

Workshop on Introduction to Biorisk Management and Biorisk Management Curriculum Development

SAND2014-4145P

June 2014

Mbarara University of Science and Technology (MUST)



SAND 2014-XXXXXX

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Outline

- Introductions
- Pre-Workshop Assessment
- Teaching models and approaches, the Global Biorisk Management Curriculum (GBRMC)
- Orientation to Biorisk Management
- Identifying audience, context, learning objectives
- Curriculum design





Roundtable Introductions

- Your name?
- Your position?
- Your Department, Role?





International Biological Threat Reduction

Innovative solutions for countering biological threats globally

- Promote the responsible use of biological agents, equipment, and expertise globally.
- Strengthen capacities to safely, securely, and responsibly detect, handle, and control dangerous biological agents.
- Improve understanding and management of the risks associated with accidental and deliberate misuse of biological agents.



IBTR Core Capabilities

- **Laboratory biorisk management**

- Biorisk management standards and regulatory frameworks
- Core biorisk management program documents
- Lab design / programming expertise
- Facility specific biosafety and biosecurity threat, vulnerability, and assessments
- Biorisk (biosafety and biosecurity) upgrades



- **Biothreat identification and analysis**

- Global analysis
- Country and regional analyses



- **Capacity building and outreach**

- Biorisk management training
- Training centers
- Law enforcement



- **Building inherently safer and more secure biomedical capabilities**

- Surveillance and control
- Public and vet health
- Incident detection and response





Example: Building Human Capacity to Address Biorisks



- **Global Biorisk Management Curriculum**
 - Develop and maintain a customizable library of courses designed based on international best practices in biorisk management and sustainable training techniques
 - Catalog: <http://biosecurity.sandia.gov/gbrcm/catalog.html>
 - Network of trainers to provide document and quality control and to offer a platform for shared experiences and problem solving
- **Conduct training for different stakeholders**
 - Policy makers, lab workers, biosafety/biosecurity officers, lab directors, law enforcement
 - Topics include: biorisk management, molecular diagnostics, infectious substance shipping, and biothreat identification and response
 - Training platforms include: classroom, distance-learning, lab, tabletop exercises, and full-scale field exercises
- **Development of regional training centers**
 - Physical training centers and regional consortia
 - Train-the-Trainer programs
- **Support to international organizations' human capacity efforts, including WHO, OIE, and INTERPOL**



Terminology and Definitions

- Biosafety: The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins or their accidental release' (WHO, 2004)
- Biosecurity: Protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion, or intentional release of biological agents and toxins and related resources, as well as unauthorized access to, retention, or transfer of such material' (WHO, 2006)²
- ¹Laboratory biosafety manual, Third edition (World Health Organization, 2004)
- ² Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)



Definitions, continued

- The practices of **biosafety and biosecurity** are combined into an **integrated effort** known as **biorisk management** where the goals are, concurrently, to work safely and to keep the work secure.

Biorisk management (BRM) can be further defined as the actions taken (by laboratories or facilities which handle, store, or dispose biological agents or toxins) to control or minimize biorisk to acceptable levels in relation to employees, the community and others, as well as the environment, which could be directly or indirectly exposed to biological agents or toxins (adapted from CWA 15793:2011¹).

¹Laboratory biorisk management standard (CWA 15793:2011)

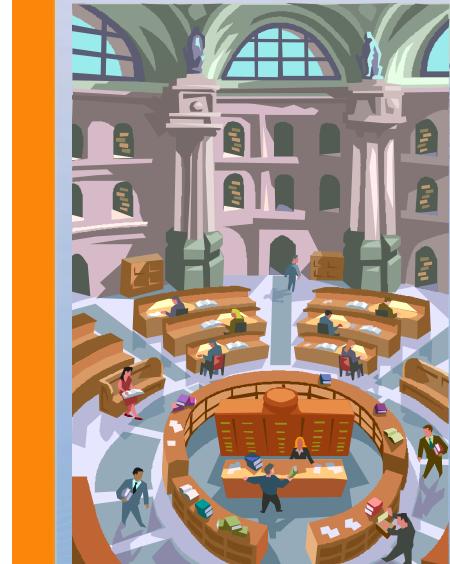




Definitions, continued

- “Dual Use” are legitimate goods and technologies that have the potential to be misappropriated and misused to cause harm
 - Dual Use Research of Concern: “Research that...can be **reasonably anticipated** to provide knowledge, products, or technologies that could be *directly* misapplied by others to **pose a threat** to public health and safety, agricultural crops and other plants, animals, the environment, or material” [National Science Advisory Board on Biosecurity]



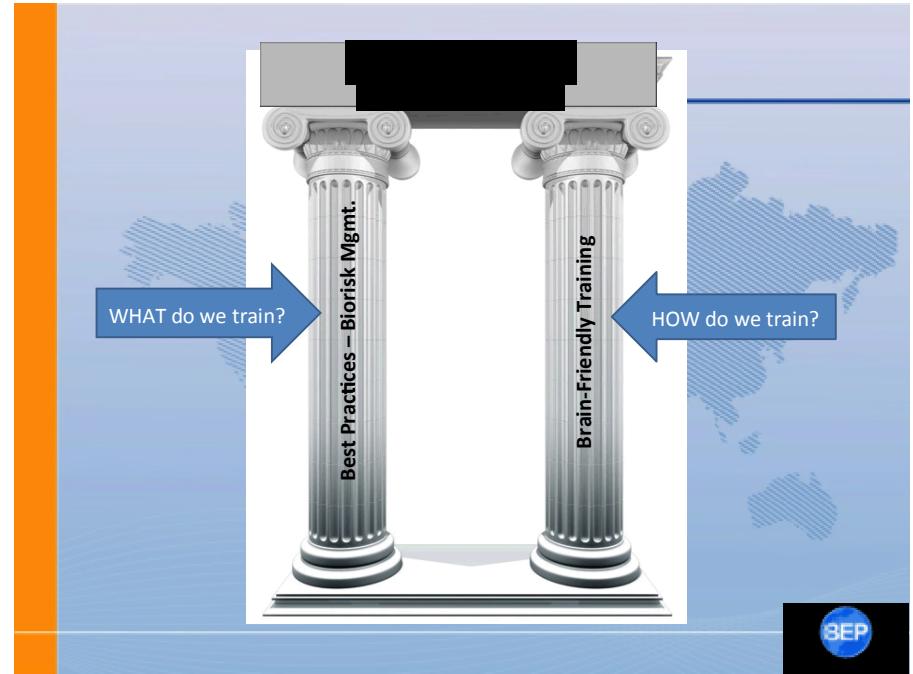


GBRMC

GBRMC = Global Biorisk Management Curriculum

Mission

- Biosafety & Biosecurity training materials. . .
 - Strategic
 - Sustainable
 - Anywhere, anytime
 - Well-branded
 - Well-managed





Biorisk Management Resources

- CWA 15793:2011 – Laboratory biorisk management standard (+ CWA 16393 guidance)
- CWA 16335 - BioSafety Professional (BSP) Competences
- World Health Organization Laboratory Biosafety Manual
- World Health Organization Laboratory Biosecurity Manual
- OECD Best Practice Guidelines for Biological Resource Centres
- Guidelines for Biosafety Laboratory Competency (MMWR Supplement Vol. 60)
- NSABB Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information
- Biological and Toxin Weapons Convention
- Local guidelines & regulations
- Current best practices
 - example: U.S. Biosafety in Microbiological and Biomedical Laboratories





Global Biorisk Curriculum Library, 1

Basic Track

Audience: all personnel involved in biorisk management

- Biorisk Management Basics
 - Orientation to biorisk management
 - Bioethics
 - Introduction to Dual Use Research of Concern
 - Biorisk Characterization & Evaluation
 - Biosafety Risk Assessment
 - Biosecurity Risk Assessment
 - Biorisk Mitigation Strategies
 - Introduction to Incident Management & Response

Laboratory-Level Track

Audience: Biorisk Management Advisors, Scientific/Laboratory Management, Lab Workforce

- Lab-Level Administrative Controls
 - Human Performance for Biorisk Management in the Laboratory
 - Developing, Evaluating, Validating, and Communicating Standard Operating Procedures
 - Hazard & Risk Communication in the Laboratory

Laboratory-Level Track, continued

- Lab-Level Operational Controls
 - Biocontainment Facility Features
 - Engineering Controls and Laboratory Equipment
 - Good Laboratory Work Practices
 - Personal Protective Equipment
 - Decontamination
 - Biological Waste Disposal
 - Laboratory Biosecurity
 - Field Biosecurity
 - Shipping Infectious Substances and Biological Specimens
- Reporting, monitoring, and Response
 - Incident Recognition and Response in the Laboratory



Global Biorisk Curriculum Library, 2

Management & Leadership Track

Audience: (Policy Makers) Top Management, Biorisk Management Advisors, Scientific/Laboratory Management

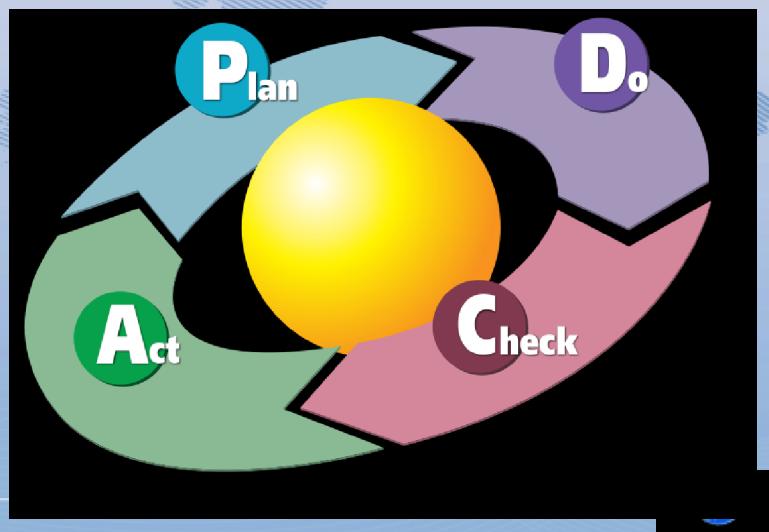
- Policy, Planning, and Assessment
 - Writing and Communicating Biorisk Management Policy
 - Considerations for Training in Biorisk Management
 - Developing, Conducting, and Maintaining a Hazard Inventory
 - Identifying Legal Requirements that Impact BRM
 - Establishing Work Program Review & Approval
 - Establishing and Communicating Biorisk Management Goals, Objectives, Roles, and Responsibilities
- Developing and Maintaining Human Capacity for Biorisk Management (Managing People)
 - Managing Human Performance in the BRM Workforce
 - Establishing and Maintaining Formal and Informal BRM Mentoring Programs
 - Establishing and Maintaining Worker Health Programs
 - Developing and Maintaining Roles & Responsibilities for Risk-based Access to, Control of, and Accountability for Biological Agents and Toxins.

Management & Leadership Track, continued

- Developing and Maintaining Physical Infrastructure for Biorisk Management
 - Understanding & Maintaining Facilities & Equipment for Biorisk Management
 - Basic Features & Maintenance for Physical and Information Security Measures
- Incident Management & Response
 - Incident Response Planning and Preparation
 - Incident Response & Investigation
 - Incident Response Evaluation & Improvement
- Measuring and Improving Biorisk Management Performance
 - Measurement and Analysis of Biorisk Management System Performance
 - Conducting Audits and Inspections to Assess Biorisk Management Performance
 - Revising and Improving a Biorisk Management System based on Performance Results
 - Establishing and Using Performance Indicators



Biorisk Management – Continuous Improvement



Biorisk Management: AMP Model (World Health Organization)



GBRMC Course Components

- Design Document
 - Course objectives, pre-requisites (for students & trainers), course outline, etc.
- Instructor's Guide
 - Detailed notes
 - Instructions and materials for interactive exercises
 - Handouts, if used
- Slide Deck
- Student Guide
 - Student workbook
 - References & resources
- Instructor and Student Evaluation materials
- References & resources
- Other materials as needed



GBRMC Components: Design Document (DD)

Orientation to Biorisk Management
Design Document – draft – February 2011

Part II: Lesson Overview

Lesson Description	Overview
Overview	Orientation to Biorisk Management intended as the first requirement for a license in the Biorisk Management (BMB) Curriculum. It is designed to introduce the basic concepts of BMB and management systems to help build a solid foundation for subsequent components of the course.
Scope	This lesson will provide an overview of biorisk management, basic concepts, and management systems to help implement a biorisk management system. This lesson will also introduce the basic concepts of biorisk management systems of assessment, mitigation, and performance.
Learning Level	Knowledge application, analysis, synthesis
Length of Course	1 hour
Lesson Objectives	At the end of this lesson, learners will be able to: <ul style="list-style-type: none">• Explain what is biorisk management and what the benefits are of applying a management system• Explain what is a management system and what the benefits are of applying a management system• Explain what is a biorisk management system and what the benefits are of applying a management system• Explain what the CITA 1710 Safeowner Biorisk Management Standard is• Explain what is ASIP (Management, Performance, and Safety) and how it can be used in biorisk management• Define what is a management system and what the benefits are of applying a management system• Explain what is a management system and what the benefits are of applying a management system
Instructional Objectives	
Performance Objectives	

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SEB



GBMRC Components: Slide Deck (SD)

Lesson Objectives: 1

- Understand the role of mitigation in the AMP model for biorisk management
- Understand the importance of a thorough risk assessment
- Appreciate that mitigation must be based on a thorough risk assessment

Lesson Objectives: 2

- List the categories of control measures and describe the hierarchy of controls
- Understand the advantages and limitations of each category of control measure
- Be prepared to learn more details about specific mitigation strategies

10 MINUTE BREAK

Group Exercise Step 1

- Using your risk assessment findings, identify at least ten different mitigation measures. Make sure these address both safety and security.
- Use a post-it note for each mitigation measure you identify
- Report your answers to the class

Group Exercise Step 2

- Engineering Controls: Physical changes to work places, equipment, materials, production facilities, or any other physical element of the work environment that prevent exposure to hazards.
- Administrative Controls: Policies, procedures, standards and guidelines that are used to prevent exposure to hazards.
- Personal Protective Equipment: Devices used by the worker to protect against hazards in the laboratory.

Group Exercise Step 3

- Considering these categories of mitigation measures, identify the following:
 - Advantages
 - Limitations
 - Identify their advantages and disadvantages
- Report your findings to the class

Advantages and Limitations

Advantage	Disadvantage
Engineering Controls	Costly to implement
Administrative Controls	May be difficult to implement
Personal Protective Equipment	May be uncomfortable to wear

Group Exercise Step 4

- Considering these categories of mitigation measures, identify the following:
 - Advantages/Disadvantages - Administrative Controls
 - Engineering Controls - Personal Protective Equipment
 - Advantages/Disadvantages - Personal Protective Equipment from the perspective of effectiveness
- Report your findings to the class

GBRMC Components: Instructor Guide (IG)

What is biorisk management?

Slide 11

Biorisk Management: the AMP Model

Block Management = Assessment, Mitigation, Performance

Background information for Instructor

Slide 12

Management System

Activity: Small group activity (15 minutes).
Objectives:

- Explain that they have just created a biorisk management system that we call the AMP model. Ask them how this system can be used repeatedly throughout training and in future modules that they will participate in.

Activity: Small group activity (15 minutes).
Objectives:

- Now that they have just created a biorisk management system, ask what is a "management system" and why is it important?
- Allow about five minutes for individual group to develop a definition.
- Allow another five minutes to discuss the benefits of a management system and why they are important.
- Finally, group report their definitions to the whole class. (five minutes)

Plenary Discussion (10 minutes).
Questions to consider:
Why are management systems important?
Directions for Instructor:

- Pool ideas on the definition of a management system
- Try to adopt a definition that everyone in the group can agree to and write this consensus definition down on a flip chart.
- Capture on a flip chart.
- Be prepared to record answers on a blank page.



GBRMC Components: Student Guide (SG)

Orientation to Bi-risk Management

Bi-risk Management

• Bi-risk management
• Take the **Bi-risk Quiz**, and place them in one of the following boxes:
- Impact
- Mitigation
- Performance

Components of Bi-risk Management

Assessment
Mitigation
Performance

Orientation to Bi-risk Management

The AMP Model

• Define a risk management system (The next activity may help you construct your definition):

Describe an AMP model:

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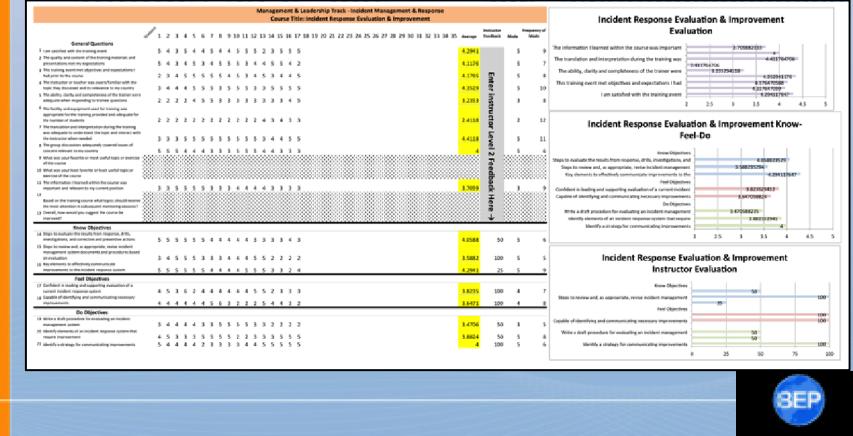
SE

GBRMC Components: Evaluations (Level 1 – Level 2)

General				Course Specific Know, Feel, Do			
Level 1 General Evaluation (Course or Training Event Name)				Level 1 Know-Feel-Do Evaluation Personal Protective Equipment			
1. I am satisfied with the training event. Strongly Agree Agree Neutral Disagree Strongly Agree				After this course, I know: 14. Know (Objective 1) - What PPE is used and what each type of PPE is used for			
Level 2 General Evaluation (Course or Training Event Name)				Level 2 Know-Feel-Do Evaluation Personal Protective Equipment			
1 Were the prerequisites and the course description adequate for the course? If not what would you change? Strongly Agree Agree Neutral Disagree Strongly Agree				Measurement of Learning (as specified by course objective(s)) during course (Completed by Instructor(s)) Was this demonstrated by all students?			
2 How were the trainees identified for the course? Based on facility staffing plans was this course appropriate for students or were their trainees in attendance that did not require the course? Strongly Agree Agree Neutral Disagree Strongly Disagree				100% 75% 50% 25% 0%			
3 Do you believe the course matched the trainee's expertise and knowledge base? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
4 Were there any cultural limitations associated with the training? Language or translation issues? Large problem? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
5 Based on your assessment of the training event would you recommend any follow ups for the cohort or any individual student? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
6 Were there any additional materials used for demonstration or instruction that were useful to the course? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
7 Were there any issues with CBEP approved training curriculum? Content errors? Partner Nation applicability? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
8 Were there any unexpected events that altered the flow of the training event, if so what were the effects on the course? What steps were taken to reduce the impact of specified events? Strongly Agree Agree Neutral Disagree Strongly Disagree				1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35			
9 Did the students stay energized and attentive throughout the majority of the class? If no, what sections of the course lagged? What activities were more successful than others? less successful? Strongly Agree Agree Neutral Disagree Strongly Disagree				Name of student Comments regarding demonstration of learning objectives			

GBRMC Components: Evaluation Analysis Tools

Spreadsheet to Enter Evaluation Data Pre-made Graphs





Public Access Site

- <http://biosecurity.sandia.gov/gbrmc>

GBRMC Pillars – Training Techniques

- So what's different?
 - Experiential learning
 - Small group and plenary activities
 - Breaks
 - Movement & colors
 - Debriefs, recaps
 - Outcome based
 - What do you have?
 - Where do you want to go?



GBRMC Pillars – Training Techniques

- So what's different, continued?
 - Implementation “Blind”
 - No specific training scenarios anticipated
 - Comprehensive Toolkit
 - Detailed design document and instructor guide
 - Student guide and key references
 - Evaluations
 - Leave your fingerprints
 - Trainers’ Network to capture feedback, solutions, configurations, customizations, revisions, translations, etc.



Facilitate versus Teach

