

Course: Biosecurity Risk Assessment

Design Document – Draft May 2012





Part I: Course Overview

Course Description

Overview

This course is intended to offer an understanding of the basic theory underlying a biosecurity risk assessment. Through guided discussion and interactive exercises, students will learn the basic concept of a biosecurity risk assessment, and explore its benefits and as well as the challenges involved in carrying it out. The course begins with a brief introduction on risk and biosecurity risk in particular, followed by a discussion the process of assessing risk through characterization of agents and adversaries. The course concludes with a discussion of risk evaluation

Scope

The goal of this course is to offer a basic awareness of the importance of biosecurity risk assessment within the overall process of laboratory biorisk management – focusing on the risk of intentional removal (theft) of a valuable biological material

Learning Level based on Bloom's taxonomy

- ✓ knowledge
- ✓ comprehension
- ✓ application
- synthesis
- evaluation

Length of Course

4 hours

Course Objectives

At the end of this course, Students will be able to:

Organizational Objectives

- To introduce the importance of biosecurity and highlight a method to protect pathogens and toxins from theft, diversion, or misuse.

Instructional Objectives

- Explain the factors influencing the risk of loss, theft, or misuse of pathogens.
- Devise a system for reproducibly and transparently evaluating these factors to determine risk in different situations.
- Develop mitigation strategies to reduce the risk, if necessary.
- Demonstrate and explain, using the risk assessment process, that risk will be reduced using the mitigation strategies.
- Summarize how different risk acceptance levels may change mitigation strategies

Personal Objectives

Know

- How to define risk
- What information must be gathered prior to conducting a biosecurity risk assessment



- How to characterize the risk related to assets, adversaries and biosecurity vulnerability.

Feel

- Confident that the risk assessment process is robust and reproducible

Do

- Explain what a risk assessment is characterizing.
- Explain how a risk assessment is evaluated
- Determine the necessary information needed for a biosecurity risk assessment

Key Messages

1. A risk assessment is defined as a procedure that analyzes a particular process or situation in order to determine the likelihood and consequences of a certain adverse event.
2. A biosecurity risk assessment is an analytical procedure designed to characterize security risks.
3. The results of a biosecurity risk assessment will be unique to each institution and each laboratory or unit within that institution.
4. To be comprehensive, a laboratory biosecurity risk assessment should consider every asset, as well as vulnerability in an institution and its component laboratories and units.
5. A biosecurity risk assessment allows an institution and its component units to determine the relative level of security risk they face, and helps guide risk mitigation decisions so these are targeted to the most important risks.
6. To properly conduct a biosecurity risk assessment, it is important to first gather certain information about the biological agents and toxins that could be targeted by notional adversaries.
7. Adversary Characterization is the process of determining specific attributes of potential adversaries that enable them to pose a threat to a biological agent or toxin.
8. Each scenario evaluated should involve a specific biological agent or toxin, a specific adversary, and a particular way that adversary will attempt to steal and misuse the agent or toxin.
9. After generating a series of scenarios, the vulnerabilities of a facility and/or its units to the threats posed in the scenario should be assessed.
10. Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not

Evaluation Strategy

Level 1 (satisfaction):

Students will complete a satisfaction survey about their experience with the course

Level 2 (learning):

Students will complete a “learning contract” for the next steps needed to begin biorisk management implementation

Level 3

Desired behavior is for students to participate in additional learning



(behavior):

opportunities on BRM – this behavior will be evaluated three to six months post-training and may encompass additional training courses

Level 4
(organizational change):

A repeat of the training needs assessment will be performed at least annually – this annual assessment can be compared to the baseline assessment to determine improvements in biorisk management performance

Learner Description (for course design purposes)

Number of Students: 10 to 20; small groups of 5 people each

Biorisk Management Role:

- ✓ Policy Makers
- ✓ Top Management
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
- ✓ Workforce

Audience Assumptions:

(assumed range is indicated by shaded cells)

		Novice		Practitioner		Expert
Education	Scientific	1	2	3	4	5
	BRM*	1	2	3	4	5
Expertise	Scientific	1	2	3	4	5
	BRM	1	2	3	4	5
Competence	Scientific	1	2	3	4	5
	BRM	1	2	3	4	5
BRM = "biorisk management". See definitions for terms in Resources section						

**Language of instruction;
translation or
interpretation anticipated:**

English (for design purposes)

Prerequisites

Orientation to Biorisk Management

**Pre- or post-work required
for completion**

**Certificates or documents
of completion:**

Certificates of completion will be provided

**Preparation for future
coursework**

This course is a pre-requisite for all other courses in the biorisk management curriculum

Anticipated next steps

Students will participate in learning tracks, as defined by the local training needs assessment and other subject matter expert (SME) recommendations.



Instructional Environment

<i>Number of Instructors/Staff required:</i>	TBD depending on number of Students – optimal ratio is 1 trainer per no more than 12 Students
<i>Trainer Qualifications:</i>	Instructors must have completed the Global Biorisk Management Curriculum (GBRMC) orientation, including this course, and be enrolled in the GBRMC training network.

Learning Environment

Media: Instructor-led

Exercises & Activities

Experience (Activists) Students will be asked to consider their experiences with their work in regard secure handling of biological agents and toxins and facility characteristics

Reflection (Reflectors) Students will be asked to reflect on those experiences to help develop a model for a biosecurity risk assessment; Students will be asked to reflect on the next steps for conducting such an assessment upon return home

Models (Theorists) Students will be introduced, through their own experiences and reflections, to the biorisk management AMP (Assessment, Mitigation, Performance) model and to several biorisk assessment models and methodologies

Practice (Pragmatists) Students will be given the opportunity to develop examples of risk assessment models, as well as describe next steps for applying these models in their facility.

On-Site Specifics

Location TBD

Room organization Clusters of tables to facilitate small group (no more than 5 Students per group)

Dress code and/or important cultural considerations TBD

Instructional Materials

Equipment Large flip charts



& Supplies

Markers (enough for up to 5 groups plus instructor(s))
 6 x 8 inch multicolor Post-it notes (no lines)
 Student binders (1" or less) and tabs
 Pens
 Laptop computer with PowerPoint files loaded
 Projector
 Easels (x ~6)
 Name tags/lanyards or placards
 Certificates
 Notepads
 PowerPoint files
 Facilitator notes
 Student handouts/notes pages
 Course evaluation forms
 Reference materials (WHO LBM and Biorisk Management Guidance, SNL Lab Biosecurity handbook, CWA 15793:2008 and CWA guidance documents)

Student Handouts

Course agenda and schedule
 Student notes
 Glossary
 CWA 15793

Resources

Dependencies

Authorities

References

CWA 15793
 CEN WS 55, 53
 WHO Laboratory Biosafety Manual
 Laboratory Biosecurity Handbook
 IBTR Training – Information Security and MC&A (SAND No. 2004-4555P, SAND No. 2005-3288 C)
 DTRA BSL-3 Training – Bioethics and Biosecurity
 CDC/WHO Laboratory Quality Management System Training Toolkit
 Biosecurity Plan Template
 Glossary of terms

Terms used in this document

- Knowledge – remembering the material in the same form as it was taught
- Comprehension – student's ability to understand the material by (for example) explaining or summarizing key messages
- Application – ability to use the material in a new or given situation
- Synthesis – ability to put together learning material in a new whole entirety. For example, using the material to create a new program or plan.
- Evaluation – ability to judge the value of the material presented



as a peer (to be able to critically advise or judge others on their application and synthesis of this learning material).

- Novice – a person who is new to the circumstances, work, etc. in which s/he is placed; beginner
- Practitioner – a person engaged in the practice of a profession; a person who practices something specified
- Expert – a person who has special skill or knowledge in some particular field; specialist; authority; trained by practice
- Education – the act of acquiring particular knowledge or skills, as for a profession
- Expertise – the process of personally observing, encountering or undergoing something; knowledge or practical wisdom gained from what one has observed, encountered, or undergone
- Competence – Possession of a suitable or sufficient skill, knowledge, experience, etc. for some specified purpose; properly qualified

Part II: Course Outline/Schedule

Day	Segment time (min)	Time	Topic	Instructional Method	Slide #	KM #	T/F
			Welcome & Introductions				
			End of Module				

KM = key messages ; T/F = teaching versus facilitation (instructor-based versus learner-based)