP), Good Laboratory Work Practices (GLWP), Infection Prevention & Control (IPC) practices. This module is designed to offer a common understanding of the terms and terminology used in biosafety (GMO-related and laboratory) and biosecurity (farm-related and laboratory), leading learners towards becoming more conversant in BRM.

Learning Outcomes

By the end of the module the learner should be able to:

i. Define the terminologies and explain the concepts of biosafety (GMO - related), laboratory biosafety, biosecurity (Field- related), laboratory biosecurity, BRM and IPC.
ii. Relate good Clinical Laboratory Practices (GCLP) and Good Laboratory Work Practices (GLWP) with BRM and how they serve to reduce biosafety and biosecurity risks.

Module Content Descriptions

Definition of terms: biosafety (GMO-related), laboratory biosafety, biosecurity (Field -related), laboratory biosecurity, BRM and IPC. Good clinical laboratory practice/Good laboratory practice and techniques: definition of GCLP/GLP, and good laboratory work practices and their integration to BRM.d good laboratory work practices is important to reduce risks associated with biological agents. Universal safety precautions are best practices when handling infectious agents.

Key Messages

i. Practicing biosafety, biosecurity, and good laboratory work practices is important to reduce risks associated with biological agents.
ii. Universal safety precautions are best practices when handling infectious agents.

References

i. National Infection Prevention and Control Guidelines for Health Care Services in Kenya, Second Edition, Nairobi, Kenya: Government of Kenya, 2015.
ii. Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-clinical Research and Development Non-serial Publication Series, revised edition, World Health Organization, 2010.
iii. United Nations Environment Programme. Convention on Biological Diversity. Cartagena protocol on Biosafety (http://www.biodiv.org/biosafety/default.asp).
iv. World Health Organization. Laboratory Biosafety Manual, Third edition. Geneva, 2004 (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_ 11/en/).
v. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
vi. World Health Organization. Dept. of Epidemic and Pandemic Alert and Response, (2006) Biorisk Management: laboratory biosecurity guidance. Geneva: World Health Organization.http://www.who.int/iris/handle/10665/69390.

Module 2: Policies and Regulations in Biorisk Management

Introduction

This module introduces the learner to the existence of local and international policies, regulations and best practices that govern BRM. Biorisk management policy is an integral part of the organization that establishes an overall sense of direction and sets the principles for BRM within the organization. The policy sets the organization's objectives for managing biorisks and delineates roles and responsibilities for safety and security. It also demonstrates that the organization and management are committed to implementing and monitoring an effective BRM system. It is the management's responsibility to develop, authorize, sing, and communicate a policy concerning the management of biorisks (biosafety and biosecurity). The policy should clearly state the overall BRM objectives and a commitment to improving BRM performance.

Learning Outcomes

By the end of the module the learner should be able to:

i. Be ready to draft policies, regulations, and guidelines on BRM.
ii. Describe international best practices in BRM.
iii. Explain how information security supports biosecurity objectives in a BRM system.
iv. Describe the national and international frame work for biosafety (GMO-related), laboratory biosafety, biosecurity (Field-related), and laboratory biosecurity.

Module Content Descriptions

Local policies, regulations and guidelines on BRM: Kenya biosafety and biosecurity policies governing biosafety and biosecurity practices and regulations **International guidelines and best practices on BRM:** Biorisk and international criminal law under the Rome statute (1998). **Information security:** importance of information security, regulations that govern VBM handling and transfer.

Key Messages

i. Policies, regulations and guidelines are key drivers for BRM since they enhance prevention and reduction of biorisk.
ii. Information security ensures prevention and reduction of public health threats attributable to handling and transfer of VBMs.

References

i. International Federation for the Biosafety Association www.IFBA.org
ii. IHR Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Implementation of IHR Core Capacities in States Parties http://www.who.int/ihr/Processes_of_IHR_Monitoring_framework_and_Indicators.pdf
iii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc.html
iv. CEN Workshop Agreement, January 2012. Ref. No. CWA 16393:2012 E
v. OIE Terrestrial Manual 2014; Chapter 3.5-Managing Biorisks. pp.12
vi. Bathula SR., Rakimol A. 2017. Global Trends in Biorisk management. Biorisk 12: 1-23

Module 3: Laboratory Biosecurity

Introduction

This module will cover the laboratory biosecurity measures, technologies, practices and procedures that are designed and implemented to prevent the unauthorized access, loss, theft, misuse, diversion, intentional release of pathogens, toxins and/or biological materials. Laboratory biosecurity describes the protection, control and accountability for VBMs within laboratories. Laboratory biosecurity is centered on five pillars of biosecurity (physical security, transport security, information security, personnel reliability, material control and accountability). The module will guide learners through the derivation of general concepts of assessment, mitigation, and performance as applied to biosecurity risks. The learners will gain knowledge on how to apply a comprehensive biological security system suitable for a laboratory. Learners will be able to relate principles of laboratory biosecurity to other situations outside the laboratory to protect Valuable Biological Materials (VBMs).

Learning Outcomes

By the end of the module the learner should be able to:

i. Facilitate biosecurity risk assessments and support the development of biosecurity risk mitigation measures.
ii. Facilitate development of a Laboratory Biosecurity Policy.
iii. Facilitate development of an Incident Response Action Plan that addresses laboratory biosecurity incidents and emergencies.
iv. Facilitate documentation of biological materials through internal and external transfers within and between facilities.
v. Integrate performance monitoring and improve the biosecurity program management system.
vi. Relate how to implement background checks in conjunction with regulatory and enforcement authorities and requirements.
vii. Explain "dual use" and bioethics as related to biological research and biosecurity.
viii. Evaluate the importance of bioethics and dual use research of concern (DURC) in BRM.

Module Content Description

International standard-setting organizations: International bodies and international legal instruments and agreements that constitute the governance framework and policies for laboratory biosecurity, the main International Biorisk conventions and treaties (CPB,

WHO, OIE, CWA, IPPC. **Identification of biosecurity stakeholders and their roles:** National stakeholders include relevant government agencies, agricultural producers and the food industry, scientific research institutes, specialist interest groups, nongovernmental organizations (NGOs) and the general public). **Pillars of biosecurity:** physical security, material control and accountability, personnel reliability, information security; transport security. **Biosecurity risk assessments:** Assessment of biological material to the risk of loss, theft, diversion taking into consideration the pillars of biosecurity. **Dual use research and Bioethics:** Dual Use Research of Concern (DURC), managing risks of dual use research, elements of bioethics, codes of conduct, principles of ethics guiding DURC research in plants, animals, and humans. **Emergency response procedures:** Fire brigade/effective fire safety program, emergency medical personnel, security personnel.

Key Messages

i. A proper biosecurity risk assessment is necessary before implementing an effective biosecurity program.
ii. Material control and accountability, transport security and information security complement other security components.
iii. Security awareness is critical in laboratory biosecurity.
iv. Dual use research of concern revolves around the potential of some research to be used for good or for ill.
v. Under National legislative frameworks for biorisk management and international criminal law under the Rome statute (1998) we, individually and as a nation, are criminally liable as a result of negligence applicable to biorisk issues.
vi. Importance of recognizing the innovation of DURC, however, it should be guided by ethics.

References

i. World Health Organization (2012). Laboratory biorisk management: strategic framework for action 2012-2016. Geneva: World Health Organization.
ii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html.
iii. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, Pg 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua=1.

iv. Kenya National Laboratory Biosafety & Biosecurity Training Curriculum, Ministry of Health, First Edition, 2016
v. CWA 15793:2011 Laboratory Biorisk Management Guidance (pending ISO/WD 35001)
vi. CWA 16939 Laboratory Biorisk Management – Guidelines for the implementation of CWA 15793:2008 http://www.uab.cat/doc/CWA16393
vii. OIE standard for animal health: www.oie.int/animal-welfare/oie- standards-and-international-trade
viii. ISPM standards for plant health: www.fao.org/docrep/013/i2080e/i2080e09.pdf

Module 4: Field Biosafety and Biosecurity

Introduction

This module will cover the biorisk protocols, procedures and processes required in the field setting to ensure safe handling, security and accounting for biological materials. These practices are established to protect workers, the community and the environment from harm resulting from intentional and unintentional release of biological materials. The module will familiarize learners with the unique challenges faced with implementing biorisk practices in environments outside the physical laboratory facility. It is based on recognition of the critical linkages between sectors and the potential for hazards to move within and between sectors, with intentional or unintentional system-wide consequences. Broadly biosafety and biosecurity measures implemented are intended to protect workers, community and environment from intentional and unintentional release to include the application of biosafety (GMO-related), field biosecurity (farm-related) procedures and laboratory biosecurity. This module will help the learners to prepare them to apply general concepts of biorisk assessment, mitigation, and performance in the field situation. The learner will delineate key concepts related to biosafety and biosecurity and their application in the field. Ultimately, the aim is to enhance national ability to protect one health, agricultural production systems, and the people and industries that depend on them.

Learning Outcomes

By the end of the module the learner should be able to:

I. Enumerate aspects of field biosafety and biosecurity including biological material control and accountability.
II. Recognize challenges and complications of containment and security in the field set-up.

III. Describe the importance of risk mitigation in the field.
IV. Communicate field bio-risks effectively.

Module Content Descriptions

Definition of additional terms used in field biosafety and biosecurity: Abiotic stress, biotic stress, bio-piracy, bio-prospecting, bioterrorism, bio-containment. **Fundamentals to field biosafety and biosecurity:** awareness, regulations, pest risk analysis, mitigation, monitoring, crisis communication to avoid public scare and panic. **Field facility requirements:** relevant physical security, facility design, waste management, pest and disease surveillance, outbreak investigations (human, animal and plant). **Biological material control and accountability:** inventories for biological agents, personnel reliability, controlled access and movement of samples across institutions and borders, and application of laboratory biosecurity-based risk mitigation in the field. **Biorisk issues in international trade and safety:** sanitary and phytosanitary standards procedures, regulation of infested biosecurity-controlled areas, power to enter infested biosecurity-controlled area.

Key Messages

i. Handling biological samples and pathogens in the field is associated with unique challenges that require biosafety and biosecurity procedures including accountability.
ii. Security awareness is crucial in the field.
iii. Biosecurity broadly applied is a strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks for the environment.

References

i. World Health Organization (2012). Laboratory biorisk management: strategic framework for action 2012-2016. Geneva: World Health
ii. Organization. Laboratory Biosafety and Biosecurity Policy Guideline
iii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html
iv. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, Pg 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua 1

v. Biosafety Act 2011. http://www.biosafetykenya.go.ke/Docs/The%20Biosafety%20(Environmental%20Release)%20Regulations,%202011(2).pdf
vi. Bail, C., Falkner R. and Marquard H. The Cartagena Protocol on Biosafety: Reconciling trade in biotechnology with environment and development. 2014: Routledge.
vii. Glossary of Biosecurity Managementttps://link.springer.com/content/pdf/bbm%3A978-94-007-1412-0%2F1.pdf
viii. Biological Safety Manual; Environmental Health and Safety- Michigan State University, 2017. https://ehs.msu.edu/_assets/docs/bio/msu-biosafety- manual.pdf
ix. Traynor P., Frederick R. and Koch M. "Biosafety in agricultural biotechnology." A workbook for training in biosafety risk assessment. Agricultural Biotechnology Support Project, 2002.
x. Sumner DA. Exotic Pests and Diseases Biology and Economics for Biosecurity. 2008, Iowa State Press. https://onlinelibrary.wiley.com/doi/book/10.1002/9780470290125

Module 5: Biorisk Management

Introduction

This module will provide awareness of BRM systems, tools and resources needed to begin implementation of the system. It provides a solid foundation to BRM concerning the Assessment, Mitigtion and Performance (AMP) model. This module is designed to establish key principles of BRM and to begin exploration of how to manage biorisks. Establishing a risk assessment process, implementing mitigation measures, and using performance indicators to evaluate the results of the implemented mitigation measures, and making improvements to the mitigation decisions based on performance measurement will be outlined in this module. The module will also provide guidance on the development of strategies to minimize the likelihood or consequences of the occurrence of biorisks. It also emphasizes the need for development of a biorisk communication strategy, with roles and responsibilities that will guide biorisk communications.

Learning Outcomes

By the end of the module the learner should be able to:

i. Define the various terms used BRM.
ii. Describe the key components of a BRM system.

iii. Explain the AMP model.
iv. Explain the importance of developing mitigation strategies for managing localized biosafety and biosecurity risks.
v. Summarize how to use information gathered from risk assessment to formulate specific risk mitigation improvement strategies.
vi. Appreciate the importance of biorisk management in health, plant and animal laboratories in the elimination or reduction of laboratory related risks.

Module Content Descriptions

Definitions of terms used in BRM: Hazard, risk, threat, biorisks & biorisk management. Concepts of BRM: Introduction to BRM, goals and objectives of a BRM system, BRM model (assessment, mitigation, performance [AMP] model), and elements of a BRM plan, training. **Biorisk assessment:** Definitions of terms used in risk assessment, and how to evaluate workplace risks. **Process and performance of risk mitigation:** managing biological risks - risk mitigation (such as, hierarchy of control - elimination, substitution, isolation, engineering control, administrative and Personal Protective Equipment [PPE], and application of the hierarchy of control for risk reduction). **Determining risk performance:** Determining acceptable risk (criteria for determination of acceptable risk). Monitoring and measuring effectiveness of controls, improvement cycle. **Risk assessment report and Biorisk communication:** Definition of risk communication, elements of biorisk assessment report communication (such as, communicator, message, recipient), communication strategy (such as, key goals of communication, multi-disciplinary approach).

Key Messages

i. Policies are crucial for implementing a successful biorisk management system.
ii. To effectively facilitate the execution of BRM, roles and responsibilities must be established and assigned.
iii. The AMP (Assessment, Mitigation and Performance) is key and powerful model for managing risks.
iv. The effectiveness and efficiency of communication process depends on the level of attention provided by the communicator and the recipient. The interpretation of the message by the recipient and the context in which the information is provided will influence the quality of the communication.
v. Implementing a comprehensive biorisk management system is critical to reduce risks associated with biological agents.

vi. A successful biorisk management program requires leadership, ongoing communication, and commitment from management.

References

i. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html
ii. OHS Risk Management Handbook, Standards Australia International, Sydney, 2004.
iii. WHO (2016). Laboratory biosafety Manual, 4th Edition
iv. WHO (2006). Biorisk Management, Laboratory biosecurity guidance
v. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition;2009
vi. CWA 15793:2011 Laboratory Biorisk Management

Module 6: Bio- Containment and Facility Design

Introduction

In describing the principles of biosafety, the elements of containment include primary and secondary containment. Containment is used to describe safe methods for managing infectious agents in the laboratory. Bio-containment is required in microbiological laboratories, field trials, screen houses, and post-entry quarantine facilities for containment of highly pathogenic organisms or agents (for instance, bacteria, viruses, toxins, animal pests, plant pests, bio-control organisms or associated articles). Bio-containment is usually achieved by isolation in environmentally and biologically secures cabinets, rooms, and quarantine facilities. This isolation prevents release into the surrounding environment during laboratory tests, biological material transfer, and scientific research and production. This module will introduce learners to the concept of bio-containment (for instance, primary, secondary, and tertiary containment) and its importance and application in BRM. The best recommendations on different primary, secondary, and tertiary containments required in a biomedical laboratory and animal and plant facilities will be provided to facilitate safe workflow. This module will also introduce learners to practice laboratory technique, security and safety equipment, and facility designs. The module discusses facility features in bio-containment laboratories and field facilities as part of the assessment of risk mitigation strategies.

Learning Outcomes

By the end of the module the learner should be able to:

i. Explain bio -containment features.
ii. Describe strategies for flow/practices in a facility design (for instance, separation of zones, and working clean to dirty) that support BRM.
iii. Define the roles and responsibilities in maintenance of laboratory equipment and the facility.

Module Content Descriptions

Principles of biosafety: Definitions of terms, elements of containment (for instance, primary, secondary, tertiary). **Bio-containment Measures:** work zones, biosafety levels, quarantine facilities, and sanitary and phytosanitary measures. **Engineering controls:** facility design, laboratory equipment, and maintenance. **Maintenance program for laboratory equipment and facility:** responsibilities, resources, and sustainability.

Key Messages

i. Engineering controls of facility must be properly maintained to support BRM.
ii. Containment facilities and laboratory equipment must be properly maintained to support BRM.

References

i. National policy guidelines for medical lab physical infrastructure;2014
ii. Centers for Disease Control and Prevention (2009), Biosafety in microbiological and biomedical laboratories HHS Publication No. (CDC) 21-1112 Revised December 2009; 5th Edition;
iii. Laboratory Biorisk Management: Biosafety and Biosecurity. Reynolds M. Salerno and Jennifer Gaudioso; CRS Press. 2015.
iv. World Health Organization (2004), Laboratory biosafety manual. WHO/CDS/CSR/LYO/2004.11– 3rd ed.
v. IPPC (2010). International standard for phytosanitary measures (ISPM 34) Design and operation of post entry quarantine stations for plants.-
vi. Laboratory Biorisk Management Standard ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf
vii. European Committee for Standardization CEN Workshop Agreement CWA 15793(2011)
viii. A management systems approach to Laboratory Biosafety.

ix. Safe and Secure Biomaterials: Matching resources to reality. Chatham House (2012) http://www.chathamhouse.org/events/view/182665
x. Guidelines for safe work practices in human and animal medical diagnostic laboratories (2012) http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm
xi. Kenya Laws, Plant Protection Act -CAP 324(2012)

Module 7: Waste Management

Introduction

Waste is a general term, which refers to material which is produced as a by -product or a remainder of a certain process. This module emphasizes the various categories of waste and gives guidance in addressing the management and disposal options that are available. It describes waste minimization methods, classification of waste types and describes the steps followed in waste handling (segregation, packaging, labeling, decontamination, collection, storage, transport and disposal), safety precaution requirements as well as developing an elaborate and verifiable waste management plan. It also includes concepts of waste management in the field.

Learning Outcomes

By the end of the module the learner should be able to:

i. Relate the elements of waste management from various sectors and the importance of effective waste management plans.
ii. Identify responsible individuals within their institute to draft institutional policies on waste management.
iii. Identify legal requirements for waste management.

Module Content Descriptions

Definitions of terms: Waste management **Classification of wastes:** health care waste (HCW)/biological waste. **Management of various wastes:** chemical waste management, electronic waste management, HCW/biological waste. **Elements of waste management plan:** waste minimization, waste identification, waste segregation, waste decontamination, waste transport, and waste disposal methods. **Field waste management:** definition and classification.

Key messages

i. Proper classification of waste guides the disposal methods to be used.
ii. Waste management is key to safe and healthy working environment.

References

i. World Health Organization, 2004. Laboratory biosafety manual Third edition (www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf)
ii. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
iii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html
iv. Kenya-Ministry of Health, National Health Care Waste Management Plan 2008-2012
v. National Health Care Waste Management Plan for Kenya 2008-2012_a.pdf)
vi. Kenya, Ministry of Health, National Infection Prevention and Control Guidelines for Health Care Workers, December 2010.
vii. CEN Workshop Agreement 15793.2011. Laboratory Biorisk Management (http://www.uab.cat/doc/CWA15793_2011)

Module 8: Shipping and Transport of Biological Materials

Introduction

This module introduces learners to guidelines and regulatory requirements including, Guidelines from World Health Organization (WHO) and the International Air Transport Association Dangerous Goods Regulations (IATA/DGR) on shipping of dangerous goods and infectious material. The focus of the training is on how to properly classify, package, mark, label, and complete the appropriate paperwork on shipping of dangerous goods and infectious material. It reminds learners of the risks associated with infectious materials. The learners will be introduced to program management requirements and security issues associated with transporting and shipping infectious substances. The module will provide awareness of international dangerous goods shipping regulations and other requirements as they relate to infectious substances. Risk assessment principles will be applied to learn how to properly classify biological agents as Category A or Category B infectious substances, or those that are exempt from shipping regulations, as per guidelines and

regulations.

Learning Outcomes

By the end of the module the learner should be able to:

i. Define terminology consistent with biosafety and biosecurity in line with shipment.
ii. Outline the statutory requirements, and national and international regulations for packaging and shipping of biological materials.
iii. Maintain and support shipping programs of organizations/institutes to include training and/ or courier contract services with an appropriate supplier.

Module Content Descriptions

An overview of classification of biological agents as Category A, Category B infectious and exempt substances; **Definition of terms:** Bio hazardous material/substance, Infectious substances and categories, Genetically Modified Organisms (GMOs), Dangerous goods. **Regulations for shipment and transport of infectious materials:** National regulations governing the shipment and transport of infectious substances, International regulations for shipment and transport of dangerous goods and infectious materials. An international regulation for an institution's shipping responsibilities on maintaining a shipping program including training records and legal responsibilities.

Key Messages

i. National and international regulatory requirements (e.g., statutes and policies) affect shipping and transport of biological materials.
ii. Different countries may have different requirements for importing and exporting biological materials.
iii. It is important to consider the import and export requirements of both the countries of origin and destination.

References

i. Global Biorisk Management Curriculum & Core Documents, Sandia National Laboratories curated library on behalf of US DTRA CBEP.
ii. Laboratory Biosafety and Biosecurity Policy guideline, 1st edition, MOH Kenya, Nairobi, Kenya: Government of Kenya, 2014.
iii. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care

Services in Nairobi, Kenya: Government of Kenya, December 2010.
iv. World Health Organization. Laboratory Biosafety Manual, 3rd edition Geneva, 2004
v. (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004 _1 1/en/)
vi. World Health Organization (WHO), Transport of Infectious Substances, Geneva, Switzerland WHO 2004
vii. World Health Organization (WHO), A guide for shippers of Infectious Substances, 2015. www.who.int/ihr/infectious_substances/en/
viii. International Air Transport Authority (IATA) Dangerous Goods Regulations and Infectious Substances Shipping Guidelines. https://www.iata.org/what we do/cargo/dgr/Pages/index.aspx

Module 9: Incident Management & Emergency Response

Introduction

This module will provide knowledge and skills required for incident management and emergency response. It describes in detail definitions of terms, incident management, and action plan and how the different levels of personnel can implement these. The module will equip learners with skills and knowledge to respond to incidents at the work place in a timely and effective manner, including minimizing risks to staff and first responders. It also provides knowledge on how to formulate messages to communicate risk.

Learning Outcomes

By the end of the module, the learner should be able to:

i. Describe terms used in incident management and emergency response.
ii. Relate elements of incident response, describe an incident response plan and containment, evaluation, and reporting in the work place.
iii. Describe an Incident Action Plan to include incident strategies and goals.
iv. Relate an Incident Command System (ICS) with respect to defined roles and responsibilities.
v. Explain the various types of emergencies and their consequences, including those related to biosafety and biosecurity.
vi. Value the significance of incident management.
vii. Explain mobilization in incident management.

Module Content Descriptions

Definitions of terms: Incident, emergency, incident scenarios, **Incident response and management:** elements of incident response, incident response plan, incident containment, incident evaluation, incident reporting. **Incident Action plan:** (for instance, incidents goals, operational period objectives, response strategies, assignment list with specific tasks, critical situation, updates and assessments, resource status updates, health and safety plan (to prevent responder injury/illness). **Incident command system:** (for instance, command operations, planning;-biosafety, biosecurity and environment, logistics, intelligence). **Incident and emergency reporting/ communication:** (for instance, goals of reporting; incident reporting strategy; incident response evaluation and improvement. **Emergency Operation Centre (EOC)** national public health emergency operations centre that functions to coordinate multi- sectoral rapid response teams and on the identification of a public health emergency. The Plant protection Service in the Ministry of Agriculture, Livestock and Fisheries (MALF) is responsible for plant health pest outbreak responders while Ad hoc committee for animal health responders.

Key Messages

i. An Incident Command System (ICS) is an important standard tool in managing incident and emergencies.
ii. To successfully contain an incident, it is important to develop an effective incident action plan, which includes mobilization of resources.
iii. Both biosafety and biosecurity incidents are included in incident action plan.

Module 10: Occupational Safety and Health

Introduction

This module will cover a cross-disciplinary area concerned with protecting the safety, health, and welfare of people engaged in work or employment. The goal of occupational safety and health programs is to promote physical, mental, and social well-being of workers in addition to providing a safe and healthy work environment. Occupational Safety and Health (OSH) may also protect co-workers, family members, employers, customers, suppliers, nearby communities, and other members of the public who are impacted by the workplace environment. This is accomplished by limiting opportunities for exposure, promptly detecting and dealing with exposures, and using information gained from work injuries to further enhance safety precautions.

This module presents Occupational Safety and Health (OSH) as the science of the anticipation, recognition, evaluation, and control of hazards arising in or from the workplace that could impair the health and well-being of workers, taking into account the possible impact on the surrounding communities and the general environment, in accordance of the OSH Act 2007. Its emphasis is on risk management for all types of hazards present in the workplace to promote the safety and health of workers, the public, and environment. This module will enlighten the learners on issues related to the well-being of workers in the workplace environment, as well as the hazards they are potentially exposed to and how the risks can be managed to protect the worker. The module will also cover issues related to policy, regulations, and guidelines on OSH that are related to facility operations.

Learning Outcomes

By the end of the module the learner should be able to:

i. Describe legal and regulatory framework, policies, regulations, and guidelines on OSH.
ii. Describe National, County and facility level organizational structure.
iii. Outline the responsibilities of management to protect the safety and health of the worker.
iv. Support the implementation of OSH through provision of resources.

Module Content Descriptions

Introduction: Objectives, scope, rationale, policy statement. Organizational structure: National, Counties and Facilities. Roles and responsibilities in relation to OSH: management and employees. Legal and regulatory framework (OSHA Act 2007 and WIBA Act 2007) policies, regulations, and guidelines, compliance, disciplinary action and compensation, monitoring and evaluation, and operational research.

Key Messages

i. OSH requires employer and worker collaboration in addressing occupational related safety issues, at all times, to protect the safety and health of the worker and to further promote the moral, economic, morale, and productivity of all staff members.
ii. Understanding regulations of OSH is important to provide guidance on employee/ employer rights and obligation.

References

i. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, December 2010. PP 83 - 91.

ii. World Health Organization. Laboratory biosafety manual. Third edition. Geneva, World Health Organization, 2004 WHO/CDS/CSR/LYO/2004.11. Part I, II & IV 3.

iii. Laws of Kenya. Work Injury Benefits Act (WIBA). CHAPTER 236. Revised Edition 2012 [2007]. Published by the National Council for Law The Parliament of Kenya Occupational Safety and Health Act, 2007.

iv. Occupational4Safety and Health Policy Guidelines for the Health Sector in Kenya, July 2014.

Module 11: Roles and Responsibilities of Key Players in Biorisk Management

Introduction

This module will cover aspects of roles and responsibilities with regards to BRM of key top managers, middle level managers, biorisk management advisors, technical staff as well as non-technical, field workers and support staff involved in BRM. It will also emphasize the importance of defining roles and responsibilities, which should be clearly communicated within the organization in terms of the actions that need to be taken, and who has required authorities and responsibilities. Defining roles and responsibilities of key players will be performed at various cadre levels and settings such as government agencies, laboratories and fields.

Learning Outcomes

By the end of the module the learner should be able to:

i. Describe the roles and responsibilities of various cadre levels of the institute/ organization.

ii. Set out/establish specific roles and responsibilities for key players in the institution for effective implementation of BRM.

iii. Document and communicate specific roles and responsibilities to key players for effective implementation of BRM.

iv. Guide how to identify roles, responsibilities and communicate BRM tasks, policies and procedures.

v. Understand their obligations and responsibilities in ensuring the success of institutional BRM program.

vi. Identify and describe the roles and responsibilities for individuals managing biosecurity risks within the organization/institute.

Module Content Descriptions

Management in Implementation of BRM Program: Various responsibilities may include: Coordination, Policy development, Framework for biorisk implementation, Resource allocation, Inculcation of safety culture, Fostering compliance and enforcement of the legislation and guidelines, Performance monitoring and evaluation, Managing human performance and workforce, Rewards and sanctions, Setting/Establishing Roles and Responsibilities, Assigning mandates/duties, Background check for personnel reliability, Document and communicate roles and responsibilities. **BRM Advisor in implementation of BRM program:** Various responsibilities may include: Provision of technical expertise and guidance, Development and approval of BRM plans, Monitoring work performance by team members, Plan and perform regular biorisk assessments, Compliance with OSH, Adherence to bioethics principles. Laboratory Manager in implementation of BRM program: Coordination of lab BRM, Prioritization of allocated resources, Lead document development (manuals, SOPs, protocols), Inventory management (equipment, chemicals, VBM), Audits of bio-containment facilities, Access control allocation, Training and mentoring of laboratory personnel, Plan and oversee the calibration and validation of lab equipment, Ensure compliance with OSH, Adherence to principles of bioethics.

Key Messages

i. Roles and responsibilities are established and assigned to key players to facilitate the execution of effective biorisk management.
ii. Every individual has a role to play in a biorisk management program in an institution.
iii. Top management is responsible for the formulation of BRM policies and is critical in human, financial and infrastructure resource allocation for the success of biorisk management program.

References

i. CEN (European Committee for Standardization) (2011). CEN Workshop agreement (CWA) on Laboratory Biorisk Management (CWA 15793). CEN Management Centre: Avenue Marnix 17, B-1000 Brussels, Belgium.

4.2 LEVEL II: PROFESSIONAL AND TECHNICAL TRACK

Module 1: Introduction to Biosafety and Biosecurity

Learning Outcomes

By the end of the module the learner should be able to:

i. Define the terms and explain the concepts of biosafety (Laboratory, farm-related, GMO-related, and aquatic animals/plants), biosecurity (Laboratory, farm-related, GMO-related, and aquatic animals/plants), BRM and IPC.
ii. Describe the principles of biosafety and biosecurity in laboratory and field.
iii. Relate Good Clinical Laboratory Practices (GCLP) and Good Laboratory Work Practices (GLWP) with BRM and how they serve to reduce biosafety and biosecurity risks.

Module Content Descriptions

Definitions of terms: Biosafety (Laboratory, farm-related, GMO-related, and aquatic animals/plants), biosecurity (Laboratory, farm-related, GMO-related, and aquatic animals/plants), BRM and IPC. **Concepts of biosafety in the laboratory and field:** Work practices, containment levels (primary and secondary), hierarchy of controls (elimination/substitution, engineering controls, administrative controls, practices and procedures, PPE), application of laboratory biosafety practices in the field, and biosafety (GMO-related practices. Concepts of biosecurity in the laboratory and field: Principles of a biosecurity program management system (for instance, physical security, personnel reliability, material control and accountability, transport security, and information security), concepts of biosecurity in relation to biosafety programmes, application of laboratory biosecurity practices in the field, and biosecurity (farm-related) practices. **Standard laboratory work practices and techniques:** universal standard precautions, risk of inadequate GLWP, chain of infection.

Key Messages

i. Practicing biosafety, biosecurity and good laboratory work practices is important to reduce risks associated with biological agents.
ii. Appreciate the importance of implementing good laboratory work practices to reinforce and strengthen biosafety and biosecurity.
iii. Universal safety precautions are best practices when handling infectious agents.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi,

Kenya: Government of Kenya, 2014.
ii. National Infection Prevention and Control Guidelines for Health Care Services in Kenya, second edition, Nairobi, Kenya: Government of Kenya, 2015.
iii. Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-clinical Research and Development Non-serial Publication Series, revised edition, World Health Organization, 2010.
iv. United Nations Environment Programme. Convention on Biological Diversity. Cartagena protocol on Biosafety (http://www.biodiv.org/biosafety/default.asp).
v. World Health Organization. Laboratory Biosafety Manual, Third edition. Geneva, 2004 (http://www.who.int/csr/resources/publications/biosafety/ WHO_CDS_ CSR_LYO_200 4_ 11/en/).
vi. World Health Organization. Dept. of Epidemic and Pandemic Alert and Response. (2006) Biorisk Management: laboratory biosecurity guidance. Geneva: World Health Organization. http://www.who.int/iris/handle/10665/69390.

Module 2: Policies and Regulations in Biorisk Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Recognize and comply with the international policies, regulations, guidelines standards and best practices in BRM.
ii. Describe the local policies, regulations, guidelines and best practices in BRM.
iii. Relate the relevant legislation, regulations, guidelines and best practices in BRM.
iv. Describe the national and international frame works for biosecurity.

Module Content Descriptions

International Guidelines and Best Practices in BRM: Definitions of terms, outline of the international policies, regulations, guidelines and best practices (Global biosafety and biosecurity best practices, guidelines and regulations, WHO Biorisk manual, OIE manual). **Local policies, regulations and guidelines on BRM:** Definition of terms, outline of the national policies, regulations, guidelines and best practices (Kenya National biosafety and biosecurity policies governing biosafety and biosecurity practices and regulations). **OSH regulatory framework:** policy, regulations and guidelines, and OSH laws awareness training.

Key Messages

i. Local policies, regulations and guidelines are important for implementing BRM.

ii. Local documents augment international regulations, guidelines, and best practices.
iii. Intellectual Property Rights (IPR) safeguards the interests of the individual, institution, and the state.
iv. National and international policies and regulations provide a governance framework for biosecurity.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
ii. Laboratory Biosecurity Guidance WHO/CDS/EPR/2006.6
iii. International Federation for the Biosafety Association www.IFBA.org
iv. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd-gbrmc.html
v. CEN Workshop Agreement, January 2012. Ref. No. CWA 16393:2012 E
vi. OIE Terrestrial Manual 2014; Chapter 3.5-Managing Biorisks. pp.12
vii. Bathula SR., Rakimol A. 2017. Global Trends in Biorisk management. Biorisk 12: 1-23

Module 3: Laboratory Biosecurity

Learning Outcomes

By the end of the module the learner should be able to:

i. Define laboratory biosecurity terms and explain the importance of biosecurity.
ii. Define insider and outsider threats.
iii. Demonstrate knowledge on the five pillars of biosecurity-(physical security, transport security, information security, personnel reliability, and material control and accountability).
iv. Define and conduct a biosecurity risk assessment.
v. Apply the use of graded protection and balanced security in the application of biosecurity pillars.
vi. Discuss the main torts and negligence's likely to arise in the course of biorisk handling and management.

vii. Explain how regularly updating and checking inventories supports biosecurity objectives.
viii. Implement measures to prevent unauthorized access to controlled information.
ix. Implement measures to support physical security and personnel reliability.
x. Explain the importance of early reporting and the chain of communication in the implementation of biosecurity response measures.
xi. Describe the value and necessity to ensure laboratory biosecurity.
xii. Define principles of bioethics and explain the elements of bioethics.
xiii. Describe the value of observing ethical code of conduct, practice and standards.
xiv. Outline common ethical dilemmas and actions to be taken.
xv. Explain bioethics and dual use principles in the practice of BRM.

Module Content Description

Definition of Terms: Laboratory biosecurity, biosecurity risk assessment, dual use research, bioethics. **International standard-setting organizations:** International bodies and international legal instruments and agreements that constitute the governance framework and policies for biosecurity, the main International Biorisk conventions and treaties. **Pillars of biosecurity:** physical biosecurity, material control and accountability, personnel reliability, document and information security, transport security, concept of graded protection and balanced security, elements of a laboratory biosecurity plan. **Biosecurity risk assessments:** Assessment of the suitability of personnel, training and adherence to VBM protection, assessment of biological material to the risk of loss, theft, diversion taking into consideration the pillars of biosecurity. **Dual use research and Bioethics:** Introduction to DURC (human, plants and animals), overview of the risks associated (risk analysis), managing risks of dual use research, elements of bioethics, ethical code-legitimate research, codes of conduct and codes of practice, confidentiality, diversity/consent, safety, accountability, professionalism, principle of bioethics (non-maleficence, maleficence, beneficence, health maximization, respect for autonomy, justice, proportionality), principles of ethics guiding DURC research in plants, animals, and humans. **Emergency response procedures:** Fire brigade/effective fire safety program, emergency medical personnel, security personnel.

Key Messages

i. A proper laboratory biosecurity risk assessment is necessary before implementing an effective biosecurity program.

ii. Material control and accountability, transport security, and information security complement other security components.
iii. Security awareness is critical in laboratory biosecurity.
iv. Dual use research of concern revolves around the potential of some research to be used for good or for ill.
v. Bioethics is an integral part of all biological research activities.
vi. Dual-use issues are guided by bioethics.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
ii. World Health Organization (2012). Laboratory biorisk management: strategic Framework for action 2012-2016. Geneva: World Health Organization.
iii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd-gbrmc.html
iv. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, PG 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua=1
v. CWA 15793:2011 Laboratory Biorisk Management Guidance (pending ISO/WD 35001)
vi. CWA 16939 Laboratory Biorisk Management - Guidelines for the implementation of CWA 15793:2008 http://www.uab.cat/doc/CWA16393.
vii. BMBL: 5 th Edition 2007 ; https://www.cdc.gov/biosafety/publications/bmbl5/

Module 4: Field Biosafety and Biosecurity

Learning outcomes

By the end of the module the learner should be able to:

i. Explain biosafety and biosecurity under field conditions.
ii. Demonstrate procedures for that are suitable for securing biological agents and toxins outside of the laboratory.
iii. Demonstrate biological material/sample collection, handling, storage and transport in the field.
iv. Recognize the need for packaging best practices.
v. Apply AMP model of BRM in the field.

Module Content Descriptions

Definition of terms used in field biosafety and biosecurity: Bioterrorism, bio-piracy, bio-prospecting, bio-containment. Fundamentals to field biosafety and biosecurity: awareness, regulations, pest risk analysis, mitigation, and monitoring. Field facility requirements: relevant physical security, facility design, waste management, pest and disease surveillance, safe handling of infectious materials in the field, genetic resources and vectors for modification, risk analysis for transformants and transgenics - humans and environment, introduction to sample handling/transportation of biological material, safety audits for Confined Field Trials (CFTs) and occupational field safety and health, outbreak investigations (human, animal and plant). **Biological material/sample accountability:** inventories for biological agents and toxins, controlled access and movement of VBMs across institutions and borders, securing biological agents and toxins in the field, personnel accountability, field sample preservatives (formalin, ethanol, methanol, dry ice, liquid nitrogen), application of laboratory biosecurity-based risk mitigation in the field. **Biorisk issues in international trade and safety:** sanitary and phytosanitary standards procedures, documentation, treatment or destruction of animals, plants and their products suspected of being infested by regulated pest or disease, regulation of infested biosecurity controlled areas, detention and testing of animals, plants and their products suspected of being infested by regulated pest or disease.

Key Messages

i. Laboratory biosafety and biosecurity measures can be adapted to field biosafety and biosecurity.
ii. Laboratory - based risk management can be utilized in the field to identify and mitigate field biorisks.
iii. Application of laboratory biosecurity measures complement other field biosafety and biosecurity components but have unique challenges for implementation.
iv. Security awareness is crucial in the field.
v. Benefits of biosecurity include early recognition of emerging pest and disease threats, ability to consider complete exposure pathways, integrated responses to threats, rationalization of controls, improved emergency preparedness and response, overall ensuring the more efficient use of available resources.
vi. Biosecurity broadly applied is a strategic and integrated approach to analyzing and managing relevant risks to human, animal and plant life and health and associated risks for the environment.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
ii. World Health Organization (2012) . Laboratory biorisk management: strategic framework for action 2012-2016. Geneva: World Health Organization. Laboratory Biosafety and Biosecurity Policy Guideline.
iii. Global Biorisk Management Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program
iv. IPPC (2010). International standard for phytosanitary measures (2010) ISPM 34), Design and operation of post entry quarantine stations for plants.
v. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, Pg 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua=1
vi. Biosafety Act 2011. http://www.biosafetykenya.go.ke/Docs/The%20Biosafety%20(Environmental%20 Release)%20Regulations,%202011(2).pdf
vii. Bail, C., Falkner R. and Marquard H. The Cartagena Protocol on Biosafety: Reconciling trade in biotechnology with environment and development. 2014: Routledge.
viii. Glossary of Biosecurity Management https://link.springer.com/content/pdf/bbm%3A978-94-007-1412-0%2F1.pdf
ix. Biological Safety Manual; Environmental Health and Safety- Michigan State University, 2017. https://ehs.msu.edu/_assets/docs/bio/msu-biosafety- manual.pdf.
x. Traynor P., Frederick R. and Koch M. "Biosafety in agricultural biotechnology." A workbook for training in biosafety risk assessment. Agricultural Biotechnology Support Project, 2002.
xi. Sumner DA. Exotic Pests and Diseases Biology and Economics for Biosecurity. 2008, Iowa State Press. https://onlinelibrary.wiley.com/doi/book/10.1002/9780470290125.
xii. National Policy guidelines for laboratory specimen referral networks, 2014.
xiii. IPPC (2010) International Standards for Phytosanitary measures Design and operation of post entry quarantine facility for plants.

Module 5: Biorisk Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Explain the Biorisk management system and discuss the key components of BRM.
ii. Explain the AMP model.
iii. Describe the importance of conducting biosafety and biosecurity risk assessments to drive mitigation measures and performance.
iv. Provide an example of how to use the information gathered from risk assessment to formulate specific risk mitigation strategies.
v. Apply effective communication skills in delivering Biorisk findings to different stakeholders.
vi. Describe the roles and responsibilities of stakeholders in regards to biorisk management.
vii. Appreciate the importance of Biorisk management in health, plant and animal laboratories in the elimination or reduction of laboratory related risks.

Module Content Descriptions

Definitions of terms: Risk: hazard; Biorisk management. Concepts of Biorisk management: introduction to Biorisk management, goals and objectives of a Biorisk management system, BRM approach, laboratory biosecurity as a complement to laboratory biosafety, BRM AMP model, countering Biorisks, elements of a laboratory BRM plan, and training. **Biorisk assessment:** definitions of terms used in risk assessment, risk characterization and evaluation, types of biological risks in workplace, biosafety and biosecurity risk assessment process, environmental risk (for instance, workplace hazards and environment risks), and purpose of evaluating workplace risk. **Process and performance of risk mitigation:** managing biological risks-risk mitigation (for instance, hierarchy of control - elimination, substitution, isolation, engineering control, administrative and PPE, and application of the hierarchy of control for risk reduction). **Determining effective performance:** determining acceptance of risk (for instance, criteria for determination of acceptable risk). Monitoring and measuring effectiveness of controls and improvement cycle. **Risk assessment report and Biorisk communication:** Definition of risk communication, risk assessment report (for instance, risk assessment report format), elements of Biorisk assessment report communication (for instance, communicator, message, recipient), communication channels, communication strategy (for instance, key goals of communication, multi-disciplinary approach).

Key Messages

i. The commitment of all players in an institution is important in policy and biorisk management plan development in order to establish and implement a successful

BRM system.

ii. To effectively facilitate the execution of BRM, roles and responsibilities must be established and assigned.

iii. The AMP (Assessment, Mitigation and Performance) is key and powerful model for managing risks.

iv. Appropriate mitigation measures, based on risk, are crucial for reducing biosafety and biosecurity risks.

v. The effectiveness and efficiency of communication process depends on the level of attention provided by the communicator and the recipient. The interpretation of the message by the recipient and the context in which the information is provided will influence the quality of the communication.

References

i. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc.html

ii. OHS Risk Management Handbook, Standards Australia International, Sydney, 2004.

iii. WHO (2016). Laboratory biosafety Manual, 4th Edition

iv. WHO (2006). Biorisk Management; Laboratory biosecurity guidance

v. Centers for Disease Control and Prevention (2009), Biosafety in microbiological and

vi. Biomedical laboratories HHS Publication No. (CDC) 21-1112 Revised December 2009; 5th edition.

vii. CWA 15793:2011 Laboratory Biorisk Management

Module 6: Bio-Containment and Facility Design

Learning Outcomes

By the end of the module the learner should be able to:

i. Describe the principles of biosafety and identify elements of bio-containment.

ii. Explain bio-containment measures, field security, and safety equipment.

iii. Outline safe laboratory workflow practices.

iv. Identify elements of different facility designs, and laboratory structural

requirements that contribute to reducing biosafety and biosecurity risks.

v. Describe aspects of the maintenance program for laboratory equipment and the facility.
vi. Select the appropriate facility and equipment based on the risk involved and appropriate strategies to mitigate that risk.
vii. Value the importance of bio-containment and engineering controls.

Module Content Descriptions

Principles of biosafety: Definitions of terms, elements of containment, primary containment (for instance, good laboratory work practices and procedure, PPE, containers and biosafety cabinets (BSCs), secondary containment (for instance, rooms and systems), field containment (greenhouses, animal handling facilities), work practices (for instance, laboratory and good field practices and techniques, good housekeeping, hand hygiene, PPE), tertiary containment, administrative controls (for instance, access control, security clearance), laboratory and facility design work flow, work area and space management, decontamination. **Bio-containment measures and engineering controls: Bio-containment measures:** definitions of terms, biosafety levels 1-4, work zones, quarantine measures, sanitary and phytosanitary measures, safety and security equipment and maintenance, code of practice for safety and security equipment, critical biosafety equipment (for instance, autoclave, BSC, centrifuge and HVAC) - type, selection and use of appropriate PPE, acquisition of PPE - purchase vs. replacement, calibrations, service and maintenance, decontamination and decommissioning of equipment. **Laboratory equipment and maintenance:** Types of biosafety cabinets (Class I-III), selection of a safety cabinet, biosafety cabinet certification, microorganism risk groups, quarantine facilities (for instance, open quarantine facility and closed quarantine facility), features of a quarantine facility, maintenance of equipment (for instance, different types of BSCs, fire extinguishers, centrifuge, autoclaves). **Facility design and laboratory layout/structural requirements:** residue laboratory, formulation laboratory, layout design considerations; safe work environment, efficient use of space, building comfortable work environment, purpose of good laboratory design, good laboratory design. Laboratory design components: space, mechanical, safety, and security.

Key Messages

i. Proper maintenance and use of laboratory equipment is key in BRM to reduce biosafety and biosecurity risks in scientific work products.

ii. Appropriate chosen facility features for bio-containment should be based on identified biorisks and risk assessment.
iii. Application of sanitary and phytosanitary measures in and around an infested area can be used to prevent unintentional release of biological material.
iv. Importance of safety and security integration into design, with workflow considerations to inherently support personnel practices and procedures that reduce biosafety and biosecurity risks.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
ii. National policy guidelines for medical lab physical infrastructure;2014
iii. Centers for Disease Control and Prevention (2009), Biosafety in microbiological and biomedical laboratories HHS Publication No. (CDC) 21-1112 Revised December 2009; 5th edition.
iv. Laboratory Biorisk Management: Biosafety and Biosecurity. Reynolds M. Salerno and Jennifer Gaudioso; CRS Press. 2015
v. PPC (2010). International standard for phytosanitary measures (2010) ISPM 34), Design and operation of post entry quarantine stations for plants. IPPC(2016) International standard for phytosanitary measures-Glossary of phytosanitary terms(ISPM 5)
vi. Laboratory Biorisk Management Standard ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/ Workshops/CWA15793_September2011.pdf
vii. European Committee for Standardization CEN Workshop Agreement CWA 15793(2011)- A management systems approach to Laboratory Biosafety.
viii. Safe and Secure Biomaterials: Matching resources to reality. Chatham House (2012) http://www.chathamhouse.org/events/view/182665
ix. Guidelines for safe work practices in human and animal medical diagnostic laboratories (2012) http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm

Module 7: Waste Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Define different terms used in waste management.

ii. Explain the elements of a waste management plan.
iii. Describe waste minimization methods, classify the different waste types and describe the steps in waste handling (for instance, segregation, packaging, labeling, decontamination, collection, storage, transport, final disposal).
iv. Classify and categorize waste as either hazardous or non-hazardous.
v. Be able to identify risks involved in the steps of waste management.
vi. Explain how management of waste in the field is different from a facility or laboratory.
vii. Explain safe management of chemical waste in the field.
viii. Explain the selection and demonstrate proper use of PPE when handling waste.
ix. Value the need to appropriately decontaminate, sterilize and disinfect work stations and equipment and waste before disposal.
x. Explain the validation of decontamination and sterilization procedures.

Module Content Descriptions

Definitions: Waste, health care waste/biological waste, hazard, risk Classification of wastes: hazardous waste, non-hazardous waste, Elements of waste management: waste minimization, waste identification, waste segregation, waste decontamination, methods of waste decontamination, waste transport, waste disposal methods - burning (such as,, incineration), burning chambers, and non-burn technologies (for instance, shredders, microwave, autoclave, burying). **Management of various wastes:** chemical waste management, electronic waste management, Health Care Waste (HCW)/biological waste; including minimization, segregation, packaging, labeling, storage, decontamination, transport, waste disposal. **Field waste management:** definition and classification of field waste, field waste management procedures, quarantine procedures, overview of chemical safety (e.g., safe handling and disposal of chemicals in the field, transportation of field biohazard materials and disposal). **Identification of risks involved in waste management:** risk assessment, mitigation, performance, innovative measures with available resources, and PPE requirements in the laboratory and the field.

Key Messages

i. Different waste types should be segregated, stored, and disposed according to the risks they present.
ii. Minimization of waste production is a key element of waste management plan.
iii. Waste management is key to safe and healthy working environment.

iv. Proper use of PPE is key to minimizing personal exposure.
v. Effectively tracking waste audit trails, including documentation, segregated storage, and appropriate packaging of the materials are key components of an effective waste management plan.

References

i. World Health Organization, 2004. Laboratory biosafety manual Third edition (www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf)
ii. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.
iii. Health Care Waste management sops, 1st edition, Ministry of Health, Government of Kenya, June 2016
iv. National guidelines for safe management of healthcare waste, Government of Kenya, 2011
v. Global Biorisk Management Curriculum course catalogue (https://www.osti.gov/servlets/purl/1432300)
vi. Kenya-Ministry of Health, National Health Care Waste Management Plan 2008-2012(http://guidelines.health.go.ke:8000/media/National_Health_Care_Waste_Management_Plan_for_Kenya_2008 - 2012_a.pdf)
vii. Kenya, Ministry of Health, National Infection Prevention and Control Guidelines for Health Care Workers, December 2010.
viii. CEN Workshop Agreement 15793.2011. Laboratory Biorisk Management
ix. (http://www.uab.cat/doc/CWA15793_2011)
x. WHO blue book on safe healthcare waste management 2nd edition 2014

Module 8: Shipping and Transport of Biological Materials

Learning Outcomes

By the end of the module the learner should be able to:

i. Define terminology consistent with biosafety and biosecurity in line with shipment.
ii. Outline categories of infectious substances.
iii. Outline how to properly classify, package, mark, label, and complete the appropriate documentation on shipping of dangerous goods.
iv. Identify properly packaged and received shipments of biological materials.
v. Describe regulations for shipment and outline the required shipping documents.
vi. Maintain and implement the institutional shipping program in accordance with

international and national regulations.

vii. Define the different levels of regulatory requirements to ship each IATA category of infectious substances.

viii. Prepare a shipment of any biological material to meet safety and regulatory requirements.

ix. Value the importance of proper packaging, marking/labeling and preparing biological agents, toxins and samples to prevent release or loss during transport or shipping.

Module Content Descriptions

Definition of terms: Bio hazardous material/substance, infectious substances and categories, cultures, patient specimens, biological products and toxins, Category A, Category B infectious and exempt substances, genetically modified microorganisms (GMMOs) and organisms (GMOs), medical or clinical wastes, dangerous goods declaration, over pack, triple packing, airway bill, universal postal union, maritime transport. **Categorization of infectious substances:** Category A, Category B infectious and exempt substances. **Regulations for shipment and transport of infectious materials:** national regulations governing the shipment and transport of infectious substances, international regulations for shipment and transport of infectious materials. **Biological material packaging:** training guidelines for shipment of infectious materials, marking and labels. **Biological material packaging process:** triple system, labeling, marking, Containment/ Quarantine material transport, packaging Quarantine guidelines, and shipment documentation. **Categorization of biological materials:** dangerous goods are assigned UN numbers and proper shipping names according to their hazard classification and their composition, classes of biohazards, categories of infectious substances-Category A, Category B, exemptions and genetically modified microorganisms and organisms. **Documentation of shipping of infectious materials:** completing airway bill and dangerous goods declaration form. Chain of custody and confidentiality.

Key Messages

i. National and international regulatory requirements (for instance, statutes and policies) affect shipping and transport of biological materials.

ii. Different countries may have different requirements for importing and exporting biological materials.

iii. It is important to consider the import and export requirements of both the

countries of origin and destination.

iv. Risk assessment is a prerequisite to determine the proper categorization of biological materials before transportation.

v. Proper packaging, labeling and marking of consignment in line with regulatory requirements is used to prevent damage/leakage of the materials during transit, preservation of the integrity of materials, and facilitation of their timely arrival at destination.

vi. An emergency and quarantine plan a in the unlikely event of accidental leakage and spillage.

vii. Packing instructions inform shippers specifically how to properly package dangerous goods. All biological agents must be "triple packaged."

viii. Different categories of infectious substances require different levels of training and demonstrated competency in order to pack and ship per IATA regulations.

References

i. Laboratory Biosafety and Biosecurity Policy guideline, 1st edition, MOH Kenya, Nairobi, Kenya: Government of Kenya, 2014.

ii. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, December 2 010.

iii. National biosafety and biosecurity guidelines: National Biosafety Act 2009; Public Health Act (Cap.242), Seeds and Plant Varieties Act (Cap.326), Plant Protection Act (Cap.324) of Kenya.

iv. World Health Organization. Laboratory Biosafety Manual , 3rd edition Geneva, 2004(http://www.who.int/csr/resources/publication s/biosafety/WHO_CDS_CSR_LYO_2004_1 1/en/).

v. World Health Organization (WHO), Transport of Infectious Substances, Geneva, Switzerland WHO 2004.

vi. Ministry of Public health and Sanitation and Ministry of Medical Services, Republic of Kenya, National Guideline s for Laboratory Referral Networks Nairobi: Republic of Kenya, July 2012.

vii. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal ;2000

viii. World Health Organization (WHO), a guide for shippers of Infectious Substances, 2015.

ix. International Air Transport Authority (IATA) Dangerous Goods Regulations and

Infectious Substances Shipping Guidelines. https://www.iata.org/what we do/cargo/dgr/Pages/index.aspx

Module 9: Incident Management & Emergency Response

Learning Outcomes

By the end of the module the learner should be able to:

i. Describe terms used in incident management and emergency response.
ii. Describe elements of incident response to create an incident response plan and report.
iii. Classify different types of fire and fire fighting equipment.
iv. Draft an Incident Action Plan to include incident strategies and goals.
v. Describe an Incident Command System (ICS) with respect to defined roles and responsibilities.
vi. Describe elements needed for biological or chemical spill management, where applicable.
vii. Explain the various types of emergencies and their consequences, including those related to biosafety and biosecurity.
viii. Assess the significance of incident management.
ix. Explain measures needed to manage incidents in the laboratory.

Module Content Descriptions

Definitions of terms: Incident, emergency, incident response and management. **Incident response and management:** elements of incident response, incident response plan, incident containment, incident evaluation, incident reporting. **Incident Action plan:** Incidents goals, operational period objectives, response strategies, assignment list with specific tasks, critical situation, updates and assessments, resource status updates, health and safety plan (to prevent responder injury/illness), physical layout of premises with evacuation plans (incident scene map), training. **Incident command system:** command operations, planning;-biosafety, biosecurity and environment, logistics, intelligence and investigations, understand how to control crowds and initiate the ICS. Spill management: biological, chemical and radiological, security incidents (malicious/deliberate), preservation of evidence in malicious incident cases. **Fire safety:** Classes of fire, types of fire extinguishers and their operations and maintenance; Training/fire drills. **Incident and emergency reporting/communication:** (goals of reporting, incident reporting strategy, incident response evaluation and improvement, incident response drills. Emergence

Operation Centre (EOC) national public health emergency operations Centre that functions to coordinate multi-sectoral rapid response teams on the identification of a public health emergency.

Key Messages

i. Incident Action Plan is critical in incident management.
ii. Incident Command System (ICS) is essential in incident management and staff should know their roles and responsibilities.
iii. Different classes of fire exist and their management differ.
iv. Management of both chemical and biological spill management is important in incident management.
v. Both biosafety and biosecurity incidents are included in incident action plan.

References

i. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, December 2010.
ii. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, October 2015.
iii. World Health Assembly resolution WHA58.3, May 2005 http://www.who.int/gb/e/e_wha58.html# Resolutions
iv. Disaster Planning and Response: Public Health Laboratories in Action, APHL, 2014. https://www.aphl.org/programs/preparedness/Documents/APHL-Disaster-Planningand- Response-Webinar_070914.pdf
v. Alert and response operations, WHO. http://www.who.int/csr/alertresponse/en/
vi. Public Health Emergency Operations Centre Network (E)C-NET) http://www.who.int/ihr/eoc_net/en/index1.html
vii. Sumner DA. Exotic Pests and Diseases Biology and Economics for Biosecurity. 2008, Iowa State Press. https://onlinelibrary.wiley.com/doi/book/10.1002/9780470290125
viii. CBRN National response plan
ix. Plant protection Act Cap 324 of GoK
x. Emergency Response Guidebook, 2016 http//icc.pub/downloads/erg/2016-erg.pdf

Module 10: Occupational Safety and Health

Learning Outcomes

By the end of the module the learner should be able to:

i. Define terms used in OSH.
ii. Explain the objectives, scope, and rationale, as well as the Legal and Regulatory framework, policies, regulations, and guidelines of OSH.
iii. Highlight the major elements of an OSH program.
iv. Identify, classify, and mitigate hazards in the health, plant and animal facility.
v. Evaluate and manage for specific exposures, implement continuous medical surveillance, report and document OSH incidents and accidents, practice OSH safety management, ensure adequate OSH supplies, conduct OSH training and capacity building, adhere to OSH guidelines, and participate in OSH monitoring and evaluation research.
vi. Appreciate the importance of OSH in laboratories for the attainment of the highest level of health and safety of all workers.

Module Content Descriptions

Introduction to OSH Objectives, scope, rationale, and definitions of terms of OSH. **Organizational Structure:** National and Counties. **Roles and Responsibilities: Management and employees:** Legal Regulatory framework: policies, regulations, and guidelines. Compliance and compensation, monitoring and evaluation, operational research. **Major elements of an occupational safety and health program:** Management commitment and employee involvement, work site analysis, hazard prevention and control, safety and health training, policies, procedures, processes, monitoring, supervision, and reporting. **Classification of OSH hazards and mitigations:** biological, chemical, physical, ergonomics, mechanical, psychosocial hazards: Risk assessment, evaluation and management for specific exposures: risk management and risk control. **Medical surveillance:** initial examination upon employment, vaccination, preventive measures - Pre - exposure Prophylaxis (PrEP), first aid, and personnel baseline serum storage. OSH reporting and documentation: accident reporting, dangerous occurrences, incident/near misses, and notifiable diseases. **Safety management and OSH supplies:** engineering controls, PPE, other safety equipment, safety signage and labels. OSH training and capacity building: induction program for new employee, induction of contracted/short- term staff, internal facility training (for instance, existing staff). **Compliance to OSH guidelines:** compliance and compensation. OSH monitoring and evaluation research: monitoring, evaluation, operational research.

Key messages

i. A properly implemented OSH program supports mitigation measures against work related exposures and injuries from biohazards.
ii. Understanding regulations of OSH is important to provide guidance on employee/ employer rights & obligations.

References

i. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, December 2010. PP 83 - 91.
ii. World Health Organization. Laboratory biosafety manual. Third edition. Geneva, World Health Organization, 2004 WHO/CDS/CSR/LYO/2004.11. Part I, II & IV 3.
iii. Laws of Kenya. Work Injury Benefits Act (WIBA). CHAPTER 236. Revised Edition 2012 [2007]. Published by the National Council for Law The Parliament of Kenya Occupational Safety and Health Act, 2007.
iv. Occupational Safety and Health Policy Guidelines for the Health Sector in Kenya, July 2014.
v. ISO 45001: 2018 Standard on Occupational Health & Safety Management Systems http://www.iso.org/iso45001
vi. ILO Occupational Health & Safety Convention, C155, and its protocol of 2002

Module 11: Roles and Responsibilities of Key Players in Biorisk Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Identify your obligations and responsibilities in ensuring the success of institutional BRM program.
ii. Outline your responsibilities in supporting BRM and OSH based on your role within the institute.
iii. Develop standard operation procedures
iv. Implement standard operating procedures for biorisk management.

Module Content Descriptions

Laboratory technical staff in implementation of BRM program: Various responsibilities may include: Development and implementation of operation procedures, collection and analysis of biological materials, surveillance for pests and diseases, routine maintenance of safety equipment, waste management, decontamination of surfaces, incident detection and notification, validation of lab equipment, packaging and transfer of biological materials, restraining of animals, carcass movement and disposal, incident reporting, compliance with OSH, material control and pathogen accountability, Biorisk management, planning monitoring and evaluation. Field technical staffs in implementation of BRM program: **Various responsibilities may include:** Development and implementation of operation procedures, Biorisk management, surveillance for pests and diseases, waste management, disinfection and decontamination, incident detection and notification, packaging and transfer of biological materials, restraining of animals, carcass movement and disposal, incident reporting, compliance with OSH, planning monitoring and evaluation.

Key messages

i. Every individual has a role and responsibility to play in a biorisk management program in an institution.
ii. All staff in an institution are responsible for adhering to the organization's policy on BRM.

References

i. CEN (European Committee for Standardization) (2011). CEN Workshop agreement (CWA) on Laboratory Biorisk Management (CWA 15793). CEN Management Centre: Avenue Marnix 17, B-1000 Brussels, Belgium.
ii. National Biosafety Authority: https://www.biosafetykenya.go.ke/
iii. IFBA/BMAK Training: http://www.bmak.or.ke/

4.3 LEVEL III: SUPPORT STAFF/NON-TECHNICAL TRACK

Module 1: Introduction to Biosafety and Biosecurity

Learning Outcomes

By the end of the module the learner should be able to:

i. Define the terminologies and concepts of biosafety (GMO-related), laboratory biosafety, biosecurity (farm-related), laboratory biosecurity, BRM, and IPC.
ii. Define universal standard precautions.

Module Content Descriptions

Definition of terms: biosafety (GMO-related), laboratory biosafety, biosecurity (farm-related), laboratory biosecurity, BRM, and IPC. Standard laboratory work practices: universal standard precautions.

Key messages

i. Practicing biosafety, biosecurity and good laboratory work practices is important to reduce risks associated with biological agents.
ii. Appreciate the importance of good laboratory work practices to reinforce and strengthen biosafety, biosecurity and work ethics.
iii. Universal safety precautions are best practices when handling infectious agents.

References

i. National Infection Prevention and Control Guidelines for Health Care Services in Kenya, second edition, Nairobi, Kenya: Government of Kenya, 2015.
ii. Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-clinical Research and Development Non serial Publication Series, revised edition, World Health Organization, 2010.
iii. United Nations Environment Programme. Convention on Biological Diversity. Cartagena protocol on Biosafety ; 2000 (http://www.biodiv.org/biosafety/default.asp).
iv. World Health Organization. Laboratory Biosafety Manual, Third edition. Geneva, 2004 (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004 _11/en/).
v. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014.

vi. World Health Organization. Dept. of Epidemic and Pandemic Alert and Response. (2006) Biorisk Management: laboratory biosecurity guidance. Geneva: World Health Organization. http://www.who.int/iris/handle/10665/69390.

Module 2: Policies and Regulations in Biorisk Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Recognize the local policies, regulations, guidelines and best practices in BRM.
ii. State the importance of information security in handling and transfer of VBMs.

Module Content Descriptions

Local policies, regulations and guidelines on BRM: Kenya National biosafety and biosecurity policies governing biosafety and biosecurity practices and regulations. **Information security:** define terms, responsibilities and duties of personnel; elements of information security (purpose, scope, objectives, access control), importance of information security, user training, Regulations that govern VBMs handling and transfer and Material Transfer Agreements (MTAs).

Key messages

i. Local policies, regulations, and guidelines on BRM, support the well-being of the staff.
ii. Information security on handling and transfer of VBM supports the safety of the staff and general public.

References

i. Laboratory Biosecurity Guidance WHO/CDS/EPR/2006.6
ii. International Federation for the Biosafety Association www.IFBA.org
iii. IHR Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Implementation of IHR Core Capacities in States Parties http://www.who.int/ihr/Processes_of_IHR_Monitoring_framework_and_Indicators.pdf
iv. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc.html

v. CEN Workshop Agreement, January 2012. Ref. No. CWA 16393:2012 E
vi. OIE Terrestrial Manual 2014; Chapter 3.5 - Managing Biorisks. pp.12
vii. Bathula, S.R. Rakimol, A. 2017. Global Trends in Biorisk management. Biorisk 12: 1-23
viii. National Biosafety act 2009
ix. Laboratory Biosafety and Biosecurity Policy guideline, First Edition, Nairobi, Kenya: Government of Kenya, 2014. Plant protection Act Cap 324

Module 3: Laboratory Biosecurity

Learning Outcomes

By the end of the module the learner should be able to:

i. Demonstrate knowledge on the five pillars of biosecurity - (physical, transport, information, personnel, and material control and accountability).
ii. Explain the benefits of early incident reporting.
iii. Describe a chain of communication in the implementation of biosecurity response measures.
iv. Observe the ethical code of conduct.
v. Appreciate the value of observing ethical code of conduct, work practice and standards.
vi. Explain the code of conduct and practice.
vii. List principles of ethics in the professional conduct.
viii. Explain ethical behavior at work stations.
ix. Give examples of bioethics and DURC in BRM.

Module Content Descriptions

Definition of terms: laboratory biosecurity, bioethics, Dual Use Research of Concern (DURC). **Pillars of biosecurity:** Physical biosecurity, material control and accountability, personnel reliability, information security (includes documents); transport security. **Transfer and storage of biological materials:** Definition of terms used in transfer and storage of biological materials, spill management, triple packaging. **Bioethics and Dual use:** basic ethical principles, virtues in ethics, codes of conduct and practice, principles of ethics in the professional conduct, ethical behavior, oversight mechanism for dual use. **Emergency response procedures:** Fire brigade/effective fire safety program, emergency medical personnel, security personnel.

Key Messages

i. Material control and accountability, transport security and information security complement other security components.
ii. Security awareness is critical in laboratory biosecurity.
iii. Dual use of concerns revolves around the potential misuse of good science.

References

i. World Health Organization (2012). Laboratory biorisk management: strategic framework for action 2012-2016. Geneva: World Health Organization. Laboratory Biosafety and Biosecurity Policy Guideline.
ii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html
iii. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, PG 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua=1
iv. Kenya National Laboratory Biosafety & Biosecurity Training Curriculum, Ministry of Health;2014
v. CWA 15793:2011 Laboratory Biorisk Management Guidance (pending ISO/WD 35001)
vi. CWA 16939 Laboratory Biorisk Management - Guidelines for the implementation of CWA 15793:2008 http://www.uab.cat/doc/CWA16393

Module 4: Field Biosafety and Biosecurity

Learning Outcomes

By the end of the module the learner should be able to:

i. Recognize biological risks in the field.
ii. Recognize challenges and complications of containment and security in the field set up.
iii. Recognize and be prepared to implement field - applied biorisk mitigation measures.

Module Content Descriptions

Definition of terms used in field biosafety and biosecurity: abiotic stress, biotic stress,

bio piracy, bio prospecting, bioterrorism, bio-containment. **Fundamentals to field biosafety and biosecurity:** awareness, regulations. **Field facility requirements:** relevant physical security, facility design, waste management, safe handling of infectious materials in the field, protocols for safe handling of hazardous biological materials (pesticides), basics to sample handling, preservation, packaging and transportation of biological material, incident reporting to the next in line (human, animal and plant). **Biological material/ sample accountability:** securing and safe handling of biological agents and toxins in the field; personnel reliability and accountability; access control, application of laboratory biosecurity - based risk mitigation in the field.

Key messages

i. Handling biological samples and pathogens in the field requires safety precautions and accountability.
ii. Application of laboratory biosecurity measures including material control and accountability, transport security, and information security complement other field biosafety and biosecurity components.
iii. Security awareness is crucial in the field.

References

i. World Health Organization (2012). Laboratory biorisk management: strategic framework for action 2012-2016. Geneva: World Health Organization. Laboratory Biosafety and Biosecurity Policy Guideline
ii. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc.html
iii. Biorisk management Laboratory biosecurity guidance, WHO, September 2006, Pg 4 http://www.who.int/ihr/publications/WHO_CDS_EPR_2006_6.pdf?ua=1
iv. Biosafety Act 2011. http://www.biosafetykenya.go.ke/Docs/The%20Biosafety%20(Environmental%20 Release)%20Regulations,%202011(2).pdf
v. Bail, C., Falkner R. and Marquard H. The Cartagena Protocol on Biosafety: Reconciling trade in biotechnology with environment and development. 2014: Routledge.
vi. Glossary of Biosecurity Management https://link.springer.com/content/pdf/bbm%3A978-94-007-1412-0%2F1.pdf

vii. Biological Safety Manual; Environmental Health and Safety- Michigan State University, 2017. https://ehs.msu.edu/_assets/docs/bio/msu-biosafety- manual.pdf
viii. Traynor P., Frederick R. and Koch M. "Biosafety in agricultural biotechnology." A workbook for training in biosafety risk assessment. Agricultural Biotechnology Support Project, 2002.
ix. Sumner DA. Exotic Pests and Diseases Biology and Economics for Biosecurity. 2008, Iowa State Press. https://onlinelibrary.wiley.com/doi/book/10.1002/9780470290125

Module 5: Biorisk Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Outline the BRM process/approach and role it plays to reduce incidents.
ii. Identify training needs according to the risks associated with the work.
iii. Appreciate the importance of Biorisk management in health, plant and animal laboratories in the elimination or reduction of laboratory related risks.

Module Content Descriptions

Definitions of terms: risk; hazard; Biorisk management. **Concepts of BRM:** introduction to BRM, goals and objectives of a BRM system, laboratory biosecurity as a complement to laboratory biosafety, BRM model, AMP model, elements of a laboratory biosecurity plan, and training. **Biorisk assessment:** definitions of terms used in risk assessment, types of biological risks in workplace, Biorisk assessment process, environmental risk (for instance, workplace hazards and environment risks), purpose of evaluating workplace risk. **Process and performance of risk mitigation:** managing biological risks-risk mitigation (for instance, hierarchy of control - elimination, substitution, isolation, engineering control, administrative and PPE, and application of the hierarchy of control for risk reduction). **Risk assessment report and Biorisk communication:** definition of risk communication, risk assessment report (for instance, risk assessment report format), elements of Biorisk assessment report communication (for instance, communicator, message, recipient), communication channels, communication strategy (for instance, key goals of communication, multi-disciplinary approach)

Key Messages

i. Implementing a comprehensive BRM system is critical to reduce risks associated

with biological agents.

ii. To effectively facilitate the execution of BRM, roles and responsibilities must be established and assigned.

iii. Appropriate mitigation measures, based on risk, are crucial for reducing biosafety and biosecurity risks.

iv. The effectiveness and efficiency of communication process depends on the level of attention provided by the communicator and the recipient. The interpretation of the message by the recipient and the context in which the information is provided will influence the quality of the communication.

References

i. Global BRM Curriculum (GBRMC) by US DOD/DTRA Cooperative Biological Engagement Program and US DOS Biosecurity Engagement Program. Sandia National Laboratories and International Biological and Chemical Threat Reduction Program https://ibctr.sandia.gov/human_capacity_development/hcd- gbrmc. html

ii. OHS Risk Management Handbook, Standards Australia International, Sydney, 2004.

iii. WHO (2016). Laboratory biosafety Manual, 4th Edition

iv. WHO (2006). Biorisk Management; Laboratory biosecurity guidance

v. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition;2009

vi. CWA 15793:20111 Laboratory Biorisk Management

Module 6: Bio-Containment and Facility Design

Learning Outcomes

By the end of the module the learner should be able to:

i. Identify appropriate practices and procedures based on specific biosafety and biosecurity risks assessment.

ii. Describe how workflow impacts laboratory safety and security.

Module Content Descriptions

Elements of containment: work zones, primary containment - good laboratory work practices, standard microbiological techniques/procedures, secondary containment -laboratory and facility design work flow, work area and space management. **Bio-**

containment measures and engineering controls: definitions of terms, types of containment, sanitary and phytosanitary measures, equipment maintenance, and decontamination and decommissioning/retiring.

Key Messages

i. Appropriate practices and procedures are key to reducing biosafety and biosecurity risks.
ii. Separation of work zones into laboratory, laboratory support, and non- laboratory zones supports biosafety and biosecurity objectives.

References

i. National policy guidelines for medical lab physical infrastructure.
ii. Centers for Disease Control and Prevention (2009), Biosafety in microbiological and biomedical laboratories HHS Publication No. (CDC) 21-1112 Revised December 2009, 5th edition.
iii. Laboratory Biorisk Management: Biosafety and Biosecurity. Reynolds M. Salerno and Jennifer Gaudioso, CRS Press. 2015.
iv. World Health Organization (2004), Laboratory biosafety manual. WHO/CDS/CSR/LYO/2004.11 - 3rd ed.
v. IPPC (2010). International standard for phytosanitary measures (2010) ISPM 34), Design and operation of post entry quarantine stations for plants. IPPC (2016) International standard for phytosanitary measures Glossary of phytosanitary terms(ISPM 5)
vi. Laboratory Biorisk Management Standard ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf
vii. European Committee for Standardization CEN Workshop Agreement CWA 15793(2011)A management systems approach to Laboratory Biosafety.
viii. Safe and Secure Biomaterials: Matching resources to reality. Chatham House (2012) http://www.chathamhouse.org/events/view/182665
ix. Guidelines for safe work practices in human and animal medical diagnostic laboratories (2012) http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm.

Module 7: Waste Management

Learning Outcomes

By the end of the module the learner should be able to:

i. Explain classification and segregation, packaging, labeling, decontamination, and transport of different wastes in the context of the laboratory and the field.
ii. Define different terms used in waste management.
iii. Identify different types of wastes.
iv. Explain safe management of chemical waste in the field.
v. Explain the potential hazards in the waste management process.
vi. Explain mitigation measures to prevent exposure to the risk identified.
vii. Explain how to report on incidents arising from the waste management processes.
viii. Explain the proper use of PPE correctly to prevent exposure.
ix. Select and utilize appropriate collection, storage and treatment methods.

Module Content Descriptions

Definitions of terms: waste, health care waste. Classification of wastes: hazardous waste, non-hazardous waste, infectious biological waste. Elements of waste management plan: waste minimization, waste identification, waste segregation, waste decontamination, waste transport, waste disposal methods – burning (that is, incineration) and non-burn technologies. **Management of various wastes:** chemical waste management, electronic waste management, Health Care Waste and infectious biological waste, radiological waste; including segregation, packaging, labeling, transport, and decontamination and waste disposal; field waste management (for instance, definition and classification of field waste, field waste management procedures, quarantine procedures). Overview of chemical safety: safe handling and use of chemicals in the field, transportation of field biohazard materials, chemical waste disposal (for instance, neutralize, dilute, incinerate, atomize) and emergency measures, innovative measures with available resources, PPE requirements in the laboratory and the field.

Key messages

i. Different waste types should be segregated, stored and disposed according to the risks they present.
ii. Proper use of PPE is key to hazard minimization.

References

i. World Health Organization, 2004. Laboratory biosafety manual. Third edition (www.who.int/csr/resources/publications/biosafety/Biosafety7.pd)
ii. Laboratory biosafety and biosecurity policy guidelines, First Edition, Nairobi, Kenya; Government of Kenya, 2014
iii. Kenya National Biosafety and Biosecurity Training Curriculum; 2014
iv. Global Biorisk Management Curriculum course catalogue (https://www.osti.gov/servlets/purl/143230)
v. Kenya-Ministry of Health, National Health Care Waste Management Plan 2008-2012(http://guidelines.health.go.ke:8000/media/National_Health_Care_Waste_Management_Plan_for_Kenya_2008-2012_a.pdf)
vi. Kenya, Ministry of Health, National Infection Prevention and Control Guidelines for Health Care Workers, December 2010.
vii. CEN Workshop Agreement 15793.2011. Laboratory Biorisk Management (http://www.uab.cat/doc/CWA15793_2011)
viii. International Federation of Biosafety Associations (IFBA): https://www.internationalbiosafety.org/
ix. Healthcare Waste Management SOPs First Edition 2016

Module 8: Shipping and Transport of Biological Materials

Learning outcomes

By the end of the module the learner should be able to:

i. Define terminology consistent with biosafety and biosecurity in line with shipment.
ii. Explain the shipping packaging procedures, triple packaging system, labeling, marking, and shipment documentation.
iii. Describe and be ready to operationalize shipping dangerous goods and infectious material procedures.

Module Content Descriptions

An overview of sample packaging, marking/labeling and shipping (refer to IATA DGR), transport security and national regulatory requirements. Definition of terms: biohazardous material/substance, infectious substances and categories, cultures, patient specimens. Biological material packaging: triple packaging system, labeling, shipment documentation.

PPE: Personal Protection Equipment (PPE) and shipping/transport safety procedures, PPE selection, and handling and use.

Key Messages

i. Shipment and transport of biological material is guided by National and International regulatory requirements (for instance, statutes and policies).
ii. In absence of National regulations, International regulations apply.
iii. Different countries may have different requirements for importing and exporting biological materials.
iv. It is important to consider the import and export requirements of both the countries of origin and destination.
v. Packing instructions inform shippers and recipients, specifically, how to properly package and receive dangerous goods respectively. All biological agents must be "triple packaged".

References

i. Laboratory Biosafety and Biosecurity Policy guideline, 1st edition, MOH Kenya, Nairobi, Kenya: Government of Kenya, 2014.
ii. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, December 2010.
iii. National biosafety and biosecurity guidelines: National Biosafety Act 2009; Public Health Act (Cap.242), Seeds and Plant Varieties Act (Cap.326), Plant Protection Act (Cap.324) of Kenya.
iv. World Health Organization. Laboratory Biosafety Manual, 3rd edition Geneva, 2004 (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_20 04_1 1/en/).
v. World Health Organization (WHO), Transport of Infectious Substances, Geneva, Switzerland WHO 2004.
vi. Ministry of Public health and Sanitation and Ministry of Medical Services, Republic of Kenya, National Guidelines for Laboratory Referral Networks Nairobi: Republic of Kenya, July 2012
vii. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal 2000
viii. World Health Organization (WHO), A guide for shippers of Infectious Substances, 2015. www.who.int/ihr/infectious_substances/en/.

Module 9: Incident Management & Emergency Response

Learning Outcomes

By the end of the module the learner should be able to:

i. Describe terms used in incident management and emergency response.
ii. Describe the elements of incident response, containment, evaluation and reporting.
ii. Explain principles of biological or chemical spill management.
iv. Explain your role in an incident scene, preserve evidence, and initiate chain of custody.

Module Content Descriptions

Definitions of terms: incident, emergency. Incident response and management: elements of incident response, incident containment, incident evaluation, incident reporting, incident and emergency scenarios, security incidents. Spill management: biological, chemical, and radiological. **Fire safety:** classes of fire, types of fire extinguishers and their operations and maintenance. **Incident and emergency reporting/communication:** (for instance, incident response and investigation, crowd control including techniques for crowd control, scene management, preservation of evidence in malicious incident cases). Understand how to control crowd and initiate the ICS.

Key Messages

i. Different classes of fire exist and their management differs.
ii. Management of both chemical and biological spill management is important in incident management
iii. Identify and report incidents and threats to security according to the laid down communication channels.

References

i. Ministry of Public Health and Sanitation, and Ministry of Medical Services, Republic of Kenya National Infection Prevention and Control Guidelines for Health Care Services in Kenya. Nairobi, Kenya: Government of Kenya, October 2015.
ii. World Health Assembly resolution WHA58.3, May 2005 http://www.who.int/gb/e/e_wha58.html# Resolutions
iii. Disaster Planning and Response: Public Health Laboratories in Action, APHL, 2014.

https://www.aphl.org/programs/preparedness/Documents/APHL-Disaster-Planning and- Response-Webinar_070914.pdf

iv. Laboratory biosafety and biosecurity policy guidelines, First Edition, Nairobi, Kenya; Government of Kenya, 2014

v. Kenya National Biosafety and Biosecurity Training Curriculum; 2014

Module 10: Occupational Safety and Health

Learning Outcomes

By the end of the module the learner should be able to:

i. Recognize occupational exposures, hazards, and preventive measures for work-place- related exposures, including field-based risks.

Module Content Descriptions

Introduction to OSH: hazards, ergonomics, occupational health laboratory and field-related risks, occupational health training, prevention and control measures, universal precautions using innovative approach, and hygiene practices in the field. **Hazard preventive measures:** prevention measures (for instance, safe procedures, PPEs, safety equipment), pre-placement process, health status and job selection - initial examination upon employment, previous occupation history and vaccinations, assessment before work begins, and personnel induction/orientation/training, and vaccinations.

Key messages

i. A properly implemented OSH program supports mitigation measures against work- related exposures and injuries from biohazards.

ii. OSH regulations provide guidelines on employer obligations and employee rights & obligations.

References

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ii. World Health Organization. Laboratory biosafety manual. Third edition. Geneva, World Health Organization, 2004 WHO/CDS/CSR/LYO/2004.11. Part I, II & IV

iii. Laws of Kenya. Work Injury Benefits Act (WIBA). CHAPTER 236. Revised Edition

2012 [2007]. Published by the National Council for Law The Parliament of Kenya Occupational Safety and Health Act, 2007.
iv. Occupational Safety and Health Policy Guidelines for the Health Sector in Kenya, July 2014.
v. Laboratory biosafety and biosecurity policy guidelines, First Edition, Nairobi, Kenya; Government of Kenya, 2014
vi. Kenya National Biosafety and Biosecurity Training Curriculum; 2014

Module 11: Roles and Responsibilities of Key Players in Biorisk Management

Learning Outcomes

By the end of the module, the learners should be able to:

i. Outline your responsibilities in supporting BRM and OSH based on your role within your institute.
ii. Understand your responsibilities in identification and reporting of incidents.
iii. Describe your role in physical security.
iv. Describe the process of background checks for personnel reliability. Describe strategies to detect and report incidents.

Module Content Descriptions

Security officers in implementation of BRM program: Various responsibilities may include: Securing physical infrastructure including access control, background check for personnel reliability by the security office, investigation of security breach, basic disinfection and decontamination, incident notification, maintain visitors' records, adherence to bioethics principles. Non-technical, field workers and support staff in implementation of BRM program: **Various responsibilities may include:** Observing sanitary measures in accordance with organizational policy, basic disinfection and decontamination, waste handling, incident notification, compliance with OSH.

Key Messages

i. Every individual has a role to play in a biorisk management program in an institution.
ii. All staff, including non-technical, field workers, support staff and security officers are responsible for adhering to the organization's policy on BRM.

References

i. Laboratory biosafety and biosecurity policy guidelines, First Edition, Nairobi, Kenya; Government of Kenya, 2014

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iii. CEN (European Committee for Standardization) (2011). CEN Workshop agreement (CWA) on Laboratory Biorisk Management (CWA 15793). CEN Management Centre: Avenue Marnix 17, B-1000 Brussels, Belgium.

5 Appendices

APPENDIX I: CURRICULUM TRACKS

LEVEL I: Management and Leadership Track	
Target audience	Cabinet Secretary, Chief administrative secretary, Permanent Secretary, Directors, Medical Superintendent, Chief executive officer, Parliamentary committees (Health, agriculture), County, Chair of Council of governors, Governor, County executive, County Directors (for health, veterinary, fisheries, crop production), County commissioner (police), Hospital administrators, Heads of departments, Head of programs and Head of divisions, Human resource managers, Hospital superintendent/Facility in charge, Game park managers, Chief security officers, Farm managers
Responsibilities	Policy development, Resource allocation (Human, infrastructure and Finances), Inculcation of safety culture, Foster compliance and enforcement of the legislation and guidelines, Support the technical leaders regarding Biorisk management offices, Performance monitoring and evaluation (Establish and using performance indicators), Managing human performance and workforce, Rewards and sanctions, Assigning mandates, Monitor, measure, continuously improve all aspects of the curriculum, Merge support and assigning mandates, Managing human performance and work forcing e.g. rewarding and sanctioning.
Biological hazards/risks	Information confidentiality, Background and personal reliability, Malicious use of materials, Pathogen risk, Bridge physical security e.g. unauthorized access

LEVEL II: Professionals/Technical Staff Track	
Target audience	Bio-scientists (Microbiologists/ biotechnologists/ agronomists/ breeders), Phlebotomists, Animal health assistant, Pathologists (animal & plant), Plant health inspectors, Biosafety & Biosecurity officers, Clinical personnel (medical doctors, clinical officers, nurses), Veterinarians, Laboratory technicians & technologists, Seed technicians, Biomedical engineers, Biorisk managers, Livestock officers, Seed inspectors, Biobank managers, Security managers, Forensic scientists, Scene of crime officers, Epidemiologists, Extension officers, Animal technicians, Emergence medical teams, Human pathologists, Biomedical Engineers/ Equipment contractors
Responsibilities	Sample collection, Sample processing (for instance, aliquoting, labeling), Sample analysis, Sample disposal, Prepare work plans and budgets, Oversee staff medical surveillance, Immobilation of animal, Conduct post mortems, Auditing bio-containment facilities, Laboratory equipment service and maintenance, Inventory management (e.g. equipment, chemical, VBM), Waste management, Facility access control, Adherence to biorisk management, Oversee/ participate in Biorisk management (AMP), Incidents management plan (contingency plans), Adherence to bioethics, Compliance with Occupational Health and Safety Program, Training support staff, Reporting and investigating biosecurity incidents, Validation of lab equipment, Follow biosecurity policies and procedures, Development of SOPs/manuals, Biological materials transfer, Inventory management, Facility security plan, Facility maintenance, Inspection of plant quarantine materials, Waste/chemical management, Reporting and investigating biosafety/biosecurity policies, Drafting biological materials transfer agreements, Sample packaging and shipments of materials, Aquaculturing
Biological hazards/risks	Pathogen exposure (Needle stick injuries, Pathogen exposure and infection, Exposure to Aerosols), Muco-cutaneous exposures, Chemical exposures, Exposure to burns, Exposure to super mutant bugs, Carcinogen and mutants, Animal injuries (bites/scratches), Exposure to Allergens, Contaminated field environments, Pharmaceutical exposures, Extreme temperatures (for instance, liquid nitrogen exposure, freezer, heat, cold room), Fires, Physical violence

	and injuries, Ergonomics, Theft of biological materials, Chain of custody of biological materials, Exposure to infectious medical waste, Introduction of invasive species, quarantine diseases and pests, Inadequate inactivation of biological materials, Misuse of equipment that can be used for dual use, Document access and control, Personnel reliability, Unintended and intended Exposure to biological materials, Intentional release of biological materials, Physical security, Information security

LEVEL III: Non-technical/Support Staff/Field and Community Workers	
Target audience	These are first responders: Police, Point of entry, Fire-fighters, Non-state actors (St. John's Ambulance, Red Cross, etc.), Emergency medical team, Game wardens, Farmers, Community worker, Traditional birth attenders, Fish handlers, Couriers, Cleaners, Drivers/ Boda Boda riders, Post mortem attendants/ Morticians, Burial experts, Security personnel's, Game rangers/ Animal Capture, Messengers, Record Officers, Secretaries, ICT officers, Plant related – Farm assistants, Incinerator operators, Artisans (plumbers, carpenters, electricians), Abattoirs/butchers/ meat handlers, Meat inspectors.
Responsibilities	Sample collection, Sample processing (Forensics), Sample packaging and labeling, Sample transportation and chain of custody, Movement of infected people and dead bodies, Movement of biological materials, Carcass movement and disposal, Scene management, Crowd control and security, Detection of hazards, Decontamination, Communication to the next in line, Data collection, Sample transportation and dispatch, Sample disposal, Laboratory decontamination and equipment service, Waste management programs, Chemical hygiene plans, Facility access control, Adherence to biorisk management, Incidents reporting, Compliance with Occupational Health and Safety Program

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