

Catalog of Courses: Global Biorisk Management Curriculum (GBRMC)

DRAFT: March 2012



Contents

Basic Track

Audience: All personnel involved in biorisk management

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

Laboratory-Level Track

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

- **Lab-Level Administrative Controls**
 - Human Performance for Biorisk Management in the Laboratory
 - Developing, Evaluating, Validating, and Communicating Standard Operating Procedures
 - Hazard & Risk Communication in the Laboratory
- **Lab-Level Operational Controls**
 - Biocontainment Facility Features
 - Engineering Controls and Laboratory Equipment
 - Good Laboratory Practices
 - Personal Protective Equipment
 - Decontamination
 - Biological Waste Disposal
 - Laboratory Biosecurity
 - Field Biosecurity
 - Shipping Infectious Substances and Biological Specimens
- **Reporting, monitoring, and Response**
 - Incident Recognition and Response in the Laboratory

Management & Leadership Track

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

- **Policy, Planning, and Assessment**
 - Writing and Communicating Biorisk Management Policy
 - Considerations for Training in Biorisk Management
 - Developing, Conducting, and Maintaining a Hazard Inventory
 - Identifying Legal Requirements that Impact BRM
 - Establishing Work Program Review & Approval
- **Developing and Maintaining Human Capacity for Biorisk Management (Managing People)**
 - Managing Human Performance in the BRM Workforce
 - Establishing and Maintaining Formal and Informal BRM Mentoring Programs
 - Establishing and Maintaining Worker Health Programs
 - Developing and Maintaining Roles & Responsibilities for Risk-based Access to, Control of, and Accountability for Biological Agents and Toxins
- **Developing and Maintaining Physical Infrastructure for Biorisk Management**
 - Understanding & Maintaining Facilities & Equipment for Biorisk Management
 - Basic Features & Maintenance for Physical and Information Security Measures
- **Incident Management & Response**
 - Incident Response Planning and Preparation
 - Incident Response & Investigation
 - Incident Response Evaluation & Improvement
- **Measuring and Improving Biorisk Management Performance**
 - Measurement and Analysis of Biorisk Management System Performance
 - Conducting Audits and Inspections to Assess Biorisk Management Performance
 - Revising and Improving a Biorisk Management System based on Performance Results
 - Establishing and Using Performance Indicators

Orientation to Biorisk Management

Overview	<i>Orientation to Biorisk Management</i> 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.
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • What a management system is; what CWA 15793 is; what the AMP model represents
Feel	<ul style="list-style-type: none"> • Confident about using the biorisk management approach and using basic biorisk management terminology
Be Able to Do	<ul style="list-style-type: none"> • Move forward to the next steps in beginning a biorisk management implementation.
Key Messages	<ol style="list-style-type: none"> 1. The importance, and distinctions between key biorisk management terminology such as: biorisk, biosafety, biosecurity, biorisk management system 2. AMP (Assessment, Mitigation, and Performance) is a simple model for managing biorisks 3. Implementing a comprehensive biorisk management system is critical to reduce the safety and security risks associated with handling, storage and disposal of biological agents 4. CWA 15793 is a comprehensive framework for managing biorisks developed through international collaboration. 5. Some of the key factors in establishing and implementing a successful biorisk management system include commitment by top management and a focus on continual improvement
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Bioethics

Overview	<i>Bioethics</i> 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 will create the foundation of conduct for individuals as they progress through the Biorisk Management (BRM) Curriculum.
Scope	This course will provide awareness of situations that can be encountered in a business setting that will contain legal, ethical, or moral dilemmas. This course will show the learner how to manage these situations and act appropriately. Stemming from the basic conduct expected out of any institutional worker, ethics related to biological studies, and specifically dual use will be taught to frame the special ethical considerations that must be taken into account while doing biological research.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • Expectations of laboratory ethical behavior and proper conduct • What actions should be taken during ethical dilemmas both at work and in life
Feel	<ul style="list-style-type: none"> • Capable of identifying and resolving ethical dilemmas
Be Able to Do	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 1. Each individual is responsible for his or her own behavior. 2. Ethical conduct is not only a key to personal integrity but reflects on the integrity of the institution. 3. Bioethics is not a separate task to research but an integral part to all activities. 4. In the absence of legal constraints, ethic conduct is still important as a societal benefit.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Introduction to Dual Use Research of Concern

Overview	<i>Introduction to Dual Use Research of Concern</i> 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	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application ✓ synthesis
Length	6 hours
<i>Course Objectives - At the end of this course, students will be able to:</i>	
Know	<ul style="list-style-type: none"> • Expectations and responsibilities as a researcher • Options for identifying DURC • The “Seven Experiments” included in DURC and alternative examples
Feel	<ul style="list-style-type: none"> • Capable of identifying potential DURC and confident mitigating the risk of potential DURC
Be Able to Do	<ul style="list-style-type: none"> • Be able to 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	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> Policy Makers Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management (who conduct research) ✓ Workforce (who conduct research)

Biorisk Characterization & Evaluation

Overview	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.
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • How to define what risk to assess • What information must be gathered prior to conducting a biosecurity risk assessment
Feel	<ul style="list-style-type: none"> • Confident that the risk assessment process is robust, transparent, and reproducible
Be Able to Do	<ul style="list-style-type: none"> • Explain what risk a risk assessment is characterizing • Show the information that is being used for the biosecurity risk assessment • Establish a risk assessment process that is robust, transparent, and reproducible.
Key Messages	<ol style="list-style-type: none"> 1. A risk assessment is defined as a procedure that analyses 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. A biological risk assessment allows a facility, laboratory, or other operation to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risks. 3. Risk Characterization is not the only important aspect of Risk Assessment. Risk Evaluation is also important. It is the process of determining, subjectively, whether a risk is high or low, and whether it's acceptable or not. 4. Both a changing hazard or threat, and a changing situation will independently alter the scenario being assessed, and thus change the risk.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Biosafety Risk Assessment

Overview	<i>Biosafety Risk Assessment</i> 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 – focusing on the risk of unintentional exposure or release of biological agents.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • How to define what risk to assess • What information must be gathered prior to conducting a biosafety risk assessment
Feel	<ul style="list-style-type: none"> • Confident that the risk assessment process is robust, transparent, and reproducible
Be Able to Do	<ul style="list-style-type: none"> • Explain what risk a risk assessment is characterizing • 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	<ol style="list-style-type: none"> 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 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
<i>Biorisk Management Role:</i>	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Biosecurity Risk Assessment

Overview	This course is intended to offer an understanding of the basic theory underlying a biosecurity risk assessment. Through guided discussion and interactive exercises, students will learn the basic concept of a biosecurity risk assessment, and explore its benefits and as well as the challenges involved in carrying it out. The course begins with a brief introduction on risk and biosecurity risk in particular, followed by a discussion the process of assessing risk through characterization of agents and adversaries. The course concludes with a discussion of risk evaluation
Scope	The goal of this course is to offer a basic awareness of the importance of biosecurity risk assessment within the overall process of laboratory biorisk management – focusing on the risk of intentional removal (theft) of a valuable biological material
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • How to define what risk to assess • What information must be gathered prior to conducting a biosecurity risk assessment
Feel	<ul style="list-style-type: none"> • Confident that the risk assessment process is robust, transparent, and reproducible
Be Able to Do	<ul style="list-style-type: none"> • Explain what risk a risk assessment is characterizing • Show the information that is being used for the biosecurity risk assessment • Establish a risk assessment process that is robust, transparent, and reproducible.
Key Messages	<ol style="list-style-type: none"> 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
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Biorisk Mitigation Strategies

Overview	<i>Biorisk Mitigation Strategies</i> is intended as an intermediary course. Participants should have already completed <i>Orientation to BRM</i> and <i>Risk Assessment</i> . They should already be familiar with the AMP model and understand the importance of and basics of how to do risk assessments. While the concepts of mitigation are introduced in <i>Orientation to BRM</i> , 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 <i>PPE</i> , <i>Waste Disposal and Decontamination</i> , <i>Writing SOPs</i> , 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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	3 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • What mitigation is and how it fits into the AMP model. Know the importance of doing a thorough risk assessment prior to implementing/evaluating mitigation control measures. Understand the various categories of control measures used to reduce risk and their advantages and limitations
Feel	<ul style="list-style-type: none"> • Prepared to learn more about specific kinds of mitigation.
Be Able to Do	<ul style="list-style-type: none"> • Categorize various mitigation efforts into the hierarchy of controls
Key Messages	<ol style="list-style-type: none"> 1. Definition of Mitigation and role in the AMP model. 2. Mitigation is most effective when based on a thorough risk assessment. 3. There are five generally recognized categories of control measures; each with various advantages and disadvantages 4. Elimination or substitution is the most effective means of mitigating risk; generally followed by engineering controls; administrative controls; practices and procedure; and finally PPE 5. It takes a combination of mitigation measures; in addition to the risk assessment, the effectiveness of mitigation also must be judged on your ability to implement them.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Introduction to Incident Management & Response

Overview	<i>Introduction to Incident Management & Response</i> is intended to offer an understanding of the basic theory and practice of incident response systems, so that lab personnel, as well as managers, can gain an appreciation for the scope and complexity of the topic. Each of the components of an effective system is briefly discussed: 1) planning & preparation, 2) response (alert, assessment, & mobilization, including outside coordination), and 3) feedback and improvement (reporting, investigation, and improvement). 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 an effective incident management and response system. Details on these components can be found in other GBRMC courses (1) <i>Incident Response Planning & Preparation</i> , 2) <i>Incident Response & Investigation</i> , 3) <i>Incident Response Evaluation & Improvement</i> , and 4) <i>Incident Recognition & Response in the Laboratory</i>)
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • The components and structure of an incident response system • The personnel who should be involved in each phase of planning. • The personnel who must be notified during an incident or test of the incident response system. • Why it is important to test the function and effectiveness of the system • Why feedback is essential to a robust incident response system
Feel	<ul style="list-style-type: none"> • Capable of being part of a team that provides expertise and consultation on an incident response system
Be Able to Do	<ul style="list-style-type: none"> • Identify stakeholders to contribute to an incident response system • Determine next steps to beginning to put an incident response system in place
Key Messages	<ol style="list-style-type: none"> 1. An incident response system is broad in scope and complexity 2. An incident response system requires the input of many stakeholders – some internal and some external. 3. Planning and preparation is essential to the success of an incident response system. 4. To determine the effectiveness of an incident response system, it must be tested. Drills and other exercises are critical to measure how well as system has been designed and communicated and if it is the appropriate system. 5. The right personnel must be notified as part of an effective incident management system. 6. Providing feedback from drills and incident response and continually improving the system is imperative for success of the system.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Human Performance for Biorisk Management in the Laboratory

Overview	<i>Personnel Management at the Laboratory Level</i> 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 (BRM).
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • That human factors impact individual, job, and organizational performance. What factors contribute to a productive work environment and effective human performance.
Feel	<ul style="list-style-type: none"> • Capable of identifying job expectations for biorisk management.
Be Able to Do	<ul style="list-style-type: none"> • Explain why consideration of human factors is important in the implementation of a biorisk management system.
Key Messages	<ol style="list-style-type: none"> 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) document job responsibilities, 2) establish performance expectations, 3) communicate responsibilities, goals, and objectives, 4) track performance results, 5) provide 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:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Developing, Evaluating and Validating Standard Operating Procedures (SOPs)

Overview	<i>Developing, Evaluating and Validating Standard Operating Procedures (SOPs)</i> 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 a 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • What an SOP is and proper use • The components of a comprehensive SOP • How to evaluate and validate an SOP • How to improve an existing SOP
Feel	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Write an SOP • Evaluate an SOP • Validate an SOP
Key Messages	<ol style="list-style-type: none"> 1. SOPs are instructional documents designed to guide “different people doing one thing the same way and achieving the same outcome.” (Kaufman) 2. SOPs are (generally) designed to achieve a single, or small, outcome – for example, correctly disposing of laboratory waste (e.g., what should I do with this contaminated glove?) 3. There are many acceptable ways to write an SOP; however, there are key components that can comprise an effective SOP. 4. Pre-designed SOP templates can be used for developing biorisk management SOPs. 5. SOPs must be evaluated and validated to assure that individuals can understand and physically accomplish the procedure and that all individuals are accomplishing the intended outcome of the SOP. 6. To consistently measure the ongoing effectiveness of an SOP, behavioral observation data metrics can be used and SOPs must be reviewed periodically and revised as needed.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Hazard & Risk Communication in the Laboratory

Overview	<i>Hazard & Risk Communication in the Laboratory</i> is designed to guide students in discussions and interactive exercises describing cases and scenarios where not all members of a laboratory are aware of identified risks. By making students aware that ALL workers entering a laboratory have a need to know what biorisks they might encounter, this course creates awareness and action for hazard communication program.
Scope	This course does NOT discuss specific legal requirements for hazard and risk communication.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	2 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • The basic information about cases where laboratory-acquired infections occurred due to the unknown presence of pathogens. • The biorisks potentially associated with “unknown” samples • Possible options for communicating known hazards and preparing for unknown hazards • The history of the international biohazard warning symbol
Feel	<ul style="list-style-type: none"> • Confident that existing biorisks have been identified, where possible, and that all workers who enter the laboratory or area where these biorisks may be encountered are aware that they are there and the nature of the biorisk. • Confident that where unknown biorisks occur, there is a specified process for treating unknowns as if they carry an identified and communicated risk.
Be Able to Do	<ul style="list-style-type: none"> • Design a hazard communication plan for a laboratory where pathogens are used or stored.
Key Messages	<ol style="list-style-type: none"> 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 sign, symbols, and other types of communication can clarify the risk profile of a laboratory or equipment. 5. Hazard communication must extend beyond those who are knowledgeable about the work.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Biocontainment Facility Features

Overview	The primary goal of the course, <i>Biocontainment Facility Features</i> , is to introduce students to the concept of primary and secondary barriers and also to the wide variety of facility features different biocontainment labs may possess. Through guided discussions and interactive exercises, students use risk assessments for agents and procedures to define the appropriate facility features necessary for risk mitigation. These risk mitigation strategies are then compared to the facility features provided in the familiar “Biosafety Levels”.
Scope	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 features of biosafety levels are not provided due to the wide variety of risk-based implementation of facility features across different biocontainment levels.
Learning Level <i>Based on Bloom’s taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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. • How different facility features relate to Biosafety Levels (BSLs; as defined by the World Health Organization) • What maintenance is required for different facility features • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Recognize appropriate risk-based facility features that contribute to biorisk mitigation • Communicate or implement necessary maintenance for chosen facility features • Substitute non-facility-based mitigation strategies, when appropriate, when a facility-based feature is not available or has been disabled. Recognize when substitution is allowable and when it is not.
Key Messages	<ol style="list-style-type: none"> 1. Appropriate facility features for biocontainment are chosen based on the identified biorisk. 2. Facility features are often grouped into “Biosafety Levels” 3. Every facility feature grouped into a specified biosafety level may not be required to mitigate risk; however, any justification for not using a specified facility feature must be based on the risk involved and appropriate strategies to mitigate that risk. 4. 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:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Engineering Controls and Laboratory Equipment

Overview	<i>Engineering Controls and Laboratory Equipment</i> is intended for participants who are familiar with biorisk management concepts, hierarchy of controls, and basic biorisk mitigation strategies. It is designed to offer an introduction to key engineering controls and equipment typically found in a biomedical research laboratory and to provide students with the basics of their operation, functions, key features and maintenance needs.
Scope	<p>This course 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:</p> <ul style="list-style-type: none"> HEPA filters BSCs Fume Hoods Clean Benches Centrifuges Transport containers Vacuum line protection Engineered safer sharps
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • The difference between primary and secondary containment. How a BSC works. Appreciate the function of a HEPA filter.
Feel	<ul style="list-style-type: none"> • Protected when properly using appropriate lab equipment and engineering controls
Be Able to Do	<ul style="list-style-type: none"> • Set up and work in BSC to avoid contamination. • Describe how a HEPA filter works.
Key Messages	<ol style="list-style-type: none"> 1. Containment facilities and equipment establish and maintain primary and secondary barriers. Primary barriers contain the agent at the source. Secondary barriers protect personnel or environment in case of a release from primary containment 2. Biosafety Cabinets provide outstanding primary containment when used properly. 3. Engineering controls must be maintained properly 4. There are a variety of equipment and design features that provide containment in a laboratory. Understanding their function is key to proper use.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Good Laboratory Practices

Overview	<i>Good Laboratory Practices</i> 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 follow 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 lesson will draw knowledge and awareness of some good laboratory practices. It does not cover all the possible practices and uses facilitated learning activities to draw out student's knowledge of good practices and common sense. It reinforces concepts learned in the Risk Mitigation lesson.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	2.5 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • Some common good laboratory practices • Why some laboratory practices are better than others • How to perform a risk assessment to determine if a GLP is good or not
Feel	<ul style="list-style-type: none"> • Confident mitigating biorisk by implementing GLPs
Be Able to Do	<ul style="list-style-type: none"> • Be able to recognize potential unsafe work practices and conditions • Wash hands properly
Key Messages	<ol style="list-style-type: none"> 1. Good laboratory practices are techniques and methods of doing work in the laboratory that reduce biorisk 2. Good laboratory practices not only reduce risk but also promote better research; more accurate results; and better data. 3. GLP can be enforced/promoted through both administrative and engineering controls
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Personal Protective Equipment

Overview	<i>Personal Protective Equipment (PPE)</i> 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. Participants 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 how and where 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • What PPE is and 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Demonstrate different types and uses of PPE. • Write laboratory procedures that include the use and maintenance of PPE appropriate to that procedure.
Key Messages	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Decontamination

Overview	<i>Decontamination</i> is designed to provide students with a working vocabulary of terms used in decontamination procedures 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 and also develop a standard operating procedure (SOP) for a specific decontamination procedure.
Scope	This course discusses decontamination in general and does NOT specify or instruct on specific legal requirements for specific decontamination procedures.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • The differences between disinfection, decontamination, and sterilization • The various decontamination methods used for surface and area decontamination • The factors that influence the efficacy of a decontamination procedure • How validation of the decontamination procedure is conducted
Feel	<ul style="list-style-type: none"> • 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 and that it is communicated appropriately, via an SOP.
Be Able to Do	<ul style="list-style-type: none"> • Select and utilize appropriate decontamination methods • Choose an appropriate validation method • Interpret the results from validation • Create a standard operating procedure (SOP) for using a specific decontaminant and decontamination procedure.
Key Messages	<ol style="list-style-type: none"> 1. Terminology used in decontamination procedures must be understood. Disinfection is not the same thing as sterilization. 2. Different methods of decontamination are necessary for different organisms, surfaces, settings, etc. 3. There are many different factors that influence the effectiveness of a decontamination procedure. These factors must be understood when choosing a decontamination method. 4. Decontamination must be validated to assure that it is effective. 5. SOPs are particularly useful for defining and outlining appropriate and effective methods of decontamination and validation of those methods.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Biological Waste Disposal

Overview	<i>Biological Waste Disposal</i> is designed to provide participants a general overview of the types of biological waste and the methods to collect, store, and treat these materials so that they are no longer considered biohazardous. Students will create, through guided discussion and interactive exercises, a matrix of acceptable methods to collect, store, and treat multiple types of biological waste
Scope	This course discusses biological waste disposal in general and does NOT specify or instruct on specific legal requirements for biological waste disposal.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
<i>Course Objectives - At the end of this course, students will:</i>	
Know	<ul style="list-style-type: none"> • The vocabulary applicable to biological waste • The factors that influence selection of treatment and disposal approaches and technologies
Feel	<ul style="list-style-type: none"> • Confident of communicating difference between types of biological wastes and the means to treat and dispose them
Be Able to Do	<ul style="list-style-type: none"> • Classify and segregate different types of biological waste • Select and utilize appropriate collection, storage, and treatment methods • Create a matrix of methods to treat and dispose different kinds of biological waste
Key Messages	<ol style="list-style-type: none"> 1. Waste should be segregated into appropriate waste types, according to the risk it presents 2. Different methods for collection and storage of biological waste are necessary for different types of waste 3. There are different treatment methods that are appropriate according to 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:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Laboratory Biosecurity

Overview	<i>Laboratory Biosecurity</i> 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.
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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	16 hours/2 days
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • The importance of laboratory biosecurity and the reasoning behind it. • Different methods for establishing physical, information, and transport security, as well as methods for materials control and accountability and personnel reliability. • Which methods are appropriate at different levels and types of risk.
Feel	<ul style="list-style-type: none"> • Confident in choosing and using different methods to assure laboratory biosecurity.
Be Able to Do	<ul style="list-style-type: none"> • Write and apply lab-level procedures to assure laboratory biosecurity. • Describe why different methods are appropriate for establishing laboratory biosecurity.
Key Messages	<ol style="list-style-type: none"> 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. 4. Material Control and Accountability, Transport Security, and Information Security complement other security components. 5. Security awareness is crucial in laboratory biosecurity.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management (who conduct research) ✓ Workforce (who conduct research)

Field Biosecurity

Overview	<i>Field Biosecurity</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Confident that appropriate procedures for securing biological agents and toxins during field work and sample transport are chosen and applied.
Be Able to Do	<ul style="list-style-type: none"> • Write and demonstrate procedures that are suitable for securing biological agents and toxins outside of the laboratory.
Key Messages	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management (who conduct research) ✓ Workforce (who conduct research)

Shipping Infectious Substances & Biological Specimens

Overview	<i>Shipping Infectious Substances & Biological Specimens</i> course introduces participants 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. Participants who successfully complete the course and pass the final exam can be certified according to International Air Transport Association (IATA) regulations. Participants will also be introduced to program management requirements and security issues associated with transporting and shipping infectious substances.
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 with participants will gain practical experience in packaging, marking, labeling and documentation. Students will create their own performance review checklists to be able to determine whether a package is properly prepared.
Learning Level Based on Bloom's taxonomy	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • What is required to properly receive, package, label, and ship biological agents and toxins.
Feel	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Determine the appropriate classification of biological agents for shipments • 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	<ol style="list-style-type: none"> 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 goods is assigned a "Proper Shipping Name" (PSN) and corresponding UN identification number. 4. Packing instructions inform shippers specifically how to properly package dangerous goods. All biological agents must be "tripled packaged". 5. Overpacks are enclosures over packages; they must be marked and labeled exactly as the inner packages. 6. 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. 7. Consideration must be given to import and export requirements for the countries of origin and destination.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Incident Recognition and Response in the Laboratory

Overview	<i>Incident Recognition and Response in the Laboratory</i> is designed to offer common terminology and processes to recognize and respond to incidents in the laboratory to ensure that those involved in laboratory operations are educated on these matters, to help identify and mitigate such events. This course will provide a framework for recognizing and responding to incidents in a laboratory setting. Students will identify examples of types of incidents and engage in discussions on the characteristics of some of these incidents. Also, students will discuss the use of appropriate SOPs, response measures, and resources.
Scope	This course provides basic guidelines and procedures for recognizing and responding to incidents in the laboratory. It does NOT provide procedures for responding to specific incidents.
Learning Level <i>based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Lesson Objectives - At the end of this lesson, learners will:	
Know	<ul style="list-style-type: none"> • What an incident is • Characteristics of different types of incidents • The principles of how to recognize an incident • What response measures are available • The principles of incident response • The principles of how to utilize this knowledge in a broader laboratory setting
Feel	<ul style="list-style-type: none"> • Empowered to define, identify and recognize incidents • Empowered to respond to incidents and discuss pros and cons of different measures • Confident that incidents may be recognized and mitigated • Empowered to mitigate existing lab-level risks of incidents
Be Able to Do	<ul style="list-style-type: none"> • Define, characterize and recognize various types of incidents • Define and explain different types of incident response measures • Assist in utilizing this knowledge in existing or future laboratory procedures
Key Messages	<ol style="list-style-type: none"> 1. Defining and recognizing an incident is the first step to responding appropriately 2. Not all incidents are emergencies requiring immediate response 3. Documenting and reporting all incidents may prevent emergencies in the future 4. Everyone in the lab has a role and responsibilities for incident response 5. Different incidents require different responses
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Writing & Communicating Biorisk Management Policy

Overview	<i>Writing & Communicating Biorisk Management Policy</i> 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.
Scope	This course provides guidelines for writing and communicating a policy statement; it will NOT provide mandatory directions and procedures for developing a policy statement.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • What is a policy statement • What is included in a policy statement • Who writes a policy statement • How is a policy statement written • Who reads a policy statement
Feel	<ul style="list-style-type: none"> • Confident conversing about basic features found in a policy statement • Confident drafting a policy statement
Be Able to Do	<ul style="list-style-type: none"> • Draft a policy statement • Develop a plan to communicate policy to all layers of the affected workforce
Key Messages	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Considerations for Training in Biorisk Management

Overview	<i>Considerations for Training in Biorisk Management</i> 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.
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • The components and steps in the training design cycle • Which steps of the training design cycle are important for managers and leadership to be involved with • How to identify learning objectives for a given biorisk management scenario • Basic training delivery techniques that make training more sustainable
Feel	<ul style="list-style-type: none"> • Capable of providing people, time, and money to appropriately prioritize and staff biorisk management training programs
Be Able to Do	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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. Analyzing the current situation and the desired outcomes are key first steps in determining the training necessary. 4. Training is not always the best way to transfer knowledge, skills, and abilities. All options should be considered. 5. Managers need to be aware of what type of delivery creates the most sustainable training environment, especially as they evaluate and assign instructors. 6. 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management ✓ Workforce

Developing, Conducting, and Maintaining a Hazard Inventory

Overview	<i>Developing, Conducting, and Maintaining a Hazard Inventory</i> is designed for students in the Management and Leadership Track. The course will establish an understanding of biological hazard identification as well as the development of standardized processes to build, perform, and maintain an inventory of biological agents and toxins. Security issues and aspects of inventory monitoring and improvement will be evaluated as well as personnel roles and responsibilities with regard to hazard inventory.
Scope	This course will provide an overview of the key aspects of developing, conducting and maintaining a laboratory hazard inventory. This course will NOT cover all aspects of biohazard identification and assessment nor will it provide a specific laboratory inventory design.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • How to identify a biological hazard as well as what features are necessary for an accurate risk assessment to create and maintain a hazard inventory. • How to collect data about biological hazards and what information should be included in a biological hazard inventory. • The importance of protecting and monitoring a biological hazard inventory.
Feel	<ul style="list-style-type: none"> • Confident in recognizing and cataloging biological hazards. • Skilled in communicating biological hazard information, mitigation processes, and the importance of a complete biological inventory process. • Prepared to implement roles and responsibilities for a biological hazard inventory and motivated to allocate laboratory resources to strengthen current biological hazard inventory policies and procedures. • Responsible for protecting information concerning biological hazards.
Be Able to Do	<ul style="list-style-type: none"> • Critically review and analyze a facility's hazardous biological inventory tracking system. • Oversee the development and maintenance of biological hazard inventory policies and procedures. • Protect sensitive biological hazard inventory information and ensure that policies and procedures reflect this goal. • Define roles and responsibilities for personnel who handle biological hazard inventory contents. • Oversee the implementation of inventory control and review policies and procedures that investigate inventory discrepancies in the biological hazards inventory. • Communicate the need for conducting and maintaining a hazard inventory.
Key Messages	<ol style="list-style-type: none"> 1. Biological hazards can be grouped according to risk group schemes and aid in risk assessment. 2. There are unique roles and responsibilities when working with the hazard inventory. 3. The inventory system should capture information about each hazard to effectively track the hazard. In addition, the system should be reviewed regularly and allow for continual improvement.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management



Identifying Legal Requirements that Impact Biorisk Management	
Overview	<p><i>Identifying Legal Requirements that Impact Biorisk Management</i> is designed for managers and leaders to identify the international, national, and local requirements that impact biorisk management at the organizational level. Although it is designed for managers and leaders, it can also be used for any worker that influences or impacts biorisk management to provide an opportunity to think through and to catalog these requirements.</p> <p><i>Note: Presenting this course will require extensive preparation on the instructor's part. The course materials provide only the framework of this exercise – it cannot anticipate all possible responses to the exercise based on the localities where it may be presented and, thus, anticipated responses are, in general, not provided.</i></p>
Scope	See above
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • How to identify legal requirements that impact biorisk management (BRM) • How to align legal requirements with BRM • What is involved in performing a gap analysis • How to perform a gap analysis
Feel	<ul style="list-style-type: none"> • Confident in identifying and understanding legal requirements that impact BRM
Be Able to Do	<ul style="list-style-type: none"> • Identify legal requirements that impact BRM • Determine how legal requirements affect BRM • Perform a gap analysis to determine if the organization and BRM system/program is in alignment with all legal requirements
Key Messages	<ol style="list-style-type: none"> 1. Legal requirements derive from a variety of sources and cover a variety of aspects of biorisk management 2. A best practice to determine alignment with legal requirements is to conduct a gap analysis 3. Legal requirements are not the only drivers for biorisk management.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Establishing Work Program Review & Approval

Overview	<i>Establishing Work Program Review & Approval</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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 terms of reference and roster for a Biorisk Management Advisory Committee
Feel	<ul style="list-style-type: none"> • Capable of establishing or improving a process to define, document, review, and approval work programs • Confident in the structure and function of a Biorisk Management Advisory Committee
Be Able to Do	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Managing Human Performance in the Biorisk Management Workforce

Overview	<i>Managing Human Performance in the Biorisk Management Workforce</i> 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.
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Capable of documenting and communicating job expectations for biorisk management. More confident in assessing and addressing issues involving human performance.
Be Able to Do	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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. People bring to their job their personal attitudes, skills, habits, and personalities. Individual characteristics influence behavior in complex and significant ways. 6. Organizational factors have the greatest influence on individual and group behavior yet they are often overlooked. 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:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Establishing and maintaining formal and informal BRM mentoring programs

Overview	<i>Establishing and maintaining formal and informal Biorisk Management Mentoring Programs</i> addresses the gap that is often found between “training” and “behavior”. Students will, through guided exercise 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.
Scope	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.
Learning Level <i>Based on Bloom’s taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Capable of implementing mentoring as a expected element of biorisk management
Be Able to Do	<ul style="list-style-type: none"> • Write a draft mentorship agreement • Identify next steps for developing a mentorship program to support and maintain biorisk management
Key Messages	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Establishing & Maintaining Worker Health Programs

Overview	<i>Establishing & Maintaining Worker Health Programs</i> is intended as a course to be taken as part of the Management & Leadership track in the Biorisk Management (BRM) Curriculum. It is designed to offer a common terminology and a process to determine effective and appropriate occupational health strategies in a laboratory setting.
Scope	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.
Learning Level Based on Bloom's taxonomy	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	7 hours/1 day
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management



Developing and Maintaining Roles & Responsibilities for Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins	
Overview	<i>Developing and Maintaining Roles & Responsibilities for Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins</i> is intended to provide management-level personnel an introduction to key considerations for managing personnel laboratory access and material control and 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.
Scope	This course will provide introductory information on developing and communicating policies and procedures related to laboratory access and material control and 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 and accountability systems, personnel screening approaches, information security, and incident response.
Learning Level Based on Bloom's taxonomy	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • 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 to develop a process to manage access and accountability based on risk. • What mechanisms are available to assure that access and accountability processes are working correctly and how they can be manipulated.
Feel	<ul style="list-style-type: none"> • Prepared and motivated to implement a risk-based access, control and material accountability measures for biological agents and toxins. • Confident using the learned tools and techniques to ensure those with access to biological agents and toxins are competent and reliable.
Be Able to Do	<ul style="list-style-type: none"> • 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.
Key Messages	<ol style="list-style-type: none"> 1. Material access, control, and accountability measures help create a safe and secure environment for handling biological agents by ensuring complete and timely knowledge of what materials exist, where they are, and who is accountable for them. 2. Designation of "accountable individuals" who oversee the control of biological agents and toxins within the facility, and their specific roles and responsibilities, is a key aspect of an access and accountability plan. 3. Regular reviews and reports of the access and accountability system (inventory, audit, etc) are needed to ensure that the system is functioning correctly.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Understanding & Maintaining Facilities & Equipment for Biorisk Management

Overview	<i>Understanding & Maintaining Facilities & Equipment for Biorisk Management</i> 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.
Scope	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.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Capable of providing people, time, and money to appropriately maintain biocontainment facilities and equipment
Be Able to Do	<ul style="list-style-type: none"> • Describe key considerations for managers to maintain biocontainment facilities and equipment • Identify the necessary people, time, and money necessary to maintain biocontainment facilities and equipment and thus support and lead the effort towards biorisk management.
Key Messages	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Basic Features & Maintenance for Physical and Information Security Measures

Overview	<p><i>Basic Features and Maintenance for Physical and Information Security Measures</i> is intended to be one of the principal courses on biosecurity for students in the Management & 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.</p>
Scope	<p>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.</p>
Learning Level Based on Bloom's taxonomy	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension
Length	4 hours
Course Objectives - At the end of this course, students will be able to:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Confident conversing about basic features of and maintenance requirements for physical and information security measures
Be Able to Do	<ul style="list-style-type: none"> • Provide support for the placement and maintenance of physical and information security measures
Key Messages	<ol style="list-style-type: none"> 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, continuing maintenance and upkeep, as well as re-assessments of design and purpose.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Incident Response Planning and Preparation

Overview	<i>Incident Response Planning and Preparation</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Lesson Objectives - At the end of this lesson, learners will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Confident in leading and supporting the development of an incident response plan and overseeing preparation to implement the plan.
Be Able to Do	<ul style="list-style-type: none"> • Write a draft incident response plan • Write a preparation action plan
Key Messages	<ol style="list-style-type: none"> 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 mobilize 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Incident Response & Investigation

Overview	<i>Incident Response & Investigation</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	6 to 8 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Incident Response Evaluation & Improvement

Overview	<i>Incident Response Evaluation & Improvement</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	2 to 4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Confident in leading and supporting evaluation of a current incident response system • Capable of identifying and communicating necessary improvements
Be Able to Do	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Measurement and Analysis of Biorisk Management System Performance

Overview	<i>Measurement and Analysis of Biorisk Management System Performance</i> 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	8 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • Define “performance” in biorisk management system context. • CWA 15793 requirements that are most relevant to performance evaluation • The connection between performance evaluation and the PDCA cycle for biorisk management. • Definitions for performance indicators and metrics • Various performance evaluation methods • How to plan a performance measurement program.
Feel	<ul style="list-style-type: none"> • Capable of describing why measuring biorisk management performance is important • Confident in leading and supporting initiatives to develop organization-specific biorisk management performance measurements
Be Able to Do	<ul style="list-style-type: none"> • Explain why biorisk management performance measurements are important • Defining next steps for more fully establishing, using, and evaluating biorisk management performance measurement
Key Messages	<ol style="list-style-type: none"> 1. The only way to document effective performance is to measure it 2. A measurement is not necessarily a number 3. A biorisk management system is described by CWA 15793:2011 and therefore it is important to refer to this document while defining what measurements of performance are important. 4. Performance can be measured by looking at both activities and outcomes of a biorisk management system 5. Establishing performance indicators must occur during planning objectives, roles, and responsibilities 6. Many opportunities for performance measurements are already integrated and established in current practices.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Conducting Audits and Inspections to Assess Biorisk Management Performance

Overview	This course is an adjunct to <i>Establishing and Using Performance Indicators</i> . 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 <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Capable of leading and supporting audit and inspection initiative, where appropriate.
Be Able to Do	<ul style="list-style-type: none"> • Develop an audit or inspection procedure • Evaluate results from an audit or inspection.
Key Messages	<ol style="list-style-type: none"> 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 “gotcha” 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:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Revising and Improving a Biorisk Management System based on Performance Results

Overview	<i>Revising and Improving a Biorisk Management System based on Performance Results</i> is designed to teach and create processes for completing the biorisk management system feedback loop. By using the data from performance indicator measurements, gaps or improvements to various aspects of the biorisk management system can be identified and evaluated. Students will, through guided discussion and interactive exercises, explore the mechanisms to assure that improvements to the system are made and communicated.
Scope	This course will result in draft procedures for biorisk management system performance evaluation & improvement – this draft will provide a template to be completed at the student's organization, with appropriate stakeholder participation and consensus.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	2 to 4 hours
Course Objectives - At the end of this course, students will:	
Know	<ul style="list-style-type: none"> • Steps to evaluate the results from performance indicator measurements • Steps to review and, as appropriate, revise biorisk management system documents and procedures based on evaluation • Key elements to effectively communicate improvements to the biorisk management system.
Feel	<ul style="list-style-type: none"> • Confident in leading and supporting evaluation of a current biorisk management system • Capable of identifying and communicating necessary improvements
Be Able to Do	<ul style="list-style-type: none"> • Write a draft procedure for evaluating performance indicator results for a biorisk management system • Identify elements of a biorisk management system that require improvement • Identify a strategy for communicating improvements
Key Messages	<ol style="list-style-type: none"> 1. Measurements from biorisk management performance indicators require evaluation to determine what revisions or improvements might result in an increase in performance 2. Attention to whether the performance indicator is appropriate and whether it is measuring the right aspect is important to assess BEFORE deciding to revise any aspect of biorisk management. 3. Attention to whether the particular elements of the biorisk management system are appropriate is important to assess BEFORE deciding to make any improvements or revisions. 4. Revisions to biorisk management documents and procedures must be communicated to all personnel with impacted roles & responsibilities.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management

Establishing and Using Performance Indicators

Overview	<i>Establishing and Using Performance Indicators</i> guides the students through the integration of performance indicators into the planning phase of a biorisk management system. Students will develop performance indicators for given biorisk management objectives and design procedures for collecting the data for both activity- and outcome-based performance indicators.
Scope	This course will result in draft performance indicators and data collection procedures for a few biorisk management objectives. Using this template, students will be able to establish and use performance indicators for additional biorisk management objectives at their home institution.
Learning Level <i>Based on Bloom's taxonomy</i>	<ul style="list-style-type: none"> ✓ knowledge ✓ comprehension ✓ application
Length	4 hours
<i>Course Objectives - At the end of this course, students will:</i>	
Know	<ul style="list-style-type: none"> • What a performance indicator is and why indicators are important to effective biorisk management • How to establish and measure an activity-based indicator • How to establish and measure an outcome-based indicator • Where in the biorisk management system process performance indicators should be established and measured
Feel	<ul style="list-style-type: none"> • Capable of establishing and using (measuring) both activity- and outcome-based performance indicators in biorisk management
Be Able to Do	<ul style="list-style-type: none"> • Develop activity- and outcome-based indicators for specific biorisk management objectives • Collect measurements from indicators
Key Messages	<ol style="list-style-type: none"> 1. The only way to document effective performance is to measure it 2. A measurement is not necessarily a number 3. Performance can be measured by looking at both activities and outcomes of a biorisk management system 4. Establishing performance indicators must occur during planning objectives, roles, and responsibilities 5. Performance indicator measurement collection should be integrated into routine activities.
Biorisk Management Role:	<ul style="list-style-type: none"> ✓ Policy Makers ✓ Top Management ✓ Biorisk Management Advisors/Advocates ✓ Scientific/Lab Management