Global Biorisk Management Curriculum (GBRMC)
Catalog of Courses

GLOBAL BIORISK MANAGEMENT CURRICULUM
Global Biorisk Management Curriculum Library (GBRMC)

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*Red* indicates course is available by request only. Translation updates needed. Contact GBRMC@sandia.gov
### 1. Orientation to Biorisk Management VERSION 2

<table>
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<th>Overview</th>
<th>Orientation to Biorisk Management is intended as the first course encountered by a student in the Global Biorisk Management Curriculum (GBRMC). It is designed to offer a common understanding of the foundation and terminology of Biorisk Management (BRM) and management systems and to lead students towards next steps for becoming more conversant and competent in BRM, regardless of the role they hold.</th>
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<tr>
<td>Scope</td>
<td>This course will provide awareness of biorisk management systems, tools and resources to begin implementation of a biorisk management system. This course will NOT provide details on specific components of biorisk management or of assessment, mitigation, or performance.</td>
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| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- What a management system is
- What the CWA 15793 is
- What the AMP model represents

**Feel**
- Confident about using the biorisk management approach
- Confident about using basic biorisk management terminology

**Be Able to Do**
- Move forward to the next steps in beginning a biorisk management implementation.

**Key Messages**
1. “Biosafety”, “biosecurity”, “biorisk”, and “biorisk management system” are common biorisk terms that relate to and support each other.
2. AMP (Assessment, Mitigation, and Performance) is a simple but powerful model for managing biorisks.
3. Implementing a comprehensive biorisk management system is critical to reduce both the safety and security risks associated with biological agents.
4. Some key factors for establishing and implementing a successful biorisk management system include commitment by top management and a focus on continual improvement.
5. CWA 15793 is a comprehensive framework for managing biorisks developed through international collaboration.

**Biorisk Management Role:**
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Workforce
## 2. Bioethics VERSION 2

### Overview
*Bioethics* is intended to serve as an early course in the responsibilities of scientists to act ethically and with integrity both as a scientist and as part of a larger community. It creates the foundation of conduct for individuals as they progress through the Global Biorisk Management Curriculum (GBRMC).

### Scope
This course provides awareness of ethical dilemmas that can be encountered in a laboratory setting. Students discuss how to manage these situations and act appropriately. This course also reviews additional ethical considerations that must be taken into account while working with biological materials.

The sections of the course include: Biorisk Management, Introduction to Bioethics, Codes of Conduct, Dual Use in the Life Sciences, Roles & Responsibilities, and Bioethics Case Studies.

### Learning Level Based on Bloom's taxonomy
- knowledge
- comprehension

### Length
4 hours

### Course Objectives - At the end of this course, students will:

**Know**
- Definition of bioethics
- Definition of dual use
- Expectations of ethical behavior in a laboratory
- Ways to promote bioethics
- Roles and responsibilities involved in creating a strong bioethical environment

**Feel**
- Capable of identifying and communicating ethical dilemmas

**Be Able to Do**
- Identify potential concerns in own work
- Properly communicate or report issues where appropriate
- Be held personally accountable for own actions
- Document and justify decisions as appropriate

### Key Messages
1. Each individual is responsible for his or her own behavior.
2. Both codes of conduct and regulations are used to support bioethics by defining expectations for individual and organizational behavior.
3. In the absence of legal requirements, individuals are still expected to act ethically.
4. Ethical organizations are built on ethical employees, ethical leadership, and have a strong organizational structure.
5. Each institution has a responsibility to create an environment that allows the individuals working within it to express concern should an ethical dilemma come up.

### Biorisk Management Role:
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
### 3. Introduction to Dual Use Research of Concern

**Overview**

*Introduction to Dual Use Research of Concern* is intended as an early course encountered by in the Global Biorisk Management Curriculum (GBRMC). It is designed to allow researchers to understand and respond to research that could fall under the umbrella of Dual Use Research of Concern (DURC). This will include an understanding of dual use research, responsibilities, and actions to be taken in dealing with dual use research.

**Scope**

This course will provide awareness of dual use research of concern as well as allow students to identify research with dual use potential. Students will get practice evaluating the level of concern associated with a research scenario, conduct a thorough review, and determine if the research can be classified as dual use.

**Learning Level Based on Bloom’s taxonomy**

- Knowledge
- Comprehension
- Application
- Synthesis

**Length**

6 hours

**Course Objectives - At the end of this course, students will:**

**Know**

- Expectations and responsibilities as a researcher
- Options for identifying DURC
- The “Seven Experiments” included in DURC and alternative examples

**Feel**

- Capable of identifying potential DURC and confident mitigating the risk of potential DURC

**Be Able to Do**

- Identify potential DURC research
- Properly document, report and justify decisions regarding DURC
- Communicate and understand the DURC review process
- Take responsibility for their own research

**Key Messages**

1. DURC is an issue relevant to all researchers.
2. All researchers have a role in upholding a high standard of the responsible conduct of research.
3. When a researcher identifies potential DURC the project must undergo review process to determine actual concern.
4. Reviewing and determining DURC does not necessitate cessation of the project.
5. The keys to reviewing potential DURC are documentation and justification of conclusions and decisions.

**Biorisk Management Role:**

- Biorisk Management Advisors/Advocates
- Scientific/Lab Management (who conduct research)
- Workforce (who conduct research)
### 4. Biorisk Characterization & Evaluation VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>This course is intended to offer a more complete understanding of the Risk Characterization and Evaluation processes within Biological Risk Assessment. Through guided discussion and interactive exercises, students will be offered an introduction and review of risk and risk assessment in the bioscience context, followed by a discussion the process of risk characterization. Risk evaluation and its importance within risk assessment and the acceptance of risk conclude the course.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course is intended to offer a more complete understanding of the Risk Characterization and Evaluation processes within Biological Risk Assessment. This course does not, in detail, discuss the specifics of either a biosafety or biosecurity risk assessment. These aspects are discussed within the Biosafety Risk Assessment or Biosecurity Risk Assessment courses in more detail.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom's taxonomy | ✓ knowledge  
 ✓ comprehension  
 ✓ application |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- How to assess risk.
- The difference between a hazard and a threat
- How risk characterization contributes to a risk assessment
- How risk evaluation contributes to a risk assessment

**Feel**
- Confident in characterizing the factors that contribute to risk.
- Comfortable evaluating risk

**Be Able to Do**
- Show risk as a function of likelihood and consequences
- Analyze the factors that contribute to risk characterization and evaluation

**Key Messages**
1. A risk assessment supports understanding risks based upon activities and aids risk decision making.
2. Risk Characterization is the process of identifying the factors that contribute to risk and determining the likelihood and consequences that contribute to risk.
3. Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

**Biorisk Management Role:**
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
5. Biosafety Risk Assessment

| Overview | Biosafety Risk Assessment is intended to offer an understanding of the basic theory underlying a biosafety risk assessment. Through guided discussion and interactive exercises, students will learn the basic concept of a biosafety 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 biosafety risk in particular. We will then discuss the process of assessing risk, and finally conclude with a discussion of evaluating risk within the context of specific institution or regulatory scenario. |
| Scope | The goal of this course is to offer a basic awareness of the importance of biosafety risk assessment within the overall process of laboratory biorisk management, with a focus on the risk of unintentional exposure or release of biological agents. |
| Learning Level Based on Bloom's taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

Course Objectives - At the end of this course, students will:

**Know**
- How to define what risk to assess  
- What information must be gathered prior to conducting a biosafety risk assessment

**Feel**
- Confident that the risk assessment process is robust, transparent, and reproducible

**Be Able to Do**
- Explain what risk is characterized by a risk assessment  
- Show the information that is being used for the biosafety risk assessment  
- Establish a risk assessment process that is robust, transparent, and reproducible.

**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 and will be unique to each laboratory.
2. To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.
3. A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these activities are targeted to the most important risk.
4. Risk Evaluation is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk and is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

**Biorisk Management Role:**
- Policy Makers  
- Top Management  
- Biorisk Management Advisors/Advocates  
- Scientific/Lab Management  
- Workforce
## 6. Biosecurity Risk Assessment

<table>
<thead>
<tr>
<th>Overview</th>
<th>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, followed by a discussion the process of assessing risk through characterization of agents and adversaries. The course concludes with a discussion of risk evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>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</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- How to define what risk to assess  
- 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, transparent, and reproducible

**Be Able to Do**
- Explain what risk is characterized by a risk assessment  
- Show the information that is being used for the biosecurity risk assessment  
- 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 every 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.
<table>
<thead>
<tr>
<th>Biorisk Management Role:</th>
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<tbody>
<tr>
<td>✓ Policy Makers</td>
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<tr>
<td>✓ Top Management</td>
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<tr>
<td>✓ Biorisk Management Advisors/Advocates</td>
</tr>
<tr>
<td>✓ Scientific/Lab Management</td>
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<tr>
<td>✓ Workforce</td>
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</table>
### 7. Biorisk Mitigation Strategies VERSION 2

#### Overview
*Biorisk Mitigation Strategies* is intended as an intermediary course. Students should have already completed *Orientation to BRM* and *Risk Assessment*. They should already be familiar with the AMP model and understand the importance of and basics of how to assess risk. While the concepts of mitigation are introduced in *Orientation to BRM*, this course further defines mitigation and examines the hierarchy of controls; introducing the five categories of mitigation control measures broadly. Specific mitigation activities are not discussed in detail. This course should be taken prior to any courses that discuss specific mitigation control measures such as PPE, *Waste Disposal and Decontamination*, Writing SOPs, etc.

#### Scope
This course will define mitigation and provide awareness of the five categories of control measures (hierarchy of controls) and discuss the advantages and disadvantages of each. This course will NOT provide details on specific mitigation control measures.

<table>
<thead>
<tr>
<th>Learning Level</th>
<th>Based on Bloom’s taxonomy</th>
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<tbody>
<tr>
<td>✓ knowledge</td>
<td>✓ comprehension</td>
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<tr>
<td>✓ application</td>
<td></td>
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</tbody>
</table>

| Length          | 3 hours                  |

*Course Objectives - At the end of this course, students will:*

<table>
<thead>
<tr>
<th>Know</th>
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<tbody>
<tr>
<td>• What mitigation is and how it fits into the AMP model.</td>
<td></td>
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<tr>
<td>• Know the importance of doing a thorough risk assessment prior to implementing/evaluating mitigation control measures.</td>
<td></td>
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<tr>
<td>• Understand the various categories of control measures used to reduce risk and their advantages and limitations</td>
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<table>
<thead>
<tr>
<th>Feel</th>
<th></th>
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<tbody>
<tr>
<td>• Prepared to learn more about specific kinds of mitigation</td>
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<table>
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<tr>
<th>Be Able to Do</th>
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<tbody>
<tr>
<td>• Categorize various mitigation efforts into the hierarchy of controls</td>
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</table>

<table>
<thead>
<tr>
<th>Key Messages</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Understand the value of effective mitigation and its role in the AMP model</td>
<td></td>
</tr>
<tr>
<td>2. Mitigation is most effective when based on a thorough risk assessment</td>
<td></td>
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<tr>
<td>3. There are five generally recognized categories of control measures; each with various advantages and disadvantages</td>
<td></td>
</tr>
<tr>
<td>4. Risk is most effectively reduced through elimination or substitution; followed by engineering controls, administrative controls, practice and procedures, and lastly by PPE</td>
<td></td>
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<tr>
<td>5. Different combinations of mitigation measures will typically be needed to reduce risk; the combination used will depend on your ability to implement them</td>
<td></td>
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</table>

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<tr>
<th>Biorisk Management Role:</th>
<th></th>
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<tbody>
<tr>
<td>✓ Policy Makers</td>
<td>✓ Top Management</td>
</tr>
<tr>
<td>✓ Biorisk Management Advisors/Advocates</td>
<td>✓ Scientific/Lab Management</td>
</tr>
<tr>
<td>✓ Workforce</td>
<td></td>
</tr>
</tbody>
</table>
8. Introduction to Incident Management & Response VERSION 2

Overview

*Introduction to Incident Management & Response* is intended to offer an understanding of the basic theory and practice of incident response and management, so that laboratory personnel, as well as managers, can gain an appreciation for the scope and complexity of the topic. Each of the phase of incident management is briefly discussed: 1) pre-event activities, 2) event, 3) response activities, and 4) post-event activities. The course also briefly addresses external coordination needed for major events. It is the first course in a series on incident response.

Scope

This introductory course provides an overview, rather than specifics, on the components of effective incident management and response. Details on these components can be found in other GBRMC courses (1) Incident Management: Pre-event Activities 2) Incident Management: Event and Response Activities, 3) Incident Management: Post-event Activities, and 4) Incident Management: Coordination with External Responders (these course are under development).

Learning Level Based on Bloom’s taxonomy

- knowledge
- comprehension

Length

4 hours

Course Objectives - At the end of this course, students will:

**Know**
- The terms associated with incident management and response
- The structure and phases of the incident management model
- Which personnel should be involved in each phase of incident management
- What components are essential to create robust incident management process

**Feel**
- Capable of discussing each phase of the incident management
- Confident of being part of a team that provides expertise and consultation for incident management and response

**Be Able to Do**
- Identify stakeholders to contribute to incident response procedures
- Determine what steps are necessary for an effective incident management process

**Key Messages**

1. Effective incident management entails planning and preparing for potential incidents. It also includes effective mitigation measures for actual incidents.
2. Effective incident management assesses actual incidents; mounts effective responses; and provides recovery, evaluation, and reporting mechanisms after an event.
3. In order for an institution to understand how to respond and allocate resources appropriately, they categorize the level of an incident (minor and major).
4. Although nearly every incident requires some sort of response, an emergency is an incident that will get bigger or more critical if time elapses between the event and response.
5. Incident management needs the expertise and advice of other personnel in the institution to adequately develop incident response procedures (internally or externally).
6. Standard operating procedures (SOPs) serve as a critical reference for everyone involved in incident response for all phases of incident management.

**Biorisk Management Role:**

- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
### 9. Administrative Controls for Biorisk Mitigation VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Controls for Biorisk Mitigation is intended as a course to be taken early in the General Track in the Global Biorisk Management Curriculum (GBRMC). It is designed to offer understanding of the critical administrative controls used to manage biosafety and biosecurity risks. Students will learn the different types of administrative controls, the general components of these controls, and the functional areas of biorisk management that they address.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Scope</th>
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<tbody>
<tr>
<td>This course will provide a framework for understanding the role of administrative controls in managing biorisks. The types of administrative controls will be discussed. Students will define what administrative controls are, and how they relate to other types of biorisk mitigation measures. Students will identify the various aspects of biorisk management that administrative controls are used to address. The knowledge, skills, and abilities from this course will be used in later Administrative and Operational Controls courses to develop specific controls for various administrative and operational control program plans, procedures, and supporting processes (training, communication, etc.).</td>
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<table>
<thead>
<tr>
<th>Learning Level Based on Bloom's taxonomy</th>
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<tbody>
<tr>
<td>✓ knowledge</td>
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<tr>
<td>✓ comprehension</td>
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<tr>
<td>✓ application</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Length</th>
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<tbody>
<tr>
<td>4 hours</td>
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</table>

**Course Objectives - At the end of this course, students will:**

**Know**
- The definition of an administrative control.
- Administrative controls can be very effective and are one category of biorisk mitigation measures (elimination or substitution, engineering controls, practices and procedures, and personal protective equipment).
- How policies, program plans, procedures, signs and records support a biorisk management.
- Examples of internal and external administrative controls
- CWA 15793:2011 is a useful resource for organizations seeking to establish, improve, or review administrative controls.

**Feel**
- Confident in the ability to categorize biorisk management documents according to the different categories of administrative controls.
- Prepared to undertake development of specific administrative controls, with appropriate follow-on training where needed.
- Comfortable with the role of administrative controls within a biorisk management system.

**Be Able to Do**
- Recognize and categorize biorisk management documents according to the categories of administrative controls.
- Evaluate administrative controls for the presence of key components.
- Communicate the role of administrative controls in biorisk management to others.
- Identify administrative controls used to manage biorisk in a laboratory.

**Key Messages**
1. Administrative controls are one of five categories of biorisk mitigation, and include policies, standards and guidelines used to control risks.
2. Administrative controls complement the other biorisk mitigation categories in reducing the likelihood and consequences of biorisks.
3. Administrative controls may be either external or internal to an organization.
4. Administrative controls are essential for defining, planning, and implementing many functional areas of an organization’s biorisk management system.
5. CWA 15793:2011 establishes a number of requirements related to administrative controls and is a useful resource for organizations seeking to establish, improve, or review administrative controls.

<table>
<thead>
<tr>
<th>Biorisk Management Role:</th>
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</thead>
<tbody>
<tr>
<td>✓ Top Management</td>
</tr>
<tr>
<td>✓ Biorisk Management Advisors/Advocates</td>
</tr>
<tr>
<td>✓ Scientific/Lab Management</td>
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<tr>
<td>✓ Lab Workforce</td>
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</tbody>
</table>
### Overview

*Introduction to Biorisk Management System Performance* reviews key principles of biorisk management and specifically what defines biorisk management system performance. Through guided discussion and interactive exercise, students will explore how to plan to measure biorisk management performance and what some performance measurement methods might be.

### Scope

This course is introductory in nature and is designed to establish key principles of biorisk management performance and to begin to explore how to measure performance. Establishing and using performance indicators, how to evaluate the results of performance measurement, and making improvements to the biorisk management system based on performance measurement are outlined in more detail in additional courses.

### Learning Level Based on Bloom’s taxonomy

- knowledge
- comprehension
- application

### Length

4 hours

### Course Objectives - At the end of this course, students will:

**Know**
- What biorisk management performance is
- Why biorisk management performance is important
- The planning steps to take to measure performance

**Feel**
- More confident about what performance measurements are and how to use them

**Be Able to Do**
- Integrate performance measurements into setting goals and objectives towards enhancing biorisk management capacity.

### Key Messages

1. Performance measures actual progress compared to desired progress
2. The only way to document performance is to measure it.
3. Measuring performance involves
   - targeting a goal
   - establishing measurements to track progress
   - collecting and reporting results
   - acting on findings
   - revising measurements, if needed

### Biorisk Management Role:

- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
# 11. Introduction to Laboratory Biosecurity

## Overview

*Introduction to Laboratory Biosecurity* is a course designed to familiarize students with security in life-science laboratories and introduce them to the unique challenges in this environment. It is meant to frame the way students think about laboratory security and introduce them to risk-based approaches to security. The course will guide students through the derivation of general concepts of assessment, mitigation, and performance as applied to biosecurity risks.

## Scope

This course will provide an introduction to the challenges faced by life science practitioners in securing pathogens while working in laboratories. It will also provide a framework for thinking about these challenges and their possible solutions. It will not provide prescriptive directions or procedures for securing specific agents in the laboratory or institutional setting.

## Learning Level Based on Bloom's taxonomy

- Knowledge
- Comprehension

## Length

8 hours

## Course Objectives - At the end of this course, students will:

### Know

- How to define biosecurity
- How to apply the AMP model to address biosecurity
- The 5 pillars of biosecurity (in relation to biorisk mitigation)

### Feel

- Aware of the unique challenges and importance of securing biological materials from intentional misuse
- Curious about learning more . . .

### Be Able to Do

- List next steps for enhancing biosecurity at the organization

## Key Messages

1. Biological threats are real and biosecurity is critical for the protection of biological assets from theft and deliberate misuse.
2. Biosecurity mitigation measures should be based on biosecurity risk assessment.
3. Securing biological materials presents many unique challenges.
4. The five components or ‘pillars’ of biosecurity are:
   - Physical Security
   - Material Control and Accountability
   - Transport Security
   - Information Security
   - Personnel Management
5. Program management guides and oversees the entire biosecurity program
6. Balanced security and graded security protection should inform the implementation of biosecurity risk mitigation controls

## Biorisk Management Role:

- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
**DRAFT COURSE: Human Performance for Biorisk Management in the Laboratory**

<table>
<thead>
<tr>
<th>Overview</th>
<th>Human Performance for Biorisk Management in the Laboratory is designed to give those working at the laboratory level a basic awareness of factors influencing human performance in terms of the goals of biorisk management.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course covers the basic concepts of human performance and for creating a more productive work environment, as well as some limited discussion of human behavior characteristics as these relate to biorisk management. The course does NOT address specific concepts or processes for screening or monitoring individuals for reliability or trustworthiness.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
 ✓ comprehension |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- The human factors that impact the individual, the job, and the organizational performance
- Which factors contribute to a productive work environment and effective human performance

**Feel**
- Capable of identifying job expectations for biorisk management.

**Be Able to Do**
- Explain why consideration of human factors is important in the implementation of a biorisk management system

**Key Messages**
1. Proper consideration of “human factors” is a key ingredient in effective biorisk management.
2. “Human factors” refer to environmental, organizational & job factors as well as to human and individual characteristics, which influence behavior during work which can, in turn, influence biorisk.
3. Creating a productive and trusting work environment is based on the 5 Rs: Responsibility, Relationships, Respect, Recognition, and Rewards.
4. Mismatches between job requirements and people’s capabilities provide the potential for human error. Without clearly defined job expectations, it is impossible to hold a person accountable for performing the duties of their position.
5. Job performance management is comprised of several steps: 1) documenting job responsibilities, 2) establishing performance expectations, 3) communicating responsibilities, goals, and objectives, 4) tracking performance results, 5) providing feedback, and 6) appreciating and recognizing good performance.
6. People bring to their job their personal attitudes, skills, habits, and personalities. Individual characteristics influence behavior in complex and significant ways.
7. Encouraging reporting of workplace incidents or concerns supports a productive biorisk management culture if the focus is on courses-learned, rather than assessing blame.
8. Evaluating performance incidents or personnel concerns from a job-based, individual-based, and organizational-based approach assures that competence, behavior, and capacity gaps are identified and addressed.

**Biorisk Management Role:**
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
### Overview

*Developing, Evaluating and Validating Standard Operating Procedures (SOPs)* is intended as a course to be taken early in the Laboratory-Level Track in the Global Biorisk Management Curriculum (GBRMC). It is designed to offer understanding of common terminology and the processes used to develop laboratory-level SOPs. Students will learn how to assure that SOPs are evaluated and validated so that the same task may be completed by different people with the same result.

### Scope

This course will provide a framework for developing, evaluating, and validating an SOP. The appropriate scope and uses of SOPs will be discussed. Students will develop, evaluate, and validate an SOP and become familiar with templates for biorisk management procedures. The knowledge, skills, and abilities from this course will be used in later Administrative and Operational Controls courses to develop specific SOPs for various administrative and operational control procedures.

### Learning Level Based on Bloom's taxonomy

- knowledge
- comprehension
- application

### Length

4 hours

### Course Objectives - At the end of this course, students will:

#### Know

- What an SOP and the proper use
- The components of a comprehensive SOP
- How to evaluate an SOP
- How to validate an SOP
- How to improve an existing SOP

#### Feel

- Empowered to create laboratory-level SOPs for biorisk management procedures
- Confident that SOPs communicate validated and effective approaches
- Empowered to modify existing laboratory-level SOPs to improve effectiveness

#### Be Able to Do

- Write an SOP
- Evaluate an SOP
- Validate an SOP

#### Key Messages

1. SOPs are instructional documents designed to guide different people to do the same thing and achieve the same outcome.
2. SOPs are designed to achieve a single, or small, outcome.
3. Several key components comprise an effective SOP.
4. SOPs must be validated before implementation.
5. Behavioral observation data metrics can be used to validate/measure the ongoing effectiveness of an SOP.
6. SOPs must be reviewed periodically and revised as needed.

#### Biorisk Management Role:

- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
# 3. Hazard & Risk Communication in the Laboratory VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th><em>Hazard &amp; Risk Communication in the Laboratory</em> is designed to demonstrate the importance of hazard and risk communication. This course identifies potential risks in and to the laboratory and explains how communication can protect people from those risks. Through guided discussions and interactive exercises, students will apply various communication methods to mitigate risks. By making students aware that ALL individuals entering a laboratory need to know what biorisks they might encounter while also considering security risks, this course creates awareness and prompts action for risk and hazard communication.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course does NOT discuss specific legal requirements for hazard and risk communication.</td>
</tr>
<tr>
<td>Learning Level Based on Bloom’s taxonomy</td>
<td>✓ knowledge ✓ comprehension ✓ application</td>
</tr>
<tr>
<td>Length</td>
<td>4 hours</td>
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</tbody>
</table>

**Course Objectives - At the end of this course, students will:**

**Know**
- The importance of hazard and risk communication
- The biorisks potentially associated with “unknown” samples
- How the international biohazard warning symbol is used
- Risk communication should address both safety and security
- Risk communication can be used to protect both laboratory personnel and the public
- Methods for communicating known risks and preparing for unknown risks

**Feel**
- Capable of communicating about unknown and identified biorisks
- Confident of when to use the international biohazard symbol

**Be Able to Do**
- Identify potential risks associated with “unknown” samples
- Design a risk communication plan for a laboratory where pathogens are used or stored
- Evaluate safety and security considerations in communication needs

**Key Messages**
1. Not all hazards are identified or apparent.
2. Many laboratory-acquired infections have occurred when known hazards have not been clearly identified to all those with access to a laboratory or equipment.
3. Many laboratory-acquired infections have occurred when unknown hazards are encountered.
4. Simple strategies to use signs, symbols, and other types of communication can clarify the risk profile of a laboratory or equipment.
5. Risk communication should address both safety and security.
6. Risk communication must extend beyond those who are knowledgeable about the work.

**Biorisk Management Role:**
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
- ✓ Workforce
### 4. Biocontainment Facility Features VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>The primary goal of the course, <em>Biocontainment Facility Features</em>, is to introduce students to the concept of primary and secondary barriers and to discuss the various facility feature control measures that different biocontainment laboratories may possess. Through guided discussions and interactive exercises, students use risk assessments for agents and procedures to define the appropriate facility features control measures necessary for risk mitigation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course discusses facility features in biocontainment laboratories as part of the assessment of risk mitigation strategies. Detailed requirements or best practices for specific facility feature control measure levels are not provided due to the wide variety of risk-based implementation of facility features that vary across different biocontainment levels.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

*Course Objectives - At the end of this course, students will:*

**Know**
- The definition of biocontainment
- The difference between primary and secondary containment barriers
- Which facility features are used to mitigate different types and levels of biorisk
- How different combinations of facility features are used to address different biorisk scenarios
- Which non-facility mitigation strategies can be used when a facility does not have all the features usually required for safe and secure handling

**Feel**
- Capable of identifying different facility features and how they mitigate biorisk
- Confident that chosen and maintained facility features will contribute effectively to mitigation of identified biorisk

**Be Able to Do**
- Illustrate how containment barriers provide protection
- Recognize appropriate risk-based facility features that contribute to biorisk mitigation
- Implement necessary maintenance strategies based on individual risk assessments

**Key Messages**
1. Appropriate facility features for biocontainment are chosen based on a thorough risk assessment of identified work.
2. Containment barriers are put into place to protect the worker, community, and the environment from exposure.
3. Risk control measures are broken out into three categories: core requirements, heightened control measures, and maximum control measures based on increasing levels of risk.
4. Core requirements set the minimum standards for work in a low risk biological laboratory. Heightened and maximum control measures are then added based on increased risks.
5. At times, biorisk may be mitigated using non-facility based strategies; however, the absence or unavailability of specified facility features must be justified relative to the risk involved and other available and effective biorisk mitigation strategies.

**Biorisk Management Role:**
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
**5. Engineering Controls and Laboratory Equipment VERSION 2**

<table>
<thead>
<tr>
<th>Overview</th>
<th><em>Engineering Controls and Laboratory Equipment</em> is intended for students who are already familiar with biorisk management concepts, hierarchy of controls, and biorisk mitigation strategies. It is designed to offer a cursory review of key engineering controls and equipment typically found in a biomedical research laboratory and to provide learners with the basics of their operation, functions, key features and maintenance needs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This lesson covers general use, operation, functions, features, etc. for the following equipment and engineering controls (specific information about a particular model or brand is not covered): HEPA Filters, Biosafety Cabinets, Fume Hoods, Clean Benches, Centrifuges, Transport Containers, Vacuum Line Protection, Engineered Needle Safety.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
 ✓ comprehension |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- How facilities implement appropriate control measures based on risk
- Terminology associated with containment
- The difference between primary and secondary containment barriers
- How HEPA filters provide protection
- The function of different types of biological safety cabinets
- How to safely work with engineering control equipment (BSC, Centrifuge, etc.)

**Feel**
- Confident describing different classes of mitigation control measures used for containing biological risks in the laboratory
- Capable of selecting appropriate engineering controls to help achieve containment
- Protected when properly using engineering controls

**Be Able to Do**
- Describe how to select the appropriate ventilation equipment to provide the appropriate protection
- Identify common issues with engineering control equipment

**Key Messages**
1. Engineering controls are used for containing biological risks in the laboratory. Because there are a variety of equipment and design features, understanding their function is key to proper use.
2. Ventilation equipment is a type of engineering control that uses airflow to protect the worker, sample, and/or the environment.
3. Biosafety cabinets provide outstanding protection through directional airflow and HEPA filtration when used properly. It is important to select the correct type of cabinet based on the type of work it will be used for.

**Biorisk Management Role:**
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
| ✔  Workforce |
### 6. Good Laboratory Work Practices VERSION 2

| **Overview** | **Good Laboratory Work Practices** is a course designed to introduce students to some of the practices and procedures that have been shown to reduce or mitigate biorisk. It should be coupled with other risk mitigation courses such as PPE and Engineering Controls. It is intended to follow after the general Risk Mitigation module. |
| **Scope** | This course will draw knowledge and awareness of some good laboratory work practices. Though it does not cover all the possible practices, it uses facilitated learning activities to draw out student’s knowledge of good practices and common sense. It reinforces concepts learned in the Risk Mitigation course. |
| **Learning Level Based on Bloom’s taxonomy** | ✓ knowledge  
✓ comprehension  
✓ application |
| **Length** | 2.5 hours |

**Course Objectives - At the end of this course, students will:**

- **Know**
  - Some common good laboratory work practices  
  - Why some laboratory practices are better than others  
  - How to perform a risk assessment to determine if a GLWP is good or not

- **Feel**
  - Confident mitigating biorisk by implementing GLWPs

- **Be Able to Do**
  - Be able to recognize potential unsafe work practices and conditions  
  - Wash hands properly

**Key Messages**

1. Good Laboratory Work Practices are techniques and methods of doing work in the laboratory that reduce biorisk.  
2. Barriers to Good Laboratory Work Practices can be overcome through various strategies.  
3. The AMP model (Assessment, Mitigation, Performance) is applicable to the maintenance of Good Laboratory Work Practices.

| **Biorisk Management Role:** | ✓ Policy Makers  
✓ Top Management  
✓ Biorisk Management Advisors/Advocates  
✓ Scientific/Lab Management  
✓ Workforce |
# Personal Protective Equipment

## Overview

*Personal Protective Equipment* (PPE) is designed for lab workers who use PPE and those who may be responsible for selection and purchase of PPE. Students will discover the various options for PPE and how it is used to prevent exposures in both day to day setting and emergency procedures. Students will gain an understanding of how to properly use PPE and develop measures for checking, maintaining, donning and doffing PPE.

## Scope

This course will provide awareness of various kinds of PPE and a general overview of principles used to select appropriate PPE, and circumstances under which they may be used. Participants will have some hands-on practice with some limited examples of PPE. This course will NOT provide details on every type of PPE and options for use, nor will this training cover the specifics of how to use, decontaminate, remove, or maintain specific PPE.

## Learning Level Based on Bloom’s taxonomy

- knowledge
- comprehension
- application

## Length

4 hours

## Course Objectives - At the end of this course, students will:

### Know

- What PPE is
- What each type of PPE is used for.
- Which types of PPE are appropriate for different settings and risk levels.
- Specific procedures for use and maintenance.
- How to integrate the use of PPE into current laboratory procedures.

### Feel

- Confident that suitable PPE has been chosen for laboratory procedures and activities.
- Confident of proper PPE use and maintenance is understood by all those in the laboratory.

### Be Able to Do

- Demonstrate different types and uses of PPE.
- Write laboratory procedures that include the use and maintenance of PPE appropriate to that procedure.

## Key Messages

1. Understand why PPE is one of the key controls to mitigate biorisks but in the last level in the “Hierarchy of Controls” for several reasons.
2. There are many types/kinds of PPE with various advantages and limitations
3. The selection of PPE is based on several factors but most importantly on a thorough risk assessment.
4. It is important to plan the order of donning and doffing PPE and follow that plan to reduce risk.

## Biorisk Management Role:

- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Workforce
8. Decontamination VERSION 2

| Overview | Decontamination is designed to provide students with a working vocabulary of decontamination terms and a familiarity with the types of decontamination procedures commonly used for decontamination of objects and surfaces contaminated with biological agents. Students, through guided discussions and interactive exercises, determine the benefits and limitations to chemical and physical methods of decontamination.  

Notes:  
- Prior to teaching the course, the instructor should be familiar with:  
  - Autoclave manufacturing guidelines  
  - Manufacturers operations manuals for various equipment  
- This course discusses decontamination in general and does NOT specify or instruct on specific legal requirements for specific decontamination procedures. |

| Scope | This course provides information on decontaminating objects and surfaces contaminated with biological agents and the benefits and limitations of those decontamination methods. |

| Learning Level Based on Bloom's taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |

| Length | 8 hours |

Course Objectives - At the end of this course, students will:

Know  
- The various decontamination methods used for surface and area decontamination.  
- The factors that influence the efficacy of a decontamination procedure.  
- The hazards and limitations of decontamination methods.  
- How validation of the decontamination procedure is conducted.  

Feel  
- Capable of distinguishing among the types and methods of decontamination relative to the risks involved and the nature of the object or surface to be decontaminated.  
- Confident that the method chosen is appropriate.  

Be Able to Do  
- Select and utilize appropriate decontamination methods.  
- Choose an appropriate validation method.  
- Interpret the results from validation.  

Key Messages  
1. Biological decontamination is a process to reduce or remove unwanted or hazardous pathogens. There are many methods of decontamination.  
2. No one decontamination method is ideal, each method has strengths and limitations. Understanding the strengths and limitations is key to their use.  
3. Disinfection and sterilization are types of decontamination methods. Disinfection is less rigorous than sterilization. Sterilization is the complete removal of all organisms.  
4. Many factors determine the efficacy of a particular disinfectant. These must be understood when selecting the appropriate disinfectant.  
5. Some pathogens have resistance to various disinfectants and decontamination methods.  
6. Autoclaves can be used to sterilize things through wet heat and the application of appropriate time, pressure, and temperature. Wet heat is more effective than dry heat.  
7. Decontamination validation is a vital process to ensure that pathogens are successfully removed to ensure that risk is mitigated.
<table>
<thead>
<tr>
<th><strong>Biorisk Management Role:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Policy Makers</td>
</tr>
<tr>
<td>✓ Top Management</td>
</tr>
<tr>
<td>✓ Biorisk Management Advisors/Advocates</td>
</tr>
<tr>
<td>✓ Scientific/Lab Management</td>
</tr>
<tr>
<td>✓ Workforce</td>
</tr>
</tbody>
</table>
## 9. Biological Waste Disposal VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>Biological Waste Disposal is designed to provide participants a general overview of the different types of biological waste. The course will also discuss the waste management process to ensure that materials are disposed of properly and are no longer considered biohazardous. Students will create, through guided discussion and interactive exercises, a matrix of acceptable methods to segregate, collect, store, transport, treat, and dispose multiple types of biological waste.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course discusses biological waste disposal in general and does NOT specify or instruct on specific legal requirements for biological waste disposal.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge
✓ comprehension
✓ application |
| Length | 4 hours |

**Course Objectives** - At the end of this course, students will:

### Know
- The vocabulary applicable to biological waste
- The different types of biological waste
- The steps in the waste management process
- The risks associated with handling/treating biological waste
- The different approaches/methods used throughout the waste management process

### Feel
- Capable of categorizing different types of biological waste
- Confident choosing the appropriate method to treat and dispose biological waste

### Be Able to Do
- Segregate different types of biological waste
- Select and utilize appropriate methods throughout the waste management process based on the type of biological waste

### Key Messages
1. Waste should be segregated into appropriate waste types, based on the physical form of the waste.
2. Different methods for collection and storage of biological waste are necessary for different types of waste.
3. The type of treatment and disposal methods used depends on the risk the waste type presents.
4. Although legal requirements vary according to location, the basic principles of biological waste disposal and treatment remain the same due to the risk associated with each waste type.

| Biorisk Management Role: | ✓ Biorisk Management Advisors/Advocates
✓ Scientific/Lab Management
✓ Workforce |
## 10. Laboratory Biosecurity

<table>
<thead>
<tr>
<th><strong>Overview</strong></th>
<th>Laboratory Biosecurity is a course designed to familiarize students with security in life-science laboratories and introduce them to the unique challenges in this environment. It is meant to frame the way students think about laboratory security and introduce them to risk based approaches to security. The course will guide students through the derivation of general concepts of assessment, mitigation, and performance as applied to biosecurity risks. The students will then learn how to apply a comprehensive biological security system suitable for a laboratory.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>This course will provide an introduction to the challenges faced by life science practitioners in securing pathogens while working in laboratories. It will also provide a framework for thinking about these challenges and their possible solutions. It will not provide prescriptive directions or procedures for securing specific agents in the laboratory or institutional setting.</td>
</tr>
</tbody>
</table>
| **Learning Level Based on Bloom’s taxonomy** | ✓ knowledge  
 ✓ comprehension  
 ✓ application |
| **Length** | 16 hours/2 days |

**Course Objectives - At the end of this course, students will:**

**Know**
- The importance of laboratory biosecurity and the reasoning behind it
- Different methods for establishing physical, information, and transport security
- Different methods for materials control and accountability and personnel reliability
- Which methods are appropriate at different levels and types of risk

**Feel**
- Confident in choosing and using different methods to assure laboratory biosecurity

**Be Able to Do**
- Write and apply lab-level procedures to assure laboratory biosecurity.
- Describe why different methods are appropriate for establishing laboratory biosecurity

**Key Messages**
1. A proper biosecurity risk assessment is necessary before implementing an efficient and effective biosecurity program.
2. Securing pathogens and toxins can be very different from securing other kinds of materials.
3. Physical Security is only one component of a successful laboratory biosecurity program.
5. Security awareness is crucial in laboratory biosecurity.

**Biorisk Management Role:**
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management (who conduct research)
- ✓ Workforce (who conduct research)
### 11. Field Biosecurity

**Overview**

*Field Biosecurity* is a course designed to familiarize students with the unique challenges of conducting biosecurity in environments outside the life-science facility. It is meant to frame the way students think about biosecurity in the field, and apply general concepts of biosecurity risk assessment, mitigation, and performance to wide, open and often isolated environments.

**Scope**

This course will provide an introduction to the challenges faced by life-science practitioners in securing pathogens while working in the field. It will also provide a framework for thinking about these challenges and their possible solutions, and allow students to explore these challenges and possible solutions through situational activities. It will NOT provide mandatory directions and procedures for securing specific agents during work in the field.

**Learning Level Based on Bloom’s taxonomy**

- knowledge
- comprehension
- application

**Length**

8 hours

**Course Objectives - At the end of this course, students will:**

- **Know**
  - How procedures in the field differ from the laboratory in terms of the ability to secure biological agents and toxins
  - What procedures are suitable for securing biological agents and toxins outside of the laboratory

- **Feel**
  - Confident that appropriate procedures for securing biological agents and toxins during field work and sample transport are chosen and applied

- **Be Able to Do**
  - Write and demonstrate procedures that are suitable for securing biological agents and toxins outside of the laboratory

**Key Messages**

1. Field work with pathogens and toxins is very different from laboratory work – security is also different in the field versus the laboratory.
2. Many laboratory biosecurity measures can be modified and adapted to field work.
3. The same frameworks for approaching risk management in laboratories can be utilized in the field.
4. Biosecurity risk mitigation in the field places special emphasis material control and accountability as well as personnel accountability.
5. Security awareness is crucial in field biosecurity.

**Biorisk Management Role:**

- Biorisk Management Advisors/Advocates
- Scientific/Lab Management (who conduct research)
- Workforce (who conduct research)
## 12. Shipping Infectious Substances & Biological Specimens VERSION 3

**Overview**

*Shipping Infectious Substances & Biological Specimens* course introduces students to shipping dangerous goods with a focus on how to properly classify, package, mark/label, and complete the appropriate paperwork to ship infectious substances and other biological materials. Students will also be introduced to program management requirements and security issues associated with transporting and shipping infectious substances.

Students who successfully complete the course, including the hands-on activities and pass the final exam can meet all of the certification requirements according to International Air Transport Association (IATA) regulations’ competency based training requirements.

**Scope**

This course will provide awareness of international dangerous goods shipping regulations and other requirements as they relate to Class 6.2 (infectious substances) and Class 9 (dry ice). 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. Through hands on practice students will gain practical experience in packaging, marking, labeling and documentation.

**Learning Level Based on Bloom’s taxonomy**

- knowledge
- comprehension
- application

**Length**

8 hours (See Part II: Course Outline of the Design Document for options)

### Course Objectives - At the end of this course, students will:

**Know**

- The regulations that affect shipping biological agents and toxins
- The terminology related to shipping infectious substances
- How the shipping process contributes to an effective biologic risk management system
- How to provide basic planning for development and management of a biological agent shipping program

**Feel**

- Confident packaging, marking/labeling and preparing biological agents and toxins and samples to prevent release or loss during transport or shipping in accordance with international regulatory requirements

**Be Able to Do**

- Determine the appropriate classification of biological agents for shipments
- Demonstrate how to perform the seven steps in the shipping process
- Prepare a shipment of any biological material to meet safety and regulatory requirements
- Basic planning for development and management of a biological agent-shipping program

**Key Messages**

1. There can be many regulatory requirements that affect the shipment/transport of infectious substances. Observance of IATA regulations is the best way to ensure regulatory compliance.
2. Regulations have specific definitions and criteria for dangerous goods.
3. Every dangerous good is assigned a “Proper Shipping Name” (PSN) and corresponding UN number.
4. Packing instructions inform shippers specifically how to properly package dangerous goods. All biological agents must be “tripled packaged”.
5. There are six key components that must be marked/labeled on the outside of an infectious substance package.
6. Overpacks are enclosures over packages; they must be marked and labeled exactly as the inner packages.
7. There will be a variety of paperwork that may be required for shipping depending on the nature of the shipment. Shipper’s Declarations are legal documents; three copies are required for most dangerous goods shipments.

8. Before shipping high consequence agents, there are many additional considerations.

9. Different countries have different requirements for importing and exporting biological materials. Consideration must be given to import and export requirements for the countries of origin and destination. There will be a variety of paperwork that may be required for shipping depending on the nature of the shipment. Shipper’s Declarations are legal documents, three copies are required for most dangerous goods shipments.

10. Before shipping high consequence agents, there are many additional considerations.

11. Different countries have different requirements for importing and exporting biological materials. Consideration must be given to import and export requirements for the countries of origin and destination.

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Scientific/Lab Management</td>
</tr>
<tr>
<td></td>
<td>✓ Workforce</td>
</tr>
</tbody>
</table>
# 1. Writing & Communicating Biorisk Management Policy VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>Writing &amp; Communicating Biorisk Management Policy will provide an understanding of what an institutional policy statement is: how to apply it to biorisk management (BRM); why it is important for an institution to have a BRM policy in place and what purpose it serves; and provides an opportunity to develop a draft policy and to receive the feedback of instructors and students.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course provides guidelines for writing and communicating a policy statement; it will NOT provide mandatory directions and procedures for developing a policy statement.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge
✓ comprehension
✓ application |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- What is a policy statement
- What is included in a policy statement
- Who writes a policy statement
- How a policy statement is written
- Who reads a policy statement

**Feel**
- Confident conversing about basic features found in a policy statement
- Confident drafting a policy statement

**Be Able to Do**
- Draft a policy statement
- Develop a plan to communicate policy to all layers of the affected workforce
- Review a policy statement to validate that it is applicable

**Key Messages**
1. It is imperative for management to establish and communicate institutional expectations regarding safe and secure management of pathogens.
2. These expectations must be integrated with the core mission of the institution.
3. A policy states commitment and intent.
4. A policy is an instructional document and, as such is reader-centered.
5. A policy must be communicated (transmitted and received) to “count”.
6. A policy should be a living document and must reflect emerging issues and continuous improvement – policies must be reviewed and revised.

**Biorisk Management Role:**
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
## 2. Considerations for Training in Biorisk Management VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>Considerations for Training in Biorisk Management is designed for managers who oversee staff and programs where providing knowledge, skills, and abilities relevant to biorisk management through training is critical. Through guided discussion and interactive exercises, managers will determine needed training content and also identify qualifications for instructors who can deliver the content in a sustainable manner. The course also emphasizes the need for managers to be involved in the instructional design process – in particular in the identification of learning objectives and the evaluation of the training.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course is a management level course intended to increase the awareness and skills necessary to plan, prioritize, and assign appropriate people, resources, and time towards training in biorisk management. This course is not designed to instruct on training techniques.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

| Know | • The steps of the training design cycle  
• Which steps of the training design cycle are important for managers/leadership to be involved in  
• The roles and responsibilities of those involved in biorisk management at a facility  
• Basic training techniques that make trainings effective |
|---|---|
| Feel | • Capable of contributing to the training design process  
• Confident determining how to achieve desired behaviors |
| Be Able to Do | • Analyze the current situation and the desired outcome to develop learning objectives for a training event or program  
• Evaluate training events or programs to assure that biorisk management competency is established and maintained |
| Key Messages | 1. Training involves transferring knowledge, skills, and abilities to an identified person to create desired behaviors and actions in that person.  
2. The training design cycle provides steps for assuring that training is developed in a standardized and strategic manner.  
3. Managers should be involved in analyzing the current situation and the desired outcomes to assure that training is targeted to meet biorisk management goals.  
4. Managers need to be aware of what type of delivery creates the most sustainable training environment, especially as they evaluate and assign instructors.  
5. Managers must be involved in evaluation of training events to assure that the desired outcome has been reached or progress has been made towards the desired outcome. |
| Biorisk Management Role: | ✓ Policy Makers  
✓ Top Management  
✓ Biorisk Management Advisors/Advocates  
✓ Scientific/Lab Management  
✓ Workforce |
### 3. Developing and Maintaining an Inventory Management System VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th><strong>Developing and Maintaining an Inventory Management System</strong> is designed for students in the Management and Leadership Track. The course will establish an understanding of biological asset identification as well as the development of standardized processes to build and maintain an inventory of biological assets. Security issues and aspects of inventory monitoring and improvement will be evaluated as well as personnel roles and responsibilities with regard to inventory.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course will provide an overview of the key aspects of developing, and maintaining a laboratory inventory management system. This course will NOT cover all aspects of biohazard identification and assessment nor will it provide a specific laboratory inventory design.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension |
| Length | 8 hours |

Course Objectives - *At the end of this course, students will:*

**Know**
- How to identify, characterize, and prioritize assets  
- What information should be included in the inventory  
- The different types of inventory management systems  
- What items would be subject to material controls and accountability procedures  
- The importance of monitoring and protecting the inventory management system

**Feel**
- Confident implementing best practices for inventory management systems  
- Capable of developing and maintaining an inventory management system

**Be Able to Do**
- Maintain inventory information to meet basic conditions of control and accountability  
- Assign roles and responsibilities to staff throughout the inventory process  
- Ensure the appropriate procedures are in place to support an inventory management system  
- Communicate expectations for inventory processes to your staff  
- Solicit internal and external input about how to assess, implement, and evaluate the inventory management system  
- Monitor and review the inventory management system

**Key Messages**
1. Inventory management systems are a critical part of biorisk management because they address assessment, mitigation, and performance.  
2. Inventory management systems should track assets (hazards, equipment, and supplies).  
3. Performing systematic asset identification is necessary in order to perform a proper assessment of the associated risk.  
4. Assets are characterized and prioritized to decide what is most important for material control and accountability.  
5. There are several different ways to build an inventory system that accurately captures and maintains the appropriate information to track each type of asset.  
6. Managers will use input and expertise of staff and outside experts to assess, implement, and evaluate the inventory system.  
7. For the inventory to be effective it must be complete and up-to-date and therefore the system should be evaluated regularly and allow for continual improvement.  
8. It is important to have control measures in place to protect inventory-related information.
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>✓ Top Management</td>
</tr>
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<tr>
<td>✓ Scientific/Lab Management</td>
</tr>
</tbody>
</table>
# 4. Identifying Legal Requirements that Impact Biorisk Management VERSION 2

<table>
<thead>
<tr>
<th>Overview</th>
<th>Identifying Legal Requirements that Impact Biorisk Management is designed for managers and leaders to identify the international, national, and local requirements that impact biorisk management (BRM) at the organizational level. Although it is designed for managers and leaders, it can also be used for any worker that influences or impacts BRM to provide an opportunity to think through and to catalog these requirements. Note: Presenting this course will require preparation on the instructor’s part to become familiar with the legal requirements of the local country.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course provides information on the types of legal requirements for BRM that must be followed by an institution.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- How to identify legal requirements that impact BRM
- Where legal requirements originate
- How to align legal requirements with BRM
- What is involved in performing a gap analysis

**Feel**
- Confident in identifying and understanding legal requirements that impact BRM

**Be Able to Do**
- Identify legal requirements that impact BRM
- Determine how legal requirements affect BRM

**Key Messages**
1. Legal requirements derive from international and national sources and cover a variety of aspects of BRM
2. It is the responsibility of an institution’s leadership and management to understand the legal requirements for BRM in their country
3. A best practice to determine compliance with legal requirements is to conduct a gap analysis

**Biorisk Management Role:**
- ✓ Policy Makers
- ✓ Top Management
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
## 5. Establishing Work Program Review & Approval

### Overview

*Establishing Work Program Review & Approval* is designed to guide managers and leaders to develop key questions and processes necessary to ensure that the work program(s) of their organization is defined, documented, reviewed, and, as necessary, approved. The importance of this process is to identify biorisks and other impacts on biorisk management, as well as aiding in planning and prioritization of resources for planned, and perhaps more importantly, unplanned work. Because, as part of work program review & approval, many institutions use a peer-review process structured as an Institutional Biosafety or Biorisk Management Advisory Committee, the structure and function of such a committee is introduced and key documents and considerations for formation of a committee are developed as part of the interactive exercises.

### Scope

This course guides students through a decision-making process for developing a work program & review workflow at their institution, but does NOT specify any mandated format for that process.

### Learning Level Based on Bloom’s taxonomy

- knowledge
- comprehension
- application

### Length

4 hours

### Course Objectives - At the end of this course, students will:

#### Know

- Why defining, documenting, reviewing, and approving work programs is important to biorisk management
- Why a common process for defining, documenting, reviewing, and approving work programs is important to planning, prioritizing, and assigning resources
- Why review and approval of work programs by a committee, rather than an individual, is important to biorisk management
- Steps to developing a term of reference and roster for a Biorisk Management Advisory Committee

#### Feel

- Capable of establishing or improving a process to define, document, review and approve work programs
- Confident in the structure and function of a Biorisk Management Advisory Committee

#### Be Able to Do

- Determine and communicate a process to gather the data and criteria necessary for definition, documentation, review and approval of work programs
- Determine and communicate roles & responsibilities necessary for definition, documentation, review and approval of work programs, including that of a Biorisk Management Advisory Committee, if utilized

### Key Messages

1. The key to assessing priorities for the human capacity and physical infrastructure of a biorisk management system is to know what is occurring in the work program.
2. Biorisk assessment relies on an accurate picture of the agents and situations in the work program.
3. A transparent, robust, and reproducible peer-review process for defining, documenting, reviewing, and approving work helps identify “missing” hazards and issues.

### Biorisk Management Role:

- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
## 6. Establishing Goals, Objectives, Roles, Responsibilities & Performance Indicators in Biorisk Management

<table>
<thead>
<tr>
<th>Overview</th>
<th>Establishing Biorisk Management Goals, Objectives, Roles, Responsibilities, and Performance Indicators (GORRPI) is designed to: review the process of setting goals to effectively focus appropriate attention on the various components of biorisk management (BRM); it will explain why it is important for an institution to have goals and objectives for BRM in place; and will give students an opportunity to develop a template and examples for BRM goals, objectives, roles, responsibilities, and performance indicators.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course provides guidelines for writing and communicating goals, objectives, roles, responsibilities, and performance indicators. It will NOT provide mandatory directions and procedures for developing them.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge
✓ comprehension
✓ application |
| Length | 8 hours |

### Course Objectives - At the end of this course, students will:

**Know**
- What a goal is
- What an objective is
- How to write objectives that relate to a goal
- Why goals and objectives are important to BRM
- Why establishing and communicating roles and responsibilities is critical to achieving goals and objectives
- How to determine what roles and responsibilities are necessary
- Why it is critical to measure BRM performance
- How to define performance indicators

**Feel**
- Confident conversing about the planning steps required to draft effective GORRPI
- Confident drafting a document that establishes GORRPI

**Be Able to Do**
- Draft goals and objectives
- Develop a strategy to assign roles and responsibilities
- Build performance indicators to evaluate progress towards goals and objectives

### Key Messages
1. While a policy states commitment, intent, and the direction of a BRM program, goals provide a target
2. Objectives outline the steps to move towards the goal
3. In order to implement BRM, roles and responsibilities must be established and assigned
4. Performance indicators and metrics, established early in the planning process, track progress towards goals
5. Not all goals and objectives can (or should be) pursued at the same time
6. GORRPI must be reviewed and revised to reflect emerging issues and continuous improvement

### Biorisk Management Role:
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
# 7. Managing Human Performance in the Biorisk Management Workforce

<table>
<thead>
<tr>
<th>Course</th>
<th>Overview</th>
<th>Managing Human Performance in the Biorisk Management Workforce is designed to give managers the opportunity to think about human performance management in terms of the goals of biorisk management (BRM) and to provide tools for integrating BRM expectations into job and individual responsibilities and for addressing human factors in BRM concerns and incidents.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>This course covers the basic steps in human performance management and in creating a more productive work environment, as well as some limited discussion of human behavior characteristics as these relate to biorisk management. The course does NOT address specific concepts or processes for screening or monitoring individuals for reliability or trustworthiness.</td>
<td></td>
</tr>
<tr>
<td><strong>Learning Level</strong> Based on Bloom’s taxonomy</td>
<td>✓ knowledge ✓ comprehension ✓ application</td>
<td></td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>8 hours</td>
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</tr>
</tbody>
</table>

**Course Objectives - At the end of this course, students will:**

**Know**
- That human factors impact individual, job, and organizational performance
- What factors contribute to a productive work environment and effective human performance management
- Methods that can help address concerns and incidents involving the workforce

**Feel**
- Capable of documenting and communicating job expectations for biorisk management
- More confident in assessing and addressing issues involving human performance

**Be Able to Do**
- Create and communicate job expectations for using identified, risk-based mitigation strategies
- Track and measure performance based on identified expectations
- Assess and address human factors that contribute to successes and failures in biorisk management

**Key Messages**
1. Proper consideration of “human factors” is a key ingredient in effective biorisk management.
2. “Human factors” refer to environmental, organizational, and job factors as well as to human and individual characteristics which influence behavior during work which can, in turn, influence biorisk.
3. Creating a productive and trusting work environment is based on the 5 Rs: Responsibility, Respect, Recognition, and Rewards.
4. Mismatches between job requirements and people’s capabilities provide the potential for human error. Without clearly defined job expectations, it is impossible to hold a person accountable for performing the duties of their position.
5. Job performance management is comprised of several steps: 1) document job responsibilities, 2) establish performance expectations, 3) communicate responsibilities, goals, and objectives, 4) track performance results, 5) provide feedback, and 6) appreciate and recognize good performance.
6. People bring their personal attitudes, skills, habits, and personalities to their jobs. Individual characteristics influence behavior in complex and significant ways.
7. Organizational factors have the greatest influence on individual and group behavior yet they are often overlooked.
8. Encouraging reporting of workplace incidents or concerns supports a productive biorisk management culture if the focus is on lessons-learned, rather than assessing blame.
9. Evaluating performance incidents or personnel concerns from a job-based, individual-based,
and organizational-based approach assures that competence, behavior, and capacity gaps are identified and addressed.

<table>
<thead>
<tr>
<th><strong>Biorisk Management Role:</strong></th>
</tr>
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<tbody>
<tr>
<td>✓ Top Management</td>
</tr>
<tr>
<td>✓ Biorisk Management Advisors/Advocates</td>
</tr>
<tr>
<td>✓ Scientific/Lab Management</td>
</tr>
</tbody>
</table>
### 8. Establishing & Maintaining Worker Health Programs

<table>
<thead>
<tr>
<th>Overview</th>
<th><em>Establishing &amp; Maintaining Worker Health Programs</em> is intended as a course to be taken as part of the Management &amp; Leadership track in the Global Biorisk Management Curriculum (GBRMC). It is designed to offer a common terminology and a process to determine effective and appropriate occupational health strategies in a laboratory setting.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course will provide a framework for determining effective and appropriate occupational health strategies in a laboratory setting. The appropriate scope and uses of this information will be discussed. Students will be taught on core components of an occupational health system, and obtain examples of occupational health cases and courses learned with a view of increasing performance. Also, participants will engage in discussions on how to best establish a system commensurate with the occupational risk. The knowledge, skills, and abilities from this course may be used in other courses to develop specific components for various aspects, for example the liaison with general laboratory safety procedures.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 7 hours/1 day |

**Course Objectives - At the end of this course, students will:**

**Know**
- Characteristics of different components of occupational health measures  
- The principles of how to effectively and appropriately initiate an effective occupational health system  
- The principles of how to learn and improve after occupational health incidents  
- The principles of how to utilize this knowledge in a broader laboratory setting, including referencing to operational procedures

**Feel**
- Empowered to define and identify occupational health measures  
- Confident that occupational health systems may be used to effectively mitigate health related issues in the work place  
- Empowered to mitigate existing occupational health lab-level risks

**Be Able to Do**
- Define, characterize and recognize various components of an occupational health system  
- Assist in utilizing this knowledge in existing or future laboratory procedures, e.g. general laboratory safety procedures

**Key Messages**
1. A well planned occupational health system is a pivotal preventive and protective measure  
2. The scope of occupational health includes workers, co-workers, family members, employers, customers and the community.  
3. Defining core occupational health components such as prevention, protection, surveillance, liaising and treatment.  
4. The organization shall have access to appropriate occupational health expertise.  
5. An occupational health program should be commensurate with the activities and risks of the facility.  
6. The information from this course may be useful in a variety of laboratory settings and procedures.
| Biorisk Management Role: | ✓ Policy Makers  
✓ Top Management  
✓ Biorisk Management Advisors/Advocates  
✓ Scientific/Lab Management |
<table>
<thead>
<tr>
<th>Overview</th>
<th>Managing Access to, Control of, and Accountability for Biological Materials is intended to provide management-level personnel an introduction to key considerations for managing personnel laboratory access and Material Control &amp; Accountability responsibilities for both biological agents and toxins. The course will also focus on management’s role in determining personnel accountability for biological material and how it is determined, implemented, transferred, communicated, and evaluated.</th>
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<tbody>
<tr>
<td>Scope</td>
<td>This course will provide introductory information on developing and communicating policies and procedures related to laboratory access and Material Control &amp; Accountability issues. This course will NOT provide in-depth discussion of specific laboratory biosecurity issues, including physical access control systems, operational details of Material Control &amp; Accountability systems, personnel screening approaches, information security, and incident response.</td>
</tr>
<tr>
<td>Learning Level Based on Bloom’s taxonomy</td>
<td>✓ knowledge  ✓ comprehension  ✓ application</td>
</tr>
<tr>
<td>Length</td>
<td>8 hours</td>
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</tbody>
</table>

**Course Objectives - At the end of this course, students will:**

**Know**
- Which personnel groups require access and the specific requirements of each, including the inherent risks of the people to the laboratory and the risks of the laboratory to the people.
- How mitigation measures are used to control access.
- What mechanisms are available to assure that access and accountability processes are working correctly.

**Feel**
- Prepared and motivated to implement risk-based access, control, and material accountability measures for biological materials.
- Confident managing personnel laboratory access and Material Control & Accountability systems

**Be Able to Do**
- Communicate roles and responsibilities, as well as expectations, for biological material access, control, and accountability to personnel and visitors.
- Strategize implementation of material control, access, and accountability measures.
- Ensure access and accountability processes are working correctly.

**Key Messages**
1. Different groups of people require different levels of access to laboratories and biological materials based on various risk factors.
2. Access to the laboratory and materials can be controlled through mitigation measures that reduce safety and security risks while preserving the ability of the laboratory to function properly.
3. Access controls and Material Control & Accountability measures help create a safe and secure inventory by ensuring complete and timely knowledge of what materials exist, where they are, and who is accountable for them.
4. Facility leadership is ultimately responsible for controlling access privileges, ensuring mitigation measures are being followed, and polices/procedures are in place, including removing or transferring access and/or accountability with personnel changes.
5. While everyone has a minimum responsibility to follow procedures, “accountable individuals” are responsible for maintaining current inventory records and reporting any discrepancies.
6. Regular reporting and auditing of the Material Control & Accountability system is needed to
<table>
<thead>
<tr>
<th><strong>Biorisk Management Role:</strong></th>
<th>ensure the system is properly functioning.</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅ Top Management</td>
<td></td>
</tr>
<tr>
<td>✅ Biorisk Management Advisors/Advocates</td>
<td></td>
</tr>
<tr>
<td>✅ Scientific/Lab Management</td>
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</tbody>
</table>
## DRAFT COURSE: Establishing and Maintaining Formal and Informal BRM Mentoring Programs

<table>
<thead>
<tr>
<th>Overview</th>
<th>Establishing and maintaining formal and informal Biorisk Management Mentoring Programs addresses the gap that is often found between “training” and “behavior”. Students will, through guided and interactive exercises, explore the opportunities for mentoring to reinforce principles and practices of biorisk management on an individual basis. Students will develop a draft mentoring agreement for a given biorisk management objective – the agreement will define roles and responsibilities for both mentor and mentee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course will result in draft procedures for biorisk management mentoring – this draft will provide a template to be completed at the student’s organization, with appropriate stakeholder participation and consensus.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

### Course Objectives - At the end of this course, students will:

#### Know
- What mentoring can and cannot accomplish  
- Criteria for using mentoring as a means to reinforce the principles and practices of biorisk management  
- Elements to include in drafting mentoring agreements  
- Qualifications for effective mentors and mentees

#### Feel
- Capable of implementing mentoring as an expected element of biorisk management

#### Be Able to Do
- Write a draft mentorship agreement  
- Identify next steps for developing a mentorship program to support and maintain biorisk management

### Key Messages
1. Mentoring is a form of training.  
2. Mentoring, in addition to reinforcing knowledge, skills, and abilities of an individual, also addresses the comfort level and competency of that individual.  
3. A mentorship requires active participation on the part of the mentor and mentee  
4. A mentor must be qualified to reinforce desired behaviors.  
5. Mentorship agreements must include roles, responsibilities, and evaluations for both parties.

### Biorisk Management Role:
- ✓ Policy Makers  
- ✓ Top Management  
- ✓ Biorisk Management Advisors/Advocates  
- ✓ Scientific/Lab Management
### 11. Understanding & Maintaining Facilities & Equipment for Biorisk Management

<table>
<thead>
<tr>
<th>Overview</th>
<th><em>Understanding &amp; Maintaining Facilities &amp; Equipment for Biorisk Management</em> is designed as an overview of the key facility features and equipment necessary to maintain biorisk management. It is intended for managers who oversee staff and programs where biocontainment is in place. Through guided discussion and interactive exercises, managers will develop a matrix of necessary people, time, and resources for assuring that these critical components of physical infrastructure are in place and maintained.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course is a management level course intended to increase the awareness and skills necessary to plan, prioritize, and assign appropriate people, resources, and times towards biocontainment facilities and equipment. This course is NOT directed towards personnel who will actually conduct the maintenance of the facilities and equipment.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

**Course Objectives - At the end of this course, students will:**

**Know**
- The difference between primary and secondary containment barriers  
- The facility features that are used to mitigate biorisk  
- The different status phases for facilities and the differing leadership and management needs for each phase  
- The critical equipment used to mitigate biorisk

**Feel**
- Capable of providing people, time, and money to appropriately maintain biocontainment facilities and equipment

**Be Able to Do**
- Describe key considerations for managers to maintain biocontainment facilities and equipment  
- Identify the necessary people, time, and money to maintain biocontainment facilities and equipment and thus support and lead the effort towards biorisk management.

**Key Messages**
1. Managers and leaders play a critical role in biorisk management by understanding, supporting, and maintaining the human capacity necessary to staff biorisk management initiatives and the physical infrastructure necessary to house safe and secure handling of pathogens.  
2. Management is responsible for providing adequate personnel, money, and time to provide for facilities and equipment that effectively mitigate biorisk.  
3. There are five phases in the life of a facility: design, construction, operation, post-incident, and decommissioning. Each requires a different set of people, money, and time.  
4. Managers must know how to hire the right people for the job of physically maintaining facilities & equipment.

**Biorisk Management Role:**
- Policy Makers  
- Top Management  
- Biorisk Management Advisors/Advocates  
- Scientific/Lab Management
# 12. Basic Features & Maintenance for Physical and Information Security Measures

<table>
<thead>
<tr>
<th>Overview</th>
<th>Basic Features and Maintenance for Physical and Information Security Measures is intended to be one of the principal courses on biosecurity for students in the Management &amp; Leadership track. The course is designed to offer a basic understanding of the theory and practice of physical and information security systems so that managers and leaders in bioscience facilities are aware of their purpose, scope, and requirements. Institutional managers and leaders will be in a position to understand the biosecurity systems that they are ultimately responsible for and how these systems are designed, installed, and maintained. This will provide a basic level of knowledge to decision-makers that will allow for better overall institutional management of biosecurity systems.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>This course will provide awareness on the theory and practice of physical and information security systems to inform managers on the purpose, scope, and requirements of such systems. The course is designed for managers, not technical staff, and will therefore NOT provide technical details on the function, installation, and operation of systems beyond that which would be needed by leaders to understand and manage overall security in their institution.</td>
</tr>
</tbody>
</table>
| Learning Level Based on Bloom’s taxonomy | ✓ knowledge  
 ✓ comprehension |
| Length | 4 hours |

*Course Objectives - At the end of this course, students will:*

**Know**
- The reasons and settings to use physical and information security
- Different methods for attaining physical and information security
- The requirements for maintaining physical and information security over time

**Feel**
- Confident conversing about basic features of and maintenance requirements for physical and information security measures

**Be Able to Do**
- Provide support for the placement and maintenance of physical and information security measures

**Key Messages**
1. Physical and information security systems must be implemented using a risk assessment.
2. It is important to understand and define the goal of your security system before installation and during operations.
3. Physical and information security systems can be implemented in layers of protection, depending on the type and location of valuable material.
4. Different physical and information security systems have different levels of initial and maintenance cost, and different levels of effectiveness given the security situation.
5. No security system can offer 100% protection.
6. Physical and information security systems require specific, continuous maintenance and upkeep, as well as re-assessments of design and purpose.

**Biorisk Management Role:**
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
### 13. Incident Response Planning & Preparation

**Overview**

*Incident Response Planning and Preparation* is designed for managers and leaders to, through guided discussion and interactive exercises, walk through the incident response planning and preparation process and develop draft incident response and preparation action plans.

**Scope**

While this course provides templates for planning and preparing for the most common incidents, it does NOT provide specific requirements for incident response.

**Learning Level Based on Bloom’s taxonomy**

- knowledge
- comprehension
- application

**Length**

4 hours

*Lesson Objectives - At the end of this lesson, students will:*

**Know**

- Why incident planning and preparation are imperative for effective incident response
- Who the contributors are for developing the most comprehensive incident response plan
- The key elements to be included in an incident response plan

**Feel**

- Confident in leading and supporting the development of an incident response plan and overseeing preparation to implement the plan.

**Be Able to Do**

- Write a draft incident response plan
- Write a preparation action plan

**Key Messages**

1. The most effective incident response systems will be able to plan and prepare for potential incidents, alert to and assess actual incidents, and quickly mount effective responses.
2. Without proper planning and preparation, an incident response system could be unable to alert to an incident in timely fashion, properly assess that incident, or mount effectively in response.
3. In the case of incident response, planning is the process whereby a potential incident is considered and evaluated, and resources are assigned, in order to generate a response that will appropriately mitigate any adverse effects.
4. Management has the authority to make medium and long-term decisions and allocate appropriate resources towards an incident management system.
5. Management, however, needs the expertise and advice of biorisk management advisors, lab workers and other personnel in the institution to adequately make plans.
6. Planning should result in a document, developed by management in cooperation with an institution’s personnel (and others), that outlines, at a high-level, how the incident management system will operate.
7. Preparation derives directly from planning. It is the act of putting into effect an institution’s plans prior to an incident, in order to be in a position to better handle that incident when it does occur.
8. The Preparation process includes training of personnel, acquisition of equipment, storing of supplies, and physical modifications to equipment and buildings when possible, and desirable.

**Biorisk Management Role:**

- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
### Overview

*Incident Response & Investigation* is designed to walk managers and leaders through the process of responding to an incident and investigating the causes of the incident and recommending corrective and preventive action. It is preferable that students have taken the course Incident Response Planning & Preparation (or similar) and that they have developed at least a draft incident response plan. Outcomes of this course include the development of draft procedures for incident response and investigation, including identification of roles & responsibilities. In addition, development of mechanisms to test the response and investigation procedures will be discussed and a catalog of possible drills, audits, and tabletop exercises will be developed by the students.

### Scope

This course will result in draft procedures for incident response & investigation – this draft will provide a template to be completed at the student’s organization, with appropriate stakeholder participation and consensus.

### Learning Level Based on Bloom’s taxonomy

- ✓ knowledge
- ✓ comprehension
- ✓ application

### Length

4.5 hours

**Course Objectives** - At the end of this course, students will:

#### Know

- What response measures are appropriate for different incidents
- Elements to be considered in drafting response procedures
- The steps required for a comprehensive incident investigation and for drafting incident investigation procedures
- Steps for assigning appropriate corrective and preventive action and for assuring follow-up
- Methods to use to test incident response and investigation

#### Feel

- Capable of leading and supporting an organizational effort to finalize incident response and investigation procedures
- Capable of designing and supporting drills, audits, and tabletop exercises to test the function and effectiveness of incident response and investigation procedures

#### Be Able to Do

- Write and communicate incident response procedures
- Write and communicate incident investigation procedures
- Develop drills, audits, or tabletop exercises to effectively test incident response and investigation

### Key Messages

1. There are different response measures for different incidents.
2. Incident investigation procedures must be standardized and well-communicated to encourage incident reporting and appropriate corrective and preventive action.
3. Incident investigation must examine all root causes of an incident – focusing on individual AND institutional behaviors and processes.
4. Because actual testing of the incident response system cannot be predicted, it must be tested by regularly scheduled drills, audits, and tabletop exercises, for example.
5. Drills must be designed to “break” the system – the metric is not whether it breaks, but how long it takes to break.

### Biorisk Management Role:

- ✓ Policy Makers
- ✓ Top Management
- ✓ Biorisk Management Advisors/Advocates
| ✓ Scientific/Lab Management |
## 15. Incident Response Evaluation & Improvement

### Overview

*Incident Response Evaluation & Improvement* is designed to teach and create processes for completing the incident management system feedback loop. After planning & preparation and incident response & investigation (whether by actual incident or by exercise), evaluating whether planning, preparation, response, and corrective actions were effective and appropriate is key to maintaining a robust system. Students will, through guided discussion and interactive exercises, explore the mechanisms to assure that improvements to the system are made and communicated. This course will be most effective if taken after the planning & preparation and response & investigation courses (or similar).

### Scope

This course will result in draft procedures for incident evaluation & improvement – this draft will provide a template to be completed at the student’s organization, with appropriate stakeholder participation and consensus.

### Learning Level

**Based on Bloom’s taxonomy**

- knowledge
- comprehension
- application

### Length

2 to 4 hours

**Course Objectives - At the end of this course, students will:**

**Know**

- Steps to evaluate the results from responses, drills, investigations, and corrective and preventive actions
- Steps to review and, as appropriate, revise incident management system documents and procedures based on evaluation
- Key elements to effectively communicate improvements to the incident response system

**Feel**

- Confident in leading and supporting evaluation of a current incident response system
- Capable of identifying and communicating necessary improvements

**Be Able to Do**

- Write a draft procedure for evaluating an incident management system
- Identify elements of an incident response system that require improvement
- Identify a strategy for communicating improvements

**Key Messages**

1. Effective incident management systems require feedback from incidents or exercises.
2. Revisions to incident response documents and procedures are necessary when improvements are identified.
3. Revisions to incident response documents and procedures must be communicated to all personnel with impacted roles & responsibilities.

**Biorisk Management Role:**

- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
## 16. Conducting Audits and Inspections to Assess Biorisk Management Performance

### Overview
This course is an adjunct to *Establishing and Using Performance Indicators*. Audits and inspections are often used as measurements of performance for biorisk management. This course, through guided discussion and interactive exercises, addresses the benefits and limitations of audits and inspections, as well as ways to make these assessments effective. Students will design a basic audit or inspection as well as draft procedures for conducting the audit/inspection and evaluating the results.

### Scope
This course will result in draft audit or inspection procedures for given biorisk management objectives. Using this template, students will be able to expand these procedures to address a comprehensive biorisk management system at their home institution.

### Learning Level Based on Bloom's taxonomy
- knowledge
- comprehension
- application

### Length
4 hours

**Course Objectives - At the end of this course, students will:**

**Know**
- The definition of an audit and an inspection
- The benefits and limitations to audits and inspections
- Key steps to improve the effectiveness of an audit or inspection
- How to evaluate the results of an audit or inspection
- When not to use an audit or inspection as a measure of biorisk management performance

**Feel**
- Capable of leading and supporting audit and inspection initiative, where appropriate

**Be Able to Do**
- Develop an audit or inspection procedure
- Evaluate results from an audit or inspection

### Key Messages
1. Audits and inspections are often used as primary measures of biorisk management performance.
2. Effective audits and inspections involve all impacted stakeholders and are not meant to be deceitful or unexpected exercises.
3. Audits and inspections must be standardized and used over time to be effective measurements.
4. Evaluations of audits and inspections must only evaluate what the audit or inspection is designed to measure.

### Biorisk Management Role:
- Policy Makers
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
### 1. Laboratory Building Systems

**Overview**

*Laboratory Building Systems* offers a basic understanding of the systems required to support a typical laboratory, how these influence facility design and how specialized systems enhance biosafety and biosecurity. It is intended for architects, designers and bio-safety professionals. Students will learn how architectural, structural, HVAC (heating, ventilating and air conditioning), plumbing and electrical systems are influenced by laboratory designs. Through guided discussions and interactive exercises student will learn about the type of information required to design the systems, how services are distributed through a typical laboratory building and the type of redundant features required to keep facilities running in the event of power outages or component failures.

**Scope**

- The goals of this course are:
  - To prepare students to discuss building systems with architects, builders and engineers and to make them better able to provide the type of information needed to design these systems.
  - To enable students to assist in the accommodation, selection, organization and layout of building systems for a laboratory design.
  - To give students a well-rounded understanding of how building systems enhance biosafety and biosecurity.

**Learning Level based on Bloom’s taxonomy**

- **Know**
  - ✓ knowledge
  - ✓ comprehension
  - ✓ application
  - ✓ synthesis
  - ✓ evaluation

**Length**

4 hours

*Lesson Objectives - At the end of this lesson, students will:*

- **Know**
  - The unique features of laboratories that influence building system designs
  - How building systems are used to enhance biosafety and biosecurity
  - How building systems are affected by biosafety concerns and other critical factors that need to be considered when developing or analyzing system distribution and system zoning
  - System redundancy options that should be considered when developing a laboratory facility

- **Feel**
  - Confident in discussing building system requirements with architects, engineers, builders, designers, building owners and operators
  - Able to assist in the layout of building systems in a manner consistent with a given laboratory design
  - Able to discuss redundancy options for a laboratory facility with respect to the implications for biosafety and biosecurity

- **Be Able to Do**
  - Aid in gathering the information required by architects and engineers to design their systems
  - Aid in the layout, zoning and distribution of their systems
  - Develop diagrams that describe zoning and distribution concepts
  - Aid architects, engineers and clients in deciding what type of redundancy should be provided on systems supporting a laboratory facility

- **Key Messages**
  1. Laboratories have unique requirements that influence virtually all building system designs.
  2. Planning to accommodate the appropriate space for building systems is an essential part of the design process.
  3. Mechanical systems play a critical role in any lab where containment of biological agents or
4. Plumbing systems also often play a role in preventing the release of biological agents from a laboratory.
5. The distribution and zoning of all building systems must consider biological safety issues.
6. System redundancy must be considered wherever building systems are relied upon as part of the biological containment or biosecurity system.

| **Biorisk Management Role:** | ✓ Architects/Designers  
|                             | ✓ Biorisk Management Advisors/Advocates  
|                             | ✓ Scientific/Lab Management  
|                             | ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff |
## 2. Laboratory Design Best Practices

<table>
<thead>
<tr>
<th>Overview</th>
<th><em>Lab Design Best Practices</em> offers an understanding of key principles underlying the design of research and diagnostics laboratories. It is intended for architects, designers and bio-safety professionals. Students will be introduced to laboratory design best practices as they relate to; building zoning, operational efficiency, biosafety and biosecurity factors, supporting good lab protocols and flexibility. Students will participate in guided discussions, develop diagrams to illustrate best practice concepts and analyze existing plans with respect to the design principles under discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>The goal of this course is to increase students’ awareness of laboratory design issues and analytical processes which are critical for developing laboratory layouts, and to provide examples of well-designed laboratory buildings and spaces. The course is intended for those who want to be able to lead or aid in the creation of safe and efficient laboratory designs.</td>
</tr>
</tbody>
</table>
| Learning Level based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application  
✓ synthesis  
✓ evaluation |
| Length | 4 hours |

*Lesson Objectives - At the end of this lesson, students will:*

**Know**

- The principle factors which govern good laboratory design  
- The methods for analysis and development of good laboratory layouts  
- The Biosafety & Biosecurity design principles

**Feel**

- Confident in my ability to analyze a variety of efficient laboratory organization strategies  
- Confident in my ability to discuss, analyze and develop laboratory plans based on a wide range of criteria  
- Confident in my ability to identify areas where design can enhance biosafety and biosecurity

**Be Able to Do**

- Describe the critical factors that should be examined when developing or analyzing a laboratory design  
- Produce diagrams showing how laboratory plans support operations  
- Produce diagrams that identify biosafety and biosecurity features

**Key Messages**

1. Building zoning and organization should address functional relationships as well as biosafety and biosecurity concerns, service requirements, containment levels and construction types.  
2. Efficiency in laboratory layouts reduces labor, reduces energy and water consumption and simplifies safety and security design.  
3. Biological safety requires consideration at all levels of design, from the placement equipment in a room, to the organization of containment barriers around a zone, to the airflow strategy within the building.  
4. Biosecurity design can be integrated seamlessly into the building layout when considered early in planning.  
5. Laboratory design should be developed in conjunction with the protocols followed when personnel or materials or animals move from one space to another.  
6. To be sustainable laboratory designs must be flexible.

**Biorisk**

- Architects/Designers  
- Biorisk Management Advisors/Advocates
| **Management Role:** | ✓ Scientific/Lab Management  
|                      | ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff |
### 3. Laboratory Design Process

<table>
<thead>
<tr>
<th>Overview</th>
<th>Laboratory Design Process takes students through the process of developing a conceptual laboratory design from a functional space program. This course gives students the opportunity to implement lessons learned in the Laboratory Design Best Practices course. In groups students will produce conceptual diagrams and building plans for their facility and present their solutions to the class. Instructors will guide students through the process, providing critical feedback on the designs as they progress and will offer brief presentations on some of the most pertinent design drivers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>The goal of this course is to provide students with a methodology for developing, analyzing and refining laboratory designs. The course is intended for those who want to be able to lead or aid in the creation of safe and efficient laboratory designs.</td>
</tr>
</tbody>
</table>
| Learning Level based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application  
✓ synthesis  
✓ evaluation |
| Length | 4 hours |

*Lesson Objectives - At the end of this lesson, students will:*

**Know**
- How material and personnel flows, biosafety concerns and biosecurity concerns shape a laboratory facility
- How functional and safety concerns shape the layout of equipment within a laboratory or animal room
- The critical features of a laboratory plan that should be diagrammed, analyzed and agreed upon to ensure a successfully operating facility

**Feel**
- Able to design or contribute to the design of laboratory facilities
- Able to analyze laboratory plans through diagrams and discussions from a wide variety of perspectives

**Be Able to Do**
- Produce a laboratory organizational diagram based upon consideration of safety, security and operational concerns
- Produce a conceptual laboratory plan based upon safety security and operational concerns
- Produce diagrams that explain how a laboratory plan works in terms of personnel and material flows, containment concepts and security zoning
- Provide constructive criticism, based on their knowledge of critical design drivers, to others developing laboratory designs

**Key Messages**
1. Developing an understanding of the issues that will influence the design of a facility (design drivers) is a critical first step in laboratory design.
2. It is important to determine which design drivers will take precedence, and shape the overall organization of the facility.
3. Biocontainment features should be illustrated on conceptual stage plans to help ensure the facility will support safe operations.
4. Biosecurity features should be illustrated on conceptual stage plans to help ensure the facility will support secure operations.
5. Material and personnel movements and protocols should be mapped out on conceptual stage plans to help ensure the facility will support safe and efficient operating procedures.
6. Laboratory design is best when approached as an iterative and collaborative process.
| Biorisk Management Role: | ✓ Architects/Designers  
|                        | ✓ Biorisk Management Advisors/Advocates  
|                        | ✓ Scientific/Lab Management  
|                        | ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff |
# 4. Programming and Pre-Design

<table>
<thead>
<tr>
<th>Overview</th>
<th>Programming and Pre-design is intended to offer an understanding of the activities that should be carried out prior to the commencement of the design process for a laboratory facility. It is intended for architects, designers and bio-safety professionals. Through guided discussion and interactive exercises, students will learn the basic concepts of the following: conducting user interviews, setting goals for the project, recording program information, diagramming important relationships, and establishing the facility criteria that will form the basis for the design and budget of a laboratory facility.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>The goal of this course is to help students develop an understanding of; the types of discussions that should be conducted prior to commencement of design, who to involve in the process and the type of questions to ask and the types of documents and diagrams that should be developed in order to help ensure a successful design process.</td>
</tr>
</tbody>
</table>
| Learning Level based on Bloom’s taxonomy | ✓ knowledge  
✓ comprehension  
✓ application  
✓ synthesis  
✓ evaluation |
| Length | 4 hours |

*Lesson Objectives - At the end of this lesson, learners will:*

**Know**
- The definitions of programming and pre-design
- The range of ‘stakeholders’ that influence the programming process
- Key questions to ask when programming for a laboratory
- Important documents to produce for a building program
- Important pre-design criteria to record prior to embarking upon the design process

**Feel**
- Able to conduct stakeholder meetings to gather pertinent information for a laboratory design
- Able to organize program information into diagrams, charts and lists that will help to inform a laboratory design
- Able to organize pre-design criteria into drawings, diagrams and descriptions that will help to inform a laboratory design & budget

**Be Able to Do**
- Develop a list of stakeholders who will influence a laboratory design project
- Develop and ask questions that help to gather stakeholders’ input for a laboratory project
- Develop diagrams that summarize key organizational principles for a laboratory project

**Key Messages**
1. Programming is recording information about the needs, wants and aspirations of all parties involved in a construction or renovation project, balancing these with budget, codes and regulations.
2. Pre-Design is organizing criteria for design into diagrams, drawings and charts that will help to give shape to the project.
3. Programming requires input from a well-rounded group of stakeholders including building users, safety officers, security personnel, administrators, O&M personnel, owners, regulatory authorities and members of the community.
4. A well-developed program should include clearly stated goals for the project, a list of the types and numbers of occupants, charts showing how the people and departments are organized, a functional space program or space list, a list of applicable codes and regulations and a project budget.
5. Establishing detailed pre-design criteria results in more functional designs, saves time in the design process and allows for more accurate cost estimating.

| Biorisk Management Role: | ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff  
| ✓ Biorisk Management Advisors/Advocates  
| ✓ Scientific/Lab Management  
| ✓ Architects/Designers |
### DRAFT COURSE: Fundamentals of Facility Operations

| Overview | *Fundamentals of Facility Operations* is intended as the first of three courses on containment facility operations and maintenance. Containment Facility Operations or Operations will discuss where using RA fits in as a tool to safely operate a containment facility. Students will learn six major components of Operations to include: maintenance, engineering, training, safety, security and administration. From these components, operation details will be discussed for determining research facility needs, what will be studied, how flexible is the facility, where is the facility located, and immediate priorities. Specific operations plan components of communication, redundancy and flexibility, will also be discussed. Specific operation procedures are not discussed in detail. This course should be taken prior to any courses that discuss using the tools of operations and maintenance. |
| Scope | This course will define the basic components of Containment Facility Operations and discuss what to consider in day to day operations decisions. Students will learn the basics of an operations plan and the components used to support it. This course will NOT provide details on specific tools of operations and maintenance. |
| Learning Level | ✓ knowledge  
✓ comprehension  
✓ application |
| Length | 4 hours |

**Lesson Objectives - At the end of this lesson, students will:**

| Know | • What is involved in operations management  
• The importance of doing a thorough risk assessment prior to making operations decisions  
• What questions to ask concerning facility, building and laboratory systems equipment  
• What Facility Operations is and the main components of an operations plan |
| Feel | • That there is always something more to learn about Facility Operations  
• Comfortable asking questions about facility operations in order to improve facility operations  
• Comfortable with the components of an operations plan |
| Be Able to Do | • Categorize various components of facility operations into a plan for any facility  
• Ask the right questions before equipment is installed in the facility  
• Determine major components of an operations plan that would be applicable for a particular situation |
| Key Messages | 1. Facility Operations are most effective when decisions are made using a thorough risk assessment.  
2. There are many components of laboratory facility operations that may include administration, training, maintenance, engineering, safety, and security.  
3. Communications, Flexibility and Redundancy are critical in designing and carrying out facility operations.  
4. Developing a basic operations plan provides a hub or core for laboratory facility operations. |
| Bioclean Management Role: | ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff  
✓ Bioclean Management Advisors/Advocates  
✓ Scientific/Lab Management  
✓ Workforce |
**Overview**

*Fundamentals of Laboratory Maintenance* examines the maintenance tasks associated with operating a laboratory facility; the advantages and disadvantages of different maintenance strategies; and discusses a high-level overview of what a laboratory should include in their maintenance plans. It will give students the opportunity to breakdown maintenance tasks in order to decide on the most effective maintenance strategy.

**Scope**

This course provides an overview of laboratory facility maintenance.

**Learning Level based on Bloom’s taxonomy**

- knowledge
- comprehension
- application

**Length**

4 hours

**Lesson Objectives** - *At the end of this lesson, students will:*

**Know**

- What is maintenance
- What laboratory equipment needs to be maintained
- What facility equipment needs to be maintained
- What are the advantages and disadvantages of the four types of maintenance strategies
- Which equipment is critical versus non-critical
- What are the components of a maintenance plan

**Feel**

- Confident conversing about the equipment that requires maintenance in a laboratory facility
- Confident categorizing tasks required associated with maintaining a laboratory facility

**Be Able to Do**

- Identify the different types of equipment that requires maintenance
- Classify maintenance tasks by the appropriate maintenance strategy

**Key Messages**

1. To keep a laboratory facility and equipment in good working conditions, a broad variety of tasks are required.
2. The Reliability-Centered approach to maintenance applies the AMP (assessment, mitigation, and performance) model. This approach also combines the three most common maintenance approaches.
3. Reliability-Centered maintenance involves identifying actions that, when taken, will reduce the probability of failure and which are the most cost effective.
4. Focus maintenance priorities, based on the criticality of the equipment and the assessed wear and tear, in order to minimize cost and maximize benefit.
5. A maintenance plan is necessary to document the details of when maintenance should be performed, how it should be conducted, and who is responsible.

**Biorisk Management Role:**

- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
# Anthrax Powder

## Overview

The *Anthrax Powder* guided exercise is used to introduce students to concept of risk assessment and experience on emergency response procedure on sampling and decontaminating “anthrax” powder. The students will collect an “anthrax” sample from a desk and trash bin. Students will also learn the decontaminating procedures and analysis.

## Length

90 minutes

## Lesson Objectives - At the end of this lesson, students will:

### Know

- Know the importance of conducting a thorough risk assessment prior to implementing action plan on the use of proper PPE, collecting samples, and decontaminating an affected area.
- Know the different types of sampling methods, proper sample collections, and how to interpret results.

### Feel

- Confident in assessing and mitigating the risk
- Knowledgeable on how to sample and decontaminate a contaminated office space

### Be Able to Do

- How to assess and evaluated the risks during an emergency procedure
- How to collect samples
- How to decontaminate a contaminated space

## Key Messages

1. Risk assessments are important measures to help choose the correct PPE for the scenario or situation at hand.
2. Proper donning and doffing procedures are necessary and directly related to the effectiveness of the Personal Protective Equipment (PPE).
3. Decontamination of an area is necessary to prevent further or future exposure to the pathogen(s).

## Prerequisites

- Orientation to Biorisk Management
- Biorisk Characterization and Evaluation

## Recommended GBRMC Courses

- Personal Protective Equipment
- Decontamination

## Biorisk Management Role:

- ☑ Biorisk Management Advisors/Advocates
- ☑ Scientific/Lab Management
- ☑ Workforce
This Biosafety Risk Characterization guided exercise will be used to give students some practice characterizing a biosafety risk based on a FICTIONAL SCENARIO demonstrated in a laboratory. Students will work through a set of questions related to various biosecurity risk factors associated with the scenario, and use this information to characterize biosecurity risks. This exercise is intended for students who have a basic understanding of the principals of laboratory biosecurity risk characterization.

Lesson Objectives - At the end of this lesson, students will:

Know
- Documented biosafety risk characterization is an essential aspect of laboratory biosafety
- The risk factors associated with biosafety risk

Feel
- Confident in performing a basic biosafety risk characterization

Be Able to Do
- Consider and characterize risk factors associated with biosafety risk
- Characterize the likelihood and consequences of a biosafety risk based on a simple scenario

Key Messages
1. A biosafety risk assessment allows for a laboratory or facility to effectively characterize the risks associated with its different activities.
2. Using a biosafety risk assessment to identify the relative risks can aid in the development of a mitigation plan to eliminate or reduce the risks.

Prerequisites
N/A

Recommended GBRMC Courses
- Biorisk Characterization and Evaluation
- Biosafety Risk Assessment

Biorisk Management Role:
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
### Biosafety Risk Mitigation

**Overview**

The *Biosafety Risk Mitigation* guided exercise will be used to give students some practice identifying ways to minimize biosafety risk associated with an unintentional exposure risk. Students will work through a set of questions about biosafety to think about how to mitigate the risk characterized in the previous exercise (*biosafety risk characterization guided exercise*). This exercise is intended for students who have a basic understanding of the principals of laboratory biosafety including engineering controls, good laboratory work practices, and personal protective equipment. It builds upon basic knowledge of biosafety risk assessment.

| Length | 90 minutes |

**Lesson Objectives** - *At the end of this lesson, students will:*

**Know**

- That a risk assessment supports appropriate biosafety mitigation strategies
- Options for mitigating exposure risks in the lab

**Feel**

- More confident in applying risk mitigation options based on risk assessment

**Be Able to Do**

- Identify potential biosafety risk mitigation solutions based on a documented risk assessment

**Key Messages**

1. A risk assessment is a necessary tool needed to identify the risks associated with the laboratory or facility and should be used as a guide to make risk mitigation decisions.
2. All mitigations measures should be used (or considered) in combination with the risk assessment to effectively mitigate risks.

**Prerequisites**

Biosafety Risk Characterization Guided Exercise

**Recommended GBRMC Courses**

- Biorisk Characterization and Evaluation
- Biorisk Mitigation Strategies

**Biorisk Management Role:**

- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
The Biosafety Cabinet Introduction and Use guided exercise will help participants discover and visualize airflow in a Biosafety Cabinet (BSC). It will teach students how to set up and work in a BSC in a manner which protects the material they are working with, themselves and the environment. Through visualization of the airflow in a working BSC, they will see how easily it can be disrupted by common errors such as occluding the front grill, traffic walking by the cabinet, or horizontal sweeping motions of the arms in the cabinet.

**Lesson Objectives - At the end of this lesson, students will:**

**Know**
- Principles of clean to dirty
- Airflow patterns in a BSC and how they can be disrupted by improper set up or use
- Common errors which cause airflow disruption and how to avoid them

**Feel**
- Comfortable and safe using a BSC

**Be Able to Do**
- Properly set up a BSC workflow using the clean to dirty principle
- Turn on and work in a BSC in a manner which protects the product themselves and the environment
- Avoid common errors such as occluding the air intake grills, sweeping hand/arm motions, repeated in and out motions, walking briskly past the BSC, etc...

**Key Messages**
1. Several factors can affect biosafety cabinet (BSC) efficiency, it is important to properly set up and use a BSC in order to protect the worker(s), sample material, and surrounding environment.

**Prerequisites**
N/A

**Recommended GBRMC Courses**
Engineering Controls and Laboratory Equipment
Good Laboratory Work Practices

**Biorisk Management Role:**
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
Dual Use Equipment of Concern

Overview
The goal of the Dual Use Equipment of Concern guided exercise is to emphasize the ability for all laboratory equipment to potentially be used for nefarious purposes. Students will identify (1) equipment that could be used for nefarious purposes, (2) equipment that is especially indicative of malicious intent, (3) other clues that indicate a piece of equipment is being used for nefarious purposes and (4) methods to prevent the malicious use of equipment.

Length
90 minutes

Lesson Objectives - At the end of this lesson, students will:

Know
- How to identify potential dual use equipment of concern
- Options for developing national, ministerial, institutional, and laboratory programs for controlling and monitoring dual use equipment of concern

Feel
- Able to make decisions about how dual use equipment of concern fits within their mission space and jurisdiction

Be Able to Do
- Develop initial actions for monitoring the dual use equipment of concern within their own laboratories

Key Messages
1. All laboratory equipment could be used for nefarious purposes.
2. Some laboratory equipment is especially indicative of malicious intent.
3. Other clues can indicate that a piece of equipment is being used for malicious purposes.
4. Methods exist to prevent the nefarious use of equipment.

Prerequisites
N/A

Recommended GBRMC Courses
Introduction to Dual Use Research of Concern

Biorisk Management Role:
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
Personal Protective Equipment

Overview

The **Personal Protective Equipment** guided exercise includes three separate activities that will be used to build upon a basic understanding of PPE and Risk Assessment, which will teach students how to make risk-based mitigation decisions to protect themselves. This exercise is intended for students who have a basic understanding of the principals of risk assessment and PPE.

Activities:
1. Give students practice identifying appropriate PPE for a particular scenario.
2. Allow the students to identify appropriate PPE substitutes when PPE is limited and/or unavailable.
3. Practice donning and doffing PPE. In addition, each activity will serve as an opportunity for students to practice the process of understanding and evaluating the risk of exposure – risk assessment.

Length

90 minutes

Lesson Objectives - At the end of this lesson, students will:

Know
- That a risk assessment is valuable for guiding PPE selection
- The order in which PPE is donned and doffed is important

Feel
- Confident in choosing suitable PPE
- Knowledgeable about donning and doffing PPE correctly

Be Able to Do
- How to assess and evaluated the risk for PPE selection
- Don and doff PPE to minimize the risk of exposure

Key Messages
1. A thorough risk assessment is necessary to ensure the appropriate PPE is selected.

Prerequisites
N/A

Recommended GBRMC Courses
Personal Protective Equipment
Biosafety Risk Assessment

Biorisk Management Role:
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
### Communication in Biorisk Management Role-Play Exercise

| Overview | For the *Communication in Biorisk Management Role-Play Exercise* students will be assigned different biorisk management roles (such as workforce, top management, first responders, etc.) and will be asked to prepare a message for a specific audience (a different biorisk management role) based on the scenario presented. At the end, we will debrief and discuss observations and lessons learned. |
| Length | 90 minutes |

**Lesson Objectives** - *At the end of this lesson, students will:*

- **Know**
  - Communication between several roles contributes to an effective biorisk management (BRM) system
  - The impact each role has on a BRM system

- **Feel**
  - Confident communicating with others

- **Be Able to Do**
  - Communicate with others to achieve a common goal

**Key Messages**

1. Many roles take part in, and are necessary for, a functioning biorisk management system.
2. Each role has its own unique perspectives and goals.
3. Effective communication between the various roles is important for a stable and functional biorisk management system.

**Prerequisites**
N/A

**Recommended GBRMC Courses**
- Orientation to Biorisk Management
- Hazard & Risk Communication in the Laboratory
- Establishing Goals, Objectives, Roles & Responsibilities in Biorisk Management

**Biorisk Management Role:**
- ✓ Top Management
- ✓ Biorisk Management Advisors/Advocates
- ✓ Scientific/Lab Management
- ✓ Laboratory Operations Staff/ Laboratory Maintenance Staff
- ✓ Workforce
### Standard Operating Procedures

<table>
<thead>
<tr>
<th>Overview</th>
</tr>
</thead>
</table>
| The *Standard Operating Procedures* guided exercise will develop a performance-based rubric as an objective and consistent method to evaluate SOPs. This exercise will build upon existing knowledge and experience of developing SOPs. The students will work as a group to develop a rubric for SOPs that will serve as a standard of performance for which they can continually improve their own SOPs. Through developing the rubric on their own, the students will be able to take ownership of their SOPs.  

Note: This exercise will be delivered in the context of a Developing, Evaluating, and Validating Standard Operating Procedures (SOPs) and is intended to serve as an example of how to evaluate a GBRMC course “product” in a consistent manner. The GBRMC courses result in substantive tools, document drafts, and/or other relevant “products” that are relevant to the coursework and provide a starting point for further work. This exercise will cultivate appreciation as well as practice measuring performance. This is outlined in the Supplemental Follow-up Exercise to SOPs. |

<table>
<thead>
<tr>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 hours</td>
</tr>
</tbody>
</table>

**Lesson Objectives** - *At the end of this lesson, students will:*

**Know**
- What a rubric is
- Know the importance of using a standardized means to measure performance
- How continual improvement of SOPs can benefit from a rubric

**Feel**
- Prepared to use a rubric to evaluate, analyze, and improve SOPs
- Confident developing performance based metrics for SOPs

**Be Able to Do**
- Develop
- Suggest appropriate biosafety and biosecurity risk mitigation measures during sample transport

**Key Messages**
1. Using a performance based rubric developed specifically for SOPs will ensure that the SOPs will be continuously improved and stay up-to-date.

**Prerequisites**
Developing, Evaluating, and Validating Standard Operating Procedures (SOPs)

**Recommended GBRMC Courses**
N/A

**Biorisk Management Role:**
- Top Management
- Biorisk Management Advisors/Advocates
- Scientific/Lab Management
- Laboratory Operations Staff/ Laboratory Maintenance Staff
- Workforce
**Guided Exercises Guidelines**

<table>
<thead>
<tr>
<th>Description:</th>
<th>Guided Exercises are activities that are designed to supplement GBRMC courses in a locally or situational specific way. Each Guided Exercise should include at least one Key Message which outlines the fundamental concepts, knowledge, attitudes, or skills that students should acquire after completing the GE. For more information on the Guided Exercises available for use, please refer to the extensive library which summarizes the GEs below.</th>
</tr>
</thead>
</table>
| Creating a Guided Exercise Instructor/Author Instructions | Have an idea that has not been captured by one of our GBRMC Courses/Guided Exercises? The following are recommended steps to help build a productive Guided Exercise: Use the templates available on GBRMC Net to generate a GE for your event/course. Using the templates provides authors/instructors with an easy method to produce new materials that are uniform and consistent. The Guided Exercise Templates were designed to have a professional and seamless look and feel, while being distinguishably different than the GBRMC Course templates. The templates will act as a guide for the general GE layout, text colors, and theme. The following templates are available for use:  
  - **The Guided Exercise Template (GE_Template)** - For instructional information  
  - **Know, Feel, Do Evaluation (KFD)** – A blank course evaluation to be populated with the GE specific KFDs objectives  
  - **Supplemental Materials (SM) Templates: Slide Deck (SD) and Student Guide (SG)** – A PowerPoint and Word Document for instructors to populate with GE lecture materials  
  NOTE: The following must be completed to be considered for the finalization process: Guided Exercise Template, KFD Evaluation, and Supplemental Materials (if used). |
| Guided Exercise Supplemental Materials (SM): | Supplemental Materials (SM) are an optional, but a recommend addition to any GE and can be used together (Example: Scenario and a Worksheet) or individually. SMs are designed to help students develop a further understanding of the Key Message or objectives presented during the GE. Below is a list of SM options:  
  - **Worksheets**: A series of items or problems that the students work through and provide information or solutions  
  - **Slide Decks (SD) /Student Guides (SG)**: Slide Decks are PowerPoint presentations which accompany a lecture. Student Guides contain the slides used throughout the lecture for the students’ notes and records  
  - **Scenarios**: Characterize a situation in which the students are asked to identify issues/concerns, answer questions, or brainstorm solutions for the situation presented.  
  - **Virtual Simulations**: A simulation representing a real-life scenario allowing students to interact with each other in the exercise using a video game program.  
  - **Video Demonstrations**: Using a video to stimulate ideas, demonstrate examples, or prompt a discussion.  
  - **Role Playing**: Assigning roles to members of the group to demonstrate the importance and responsibilities associated with each role. |
**Post-Guided Exercises**

**Instructions:** 
After teaching your Guided Exercise, please upload the following information to GBRMC Net, or Email the GE to Hannah Cummins (contact information below):

- All GE Materials (GE Template with instructor notes, KFD Evaluation, and all Supplemental Materials)
- KFD Student Evaluation Data
- Report any errors/suggestions/comments
- Report which courses you used/taught in conjunction to the Guided Exercise for future recommendations

**Finalizing a Guided Exercise:**

The GBRMC Administration will review and finalize GE materials for future use. Metrics regarding each Guided Exercise will be evaluated, and should a GE be used consistently, it will be taken into consideration to become an official GBRMC Course. Finalized GE materials will be available on GBRMC Net for other instructors to utilize. The following components must be included to be considered a GE.

- **Design Document (DD)**
  - A design document summarizes the guided exercise and outlines the goals, objectives, key messages, KFD objectives, materials, audience designation (Basic, Laboratory, and Management and Leadership) and includes a draft instructor’s agenda.

- **Instructor Guide (IG)**
  - Provides instructions outlining the exercise and expected responses for the activities

- **Know, Feel, Do Evaluation (KFD)**
  - A listing of what the students should know, feel, and be able to do following the guided exercise in order to evaluate the GE. A KFD is a post-exercise evaluation to assess the effectiveness of the exercise.

- **Any relevant Supplemental Materials (SM)**
  - Please refer to Guided Exercise Supplemental Materials (SM) above for details.

**Additional Information**

For questions regarding Guided Exercise production please contact:

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