SAND2012-2454P

Orientation to Biorisk Management

Instructor Guide

Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
Cooperative Biological Engagement Program

Welcome & Introductions

Slide 1

Introduce Instructor(s):

[Introduce others associated with the training, as appropriate]

Name

Affiliation

Representation (I'm here on behalf of. . .)

Quick Experience Glimpse

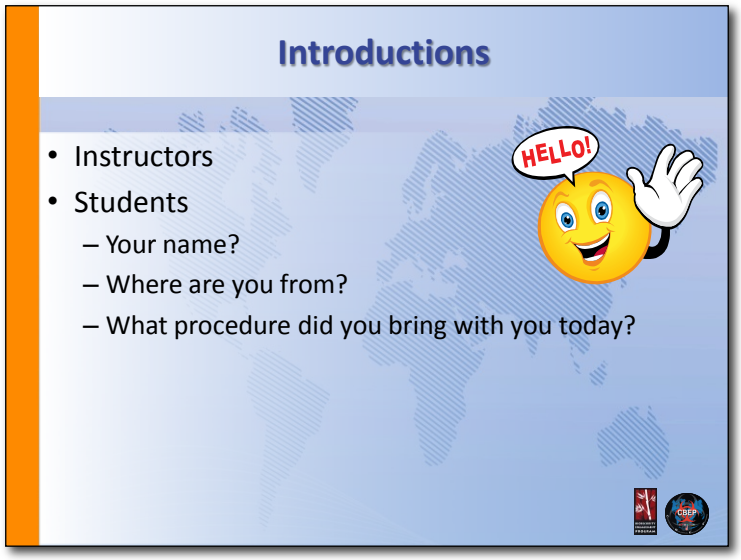
Relevancy of the Course to your experience

Welcome & Introductions

Before you introduce yourselves, I'd like to provide some reminders about this facility and the training:

1. Restrooms are. . .
2. Exits are. . .
3. Evacuation procedures are. . .
4. [any escort or restricted access procedures]
5. We will have intermittent breaks during the course, but please feel free (or not) to take a quick break if you need to at other times during the course
6. Beverages and snacks will be available at (time) and at (location). You may/may not eat and drink in this room
7. Please silence any cell phones or other noise-making devices.
8. Others. . .

Slide 2



Welcome & Introductions

Let's go around the room and let each of you introduce yourself. Please tell us your name, where you work (organization and/or title, as appropriate), and what you hope to gain from the course.

Ground rules

This will be a very interactive session and you will learn the most if you participate fully. We will not intentionally force any one to speak or to do an activity that embarrasses them – if you are uncomfortable, please speak to one of the leaders. For those of you who like to talk, please share your expertise but be aware of those around you who may be quieter and give them time to share their opinion as well. We ask that everyone respect the break times and report back promptly when asked to do so. But most of all, we want to make this a fun time to learn, so remember to smile and enjoy yourself!

Transition to Objectives

Goal

To review the Action Plan and Learning Objectives for the course and to solicit any additional learning goals from the participants.

Time

20 minutes

Welcome & Introductions

Key Messages for Instructor

1. The importance, and distinctions between key biorisk management terminology such as: biorisk, biosafety, biosecurity, biorisk management system

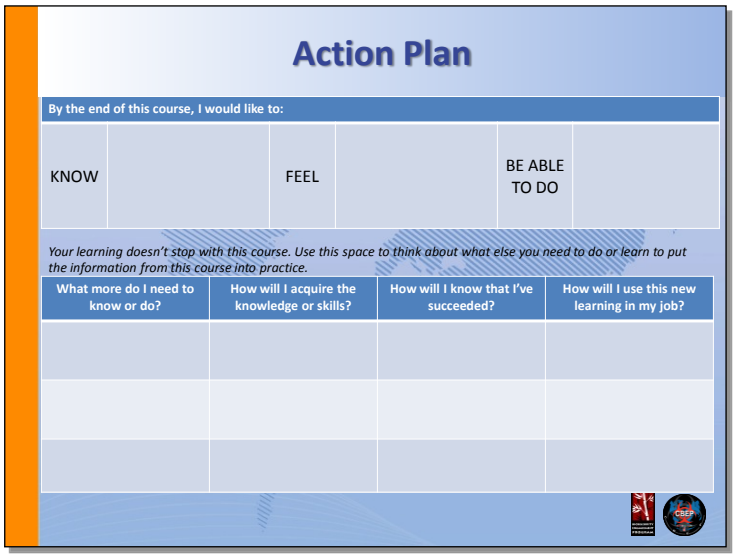
2. AMP (Assessment, Mitigation, and Performance) is a simple model for managing biorisks

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

Slide 3

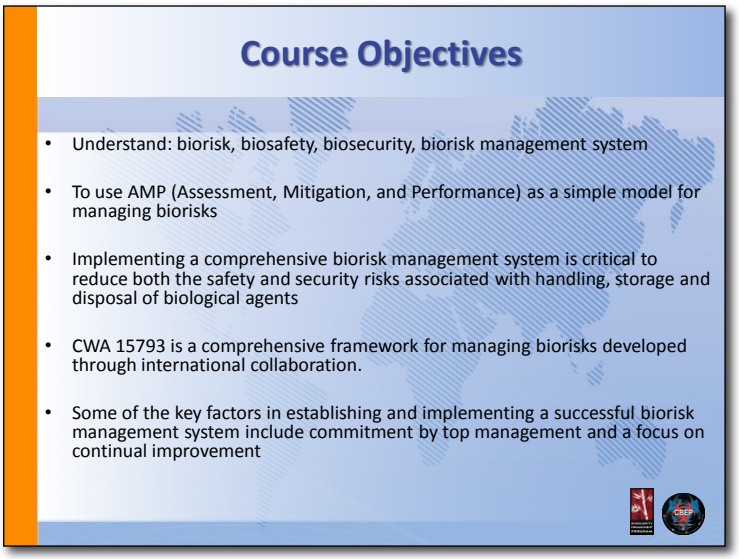


Welcome & Introductions

Instructions for the Action Plan handout:

- The Action Plan handout is on page __ of the student guide.
- It is designed to help you assess your learning of the material as we go through the course. It is also referred to as a learning contract.
- Go over each section of the Action Plan. . .
- The sections KNOW, FEEL and DO are designed to help outline personal learning objectives for this course.
- Ask each participant to think about what they would like to be able to KNOW, FEEL, and DO once this course is completed
- Tell the students that this is their own Action Plan. It does not need to be shared with anyone. It can be used during the course and after the course to help continually reach learning goals.
- Allow 5 minutes

Slide 4



Welcome & Introductions

Background Information for Instructor

Review the course objectives, these can be read from the slide. Check for understanding and verify that these objectives are consistent with student expectations.

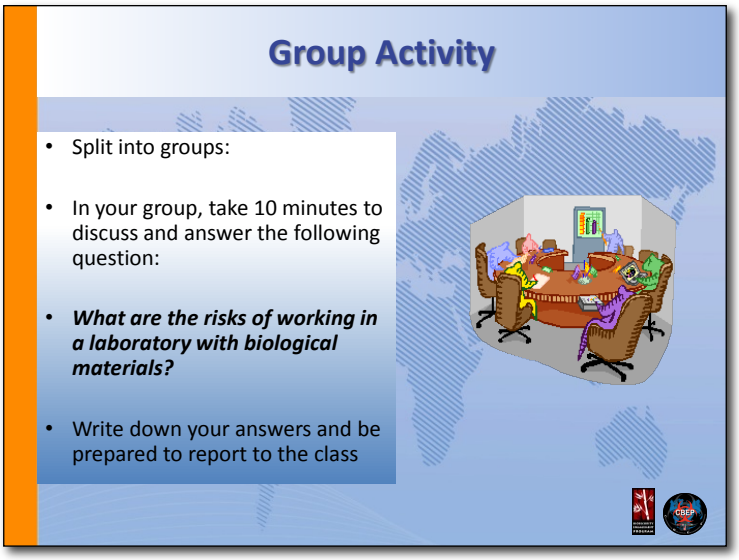
Capture any additional KNOW, FEEL, or DO or other learning goals

Capture any learning goals that will supplement course objectives and address any that are outside the scope of the course.

This course is flexible in nature. If there is a learning goal that is easily incorporated into the course, feel free to add it. Please note successful additions and consistently requested learning goals in the evaluation portion of this course and/or to GBRMC administrators.

Orientation to Biorisk Management

Slide 5



Small group activity (20 minutes).

Activity Instructions (to students)

1. Break into groups of five.
2. Address the following question for 10 minutes:
    a. What are the risks of working in a laboratory with biological materials?
3. Report your findings to the instructor when called on.

Small group activity (20 minutes).

You have 20 minutes to complete this activity

Directions for Instructor:

- Divide the room into groups of about five people each.
- Try to get at least one good English speaker in each group.
- In groups, address the following question (10 minutes): What are the risks of working in a laboratory with biological materials?
- After participants have had 10 minutes to discuss this question in their groups, go to each group one at a time and solicit one unique risk (10 minutes) and capture on the instructor's flipchart.
- Continue in this manner in a round, until all the unique risks are captured on the flip chart

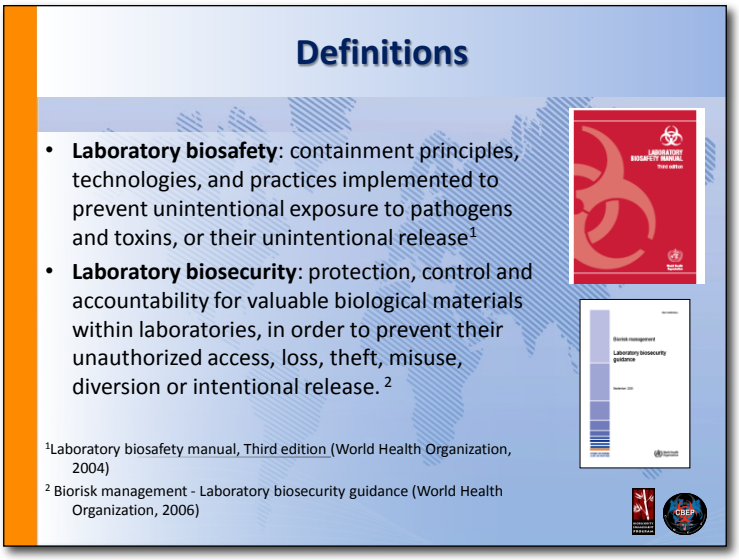
Expected Responses

- Accidental infection
- Accidental release
- Intentional theft and/or misuse
- Physical injuries (sharps, animal bites, slips, trips, falls, ergonomic injuries, burns, etc.)
- Others (e.g. Rad and chem.)

New Responses from Students:

Orientation to Biorisk Management

Slide 6



Background Information for Instructor

This slide is used to inform participants of definitions for key terms used in the course. Biosafety is about prevention of unintentional risks and biosecurity is focused on preventing intentional risks.

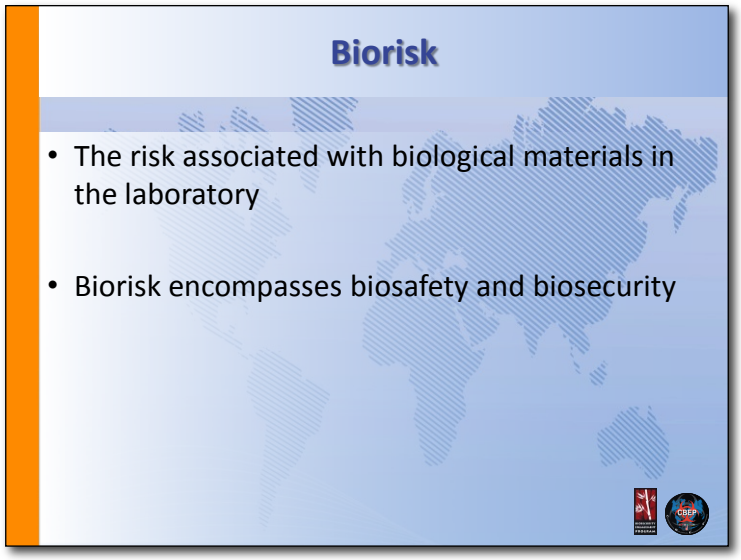
- In addition to protecting occupational workers, laboratory biosafety safeguards the public and the environment from accidents involving pathogens and toxins.
- Bioscience laboratory personnel and management have a similar responsibility to implement biosecurity systems, but the concepts of biosecurity are much less understood than biosafety.

The following can be used as examples of the different objectives of biosafety and biosecurity

- Signage: Biosafety want to advertise the fact that dangerous agents are present, while biosecurity does not want to advertise this fact
- Exits: Biosafety promotes easy exit in case of an incident, while biosecurity inherently has containment and limited egression on the agenda, e.g. the case of theft etc.

Orientation to Biorisk Management

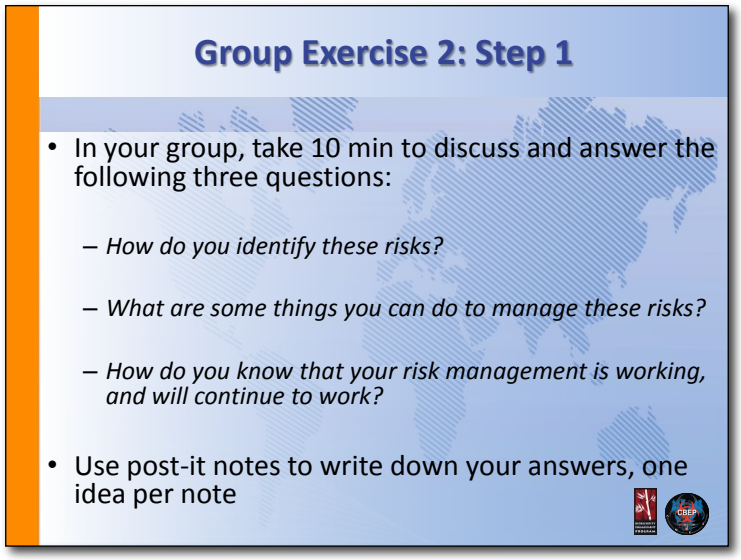
Slide 7



Background Information for Instructor

Another key definition. Point out the safety and security risks that the students identified. It is likely they may not have identified security risks but these are important considerations even if you are not working with high containment agents.

Slide 8



Small group activity (10 minutes for Step 1).

Activity Instructions (to students)

1. In your groups, use your post-it notes to identify at least three different items for each question listed. One idea per post it-note.
    a. How do you identify these risks?
    b. What are some things you can do to manage these risks?
    c. How do you know that your risk management is working, and will continue to work?
2. The instructor will be available for questioning.

Small group activity (10 minutes for Step 1).

You have 20 minutes to complete this activity

Directions for Instructor:

- Each group uses post-it notes to identify at least three different items for each question, one idea per post-it note.
- Facilitator should be checking in with each table periodically to ensure that they are addressing all three questions and are putting them down one idea per post it.
- The facilitator should notify the students that they will use the post-its in step 2 in a few minutes, after some discussion.

Expected Responses

- Risk assessment
- Hazard identification
- Research review
- Questionnaires, surveys
- PPE, BSC, SOPs
- Training
- Good laboratory practices
- Audits, inspections
- Fewer accidents (accident reporting/tracking)
- Establish a safety committee to do regular review of practices

New Responses from Students:

Slide 9

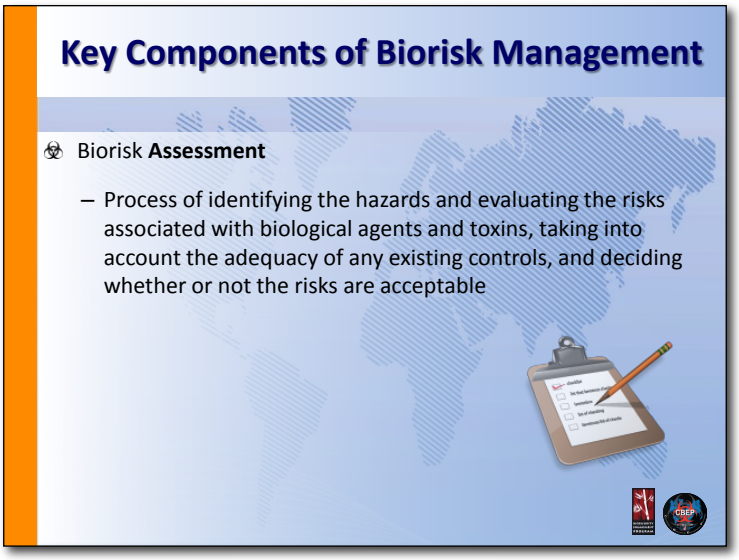
Take a Break (10 minutes)

Time Check

You should be approximately 1 hour into the course. You have 3 hours of course remaining. Indentifying risks in a lab is next.

Orientation to Biorisk Management

Slide 10



Background Information for Instructor

The instructor uses the following two slides: Biorisk Mitigation and Performance to define key components of biorisk management

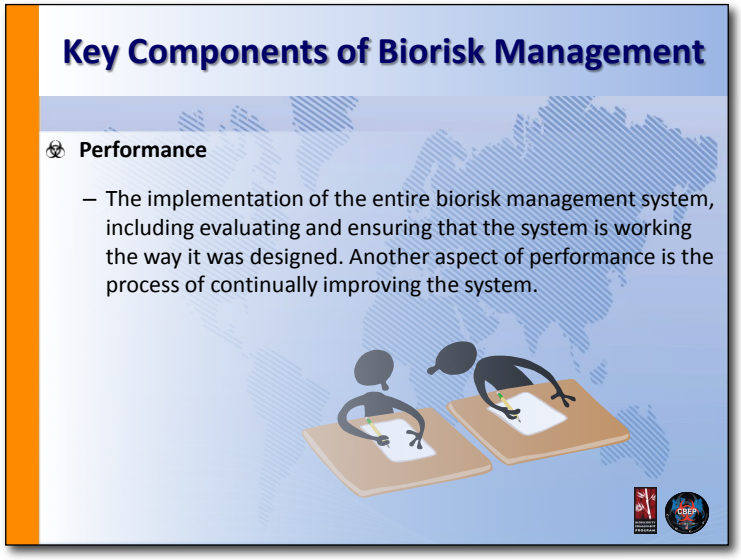
Slide 11

Orientation to Biorisk Management

Background Information for Instructor

The instructor uses the following slide: Performance to define key components of biorisk management

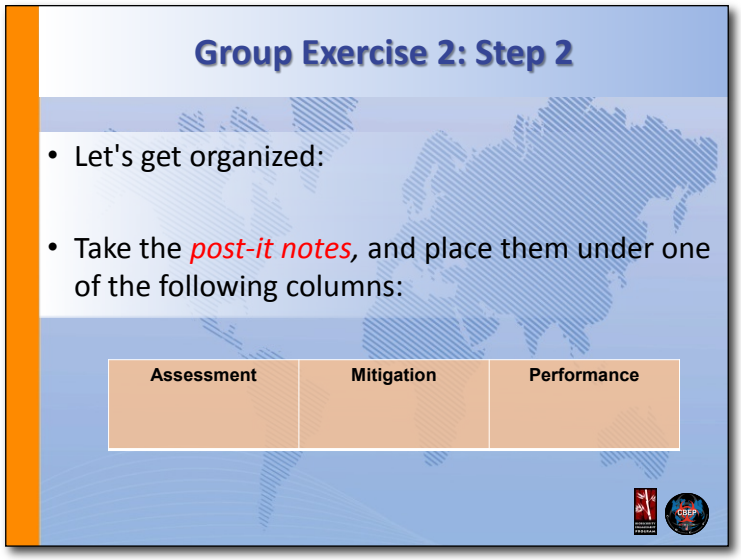
Slide 12



Background Information for Instructor

Define key components of biorisk management. Prompt the students to be ready to compare and contrast the key components of biorisk management – Assessment, Mitigation and Performance.

Slide 13



Small group activity (10 minutes for Step 2).

Activity Instructions (to students)

1. How do we organize these ideas/items?
2. Pick a post-it not from the previous exercise and place them in one of the three columns: Assessment, Mitigation, and Performance.

You have 10 minutes to complete this activity

Directions for Instructor:

- Ask the participants "How can we organize these ideas/items?"
- Draw three columns: Assessment, Mitigation, and Performance.
- Have students each pick a post-it note from the previous exercise, and place them in one of the three columns: Assessment, Mitigation, Performance

Review for accuracy and discuss in plenary any variances.

Expected Responses

Assessment:

- Risk assessment
- Hazard identification
- Research review
- Questionnaires, surveys
- Literature review

Mitigation:

- PPE, BSC, SOPs
- Training
- Good laboratory practices
- Engineering controls
- Biological Safety Cabinets

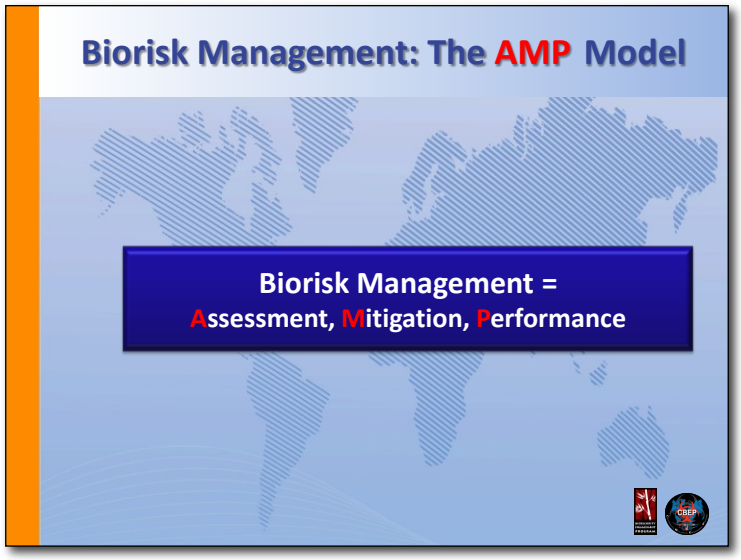
Performance:

- Audits, inspections
- fewer accidents (accident reporting/tracking)
- Establish a safety committee to do regular review of practices

Responses from Students:

Orientation to Biorisk Management

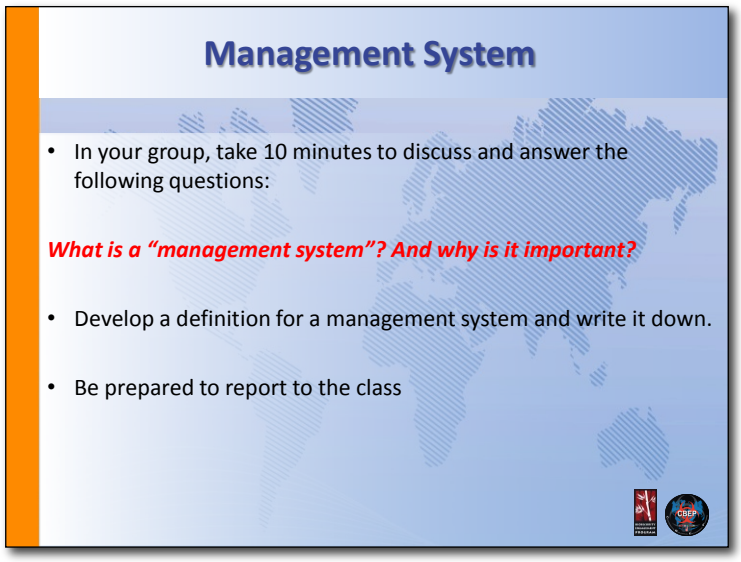
Slide 14



Background Information for Instructor

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

Slide 15



Small group activity (15 minutes).

Activity Instructions (to students)

1. Consider: What is a "management system"? And why is it important?
2. Develop a definition for a management system and write it down. Be prepared to report to the class.

You have 10 minutes to complete this activity

Directions for Instructor:

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

Plenary Discussion (10 minutes).

Question to consider:

Why are management systems important?

Directions for Instructor:

- Pool ideas on the definition of a management system
- Try to adopt a definition that everyone in the group can agree to and write this consensus definition down on a flip chart.

Capture on a flip chart:

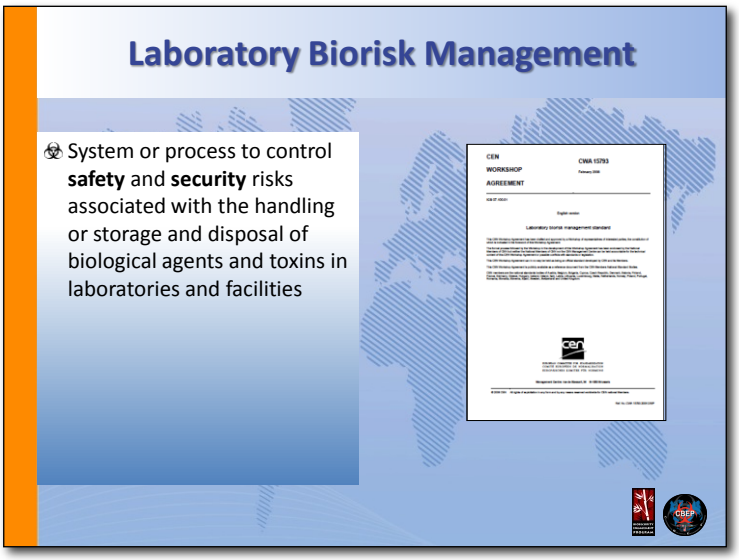
- Be prepared to record answers on a blank page.

Expected Responses

- Allows for hazards to be easily identified.
- Problems can be assessed
- Effective mitigation can be put into place and periodically evaluated.
- Overall reduces the risk

New Responses from Students:

Slide 16



Orientation to Biorisk Management

Background Information for Instructor

- Provide this "official definition" and tie the students' definition together with this one.
- Point out that the students created a rudimentary management system with their group (refer to the AMP model).
- Introduce the CWA as a comprehensive framework for managing biorisks developed through international collaboration.
- Explain that you will be discussing more details of the CWA after the break.

Slide 17

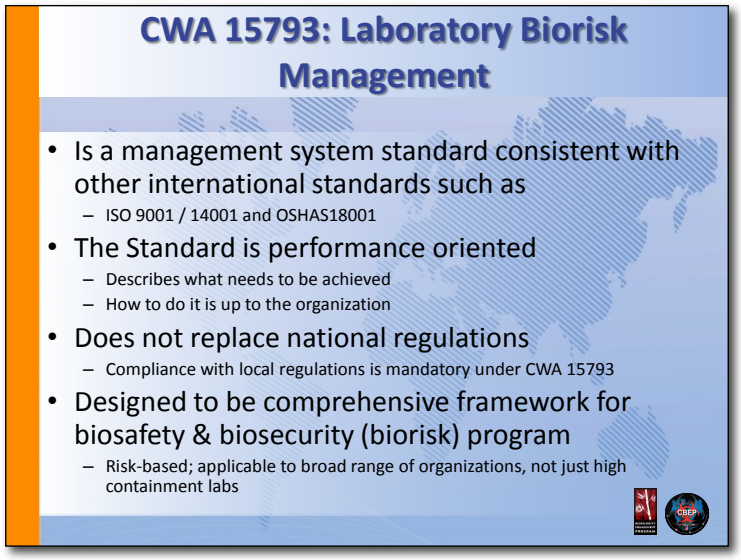
Take a Break (10 minutes)

Time Check

You should be approximately 2 hours into the course. You have 2 hours of course remaining. Management systems are next.

Orientation to Biorisk Management

Slide 18



Lecture (5 slides, 15 minutes)

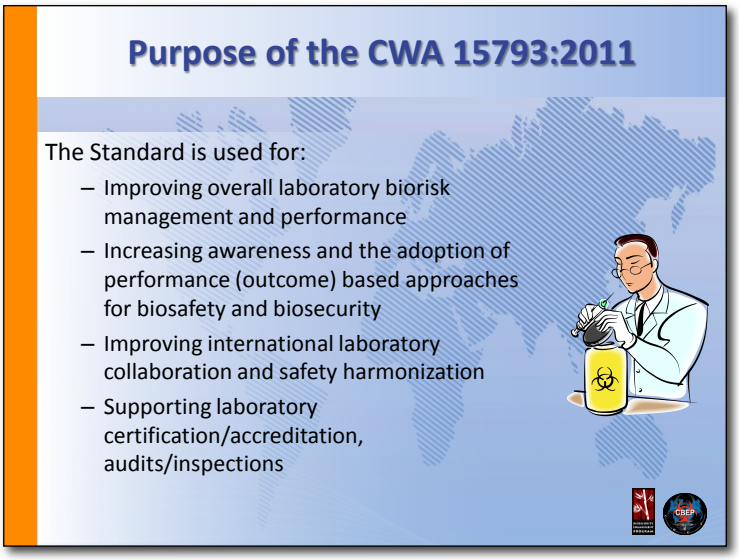
These five slides are used to introduce and describe what the CWA is, its purpose, and how it can be used. Instructor should take about 10 – 15 minutes to go through these slides.

Orientation to Biorisk Management

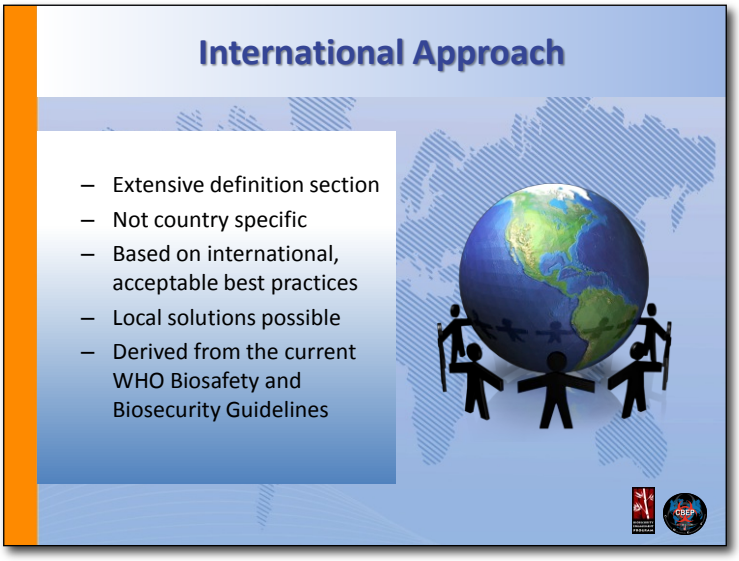
Background Information for Instructor:

- The Laboratory Biorisk Management standard was developed through a joint action between EBSA, the American Biosafety Association (ABSA) and Det Norske Veritas (DNV) with funding from the EC. The CEN Workshop process was used to develop a CEN Workshop Agreement (CWA). Seventy two participants from 24 countries ensured a truly international input.
- The scope is to set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.
- The standard will enable organizations to:
    - Establish and maintain a biorisk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment, which could be directly or indirectly exposed to biological agents or toxins.
    - Provide assurance that the requirements are in place and implemented effectively.
    - Seek and achieve certification or verification of the biorisk management system by an independent third party.
    - Provide a framework that can be used as the basis for training and raising awareness of laboratory biosafety and laboratory biosecurity guidelines and best practices within the scientific community.
- The standard is performance-based and sets out requirements for and places responsibility on organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented. The standard is suited for certification of laboratories but there not yet a formal procedure for certification developed.
- The Laboratory Biorisk Management standard CWA 15793 is freely available on the CEN web site: **ftp://ftp.cenorm.be/PUBLIC/CWAs/wokrshop31/CWA15793.pdf**
- The free download of this CWA has been made possible through funding provided by the Government of Canada's Global Partnership Program.

Slide 19



Slide 20



Slide 21

CWA 15793:2011 Examples of Topics Covered:

- Biorisk Management Policy
- Hazard identification, risk assessment and risk control
- Roles, responsibilities and authorities
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review

Slide 22

Example: Waste Management

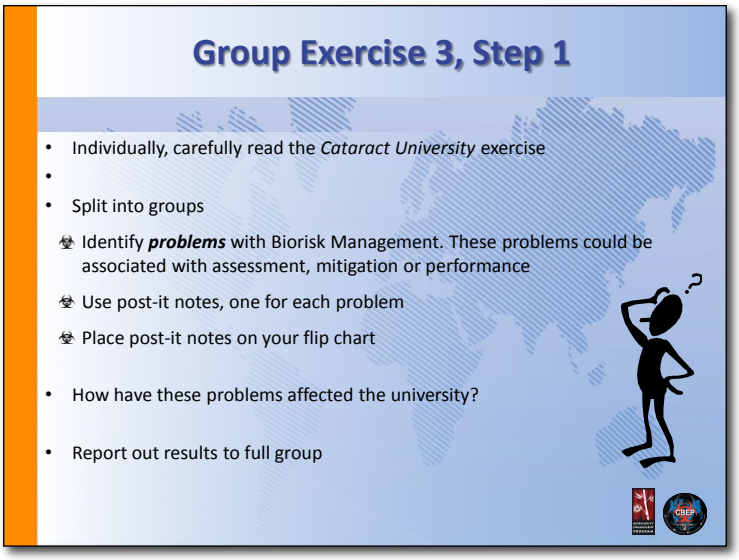
4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- The standard is not a technical document
- Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives
  - **Provides Biorisk management framework for the day-to-day functions of the institute / organization during both normal operations and times of emergency**

Orientation to Biorisk Management

Slide 23



Small group activity (30 minutes).

Activity Instructions (to students)

1. Read the Cataract University scenario.
2. Record problems you find in the scenario on your sticky-notes.
3. Arrange your findings on your flip chart of on the wall near your table.
4. After 20 minutes you will report the problems you found to the class.

You have 30 minutes to complete this activity

Directions for Instructor:

- Hand out the Cataract University scenario.
- Groups should read the scenario and write down problems, one per sticky note as they find them.
- Have them arrange their problems on their flip chart or wall near their table (20 minutes).
- After they have found several problems, have them report to the rest of the class and ask them to surmise how these problems may have affected the university. (Approximately 10 minutes)

Expected Responses

- Bad record keeping at both Cataract and Acme Labs
- Staff unaware that Alcohol doesn't kill Anthrax spores
- Poor incident reporting
- Poor absence program at Acme
- Poor SOPs
- Improper waste disposal
- Unauthorized access to the lab
- Missing samples

New Responses from Students:

Background Information for Instructor

This is the scenario that will be handed out to students:

Cataract University Scenario:

Amil works in a Biosafety Level 2 research lab at Cataract University studying anthrax vaccines. He recently visited the emergency room with a serious skin infection on his neck. Doctors determined this infection was caused by *Bacillus anthracis*, and started treating him with antibiotics. He is expected to make a full recovery.

Amil was surprised to learn of this diagnosis because he only works in the lab with the Sterne strain of *Bacillus anthracis*, a non-lethal strain used to vaccinate animals. Although the high containment lab in the adjacent building works with the fully virulent strain, Amil never enters there.

Upon learning of the infection through the news, the lab director asked for a study to be done to determine what went wrong and whether or not Amil contracted the agent in the lab. Amil reported that he had been working with Barbara two weeks prior to grow up cultures of the non-lethal, live vaccine strain. Barbara was working in the Biological Safety Cabinet (BSC) to prevent contamination. After transferring a small amount of broth culture to a micro-centrifuge tube, Barbara sealed the tube and wiped it down with alcohol before transferring the tube to Amil, who placed the tubes in a labeled container and walked them down the hallway to put them in a common use refrigerator. Amil was not wearing gloves during the process as he explained “I was not directly handling the agent and Barbara was wiping them down with alcohol so I did not think there was anything to worry about.” Neither researcher was aware of the fact that alcohol would have little effect on Bacillus spores.

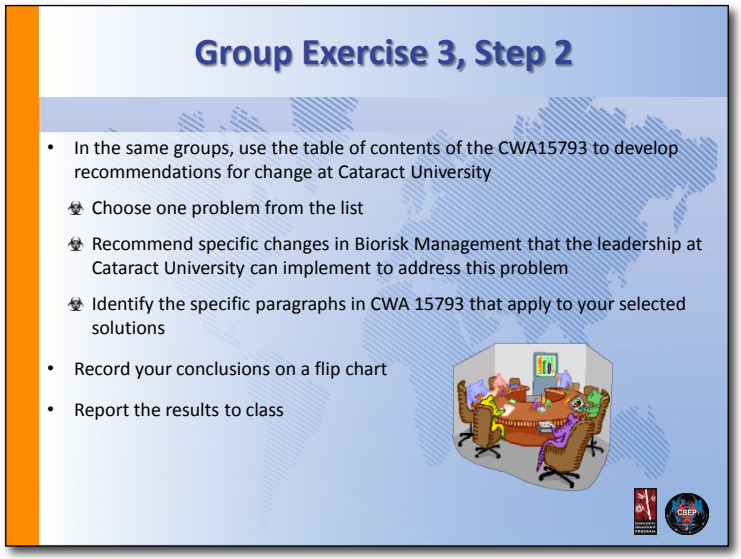
Orientation to Biorisk Management

Background Information for Instructor

Cataract University Scenario Continued:

The lab director suggested that the cultures in the lab be tested to determine whether or not the strains were indeed the vaccine version or the fully virulent strain. However, the samples turned up missing after a search of the common refrigerator where they had been stored. No one is sure what happened to them. The custodian cleaned out the refrigerator the week before and may have inadvertently tossed them in the trash be he does not remember. Fortunately, Barbara saved some of the stock solution and upon testing was surprised to find that it was the fully virulent strain of *B. antracis* and matched the strain that was cultured from Amil's lesion. Barbara had ordered the vaccine strain from Acme Labs several months ago. When questioned about the possibility o sending the wrong strain to Cataract University, a manager at Acme lab reported that it is very unlikely because they only shipped the virulent strains to labs that are registered with Acme and Cataract was not registered. However, the manager did concede that their shipping supervisor happened to be on vacation when the shipment was sent to Cataract so some of the records were not kept during that period.

Slide 24



Orientation to Biorisk Management

Small group activity (15 minutes).

Activity Instructions (to students)

1. Choose one problem from the list
2. Recommend specific changes in Biorisk Management that the leadership at Cataract University can implement to address this problem
3. Identify the specific paragraphs in CWA 15793 that apply to your selected solutions.
4. Record your conclusions on your flip chart.
5. Report the results to class.

You have 15 minutes to complete this activity

Directions for Instructor:

- This exercise is designed to get the groups to open up and begin to see the value of the CWA.
- Each group should work on a different problem.
- Allow 10 minutes for each group to:
  - Discuss solutions and specific changes in biorisk management practices that they would recommend.
  - Use the table of contents and identify the specific paragraph(s) (sections) of the CWA that apply.
- **Spend 5 minutes discussing the results in plenary discussion**

Expected Responses

- Responses should follow with the CWA recommendations for the problem the students identify and follow up on.

New Responses from Students:

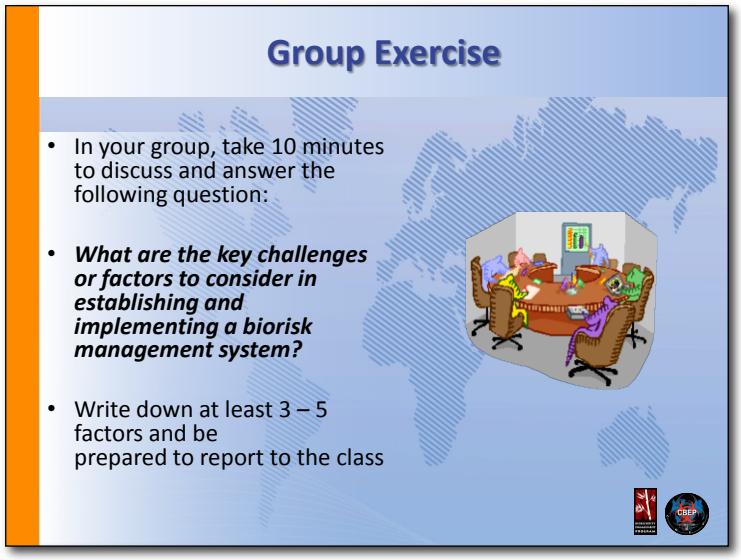
Slide 25

Take a Break (10 minutes)

Time Check

You should be approximately 3 hours into the course. You have 1 hour of course remaining. This is the last break before the end of the class.

Slide 26



Small group activity (15 minutes).

Activity Instructions (to students)

1. In your group, take 10 minutes to discuss and answer the following question:
    a. What are the key challenges or factors to consider in establishing and implementing a biorisk management system?
2. Write down at least 3-5 factors and be prepared to report to the class.

Small group activity (15 minutes).

You have 15 minutes to complete this activity

Directions for Instructor:

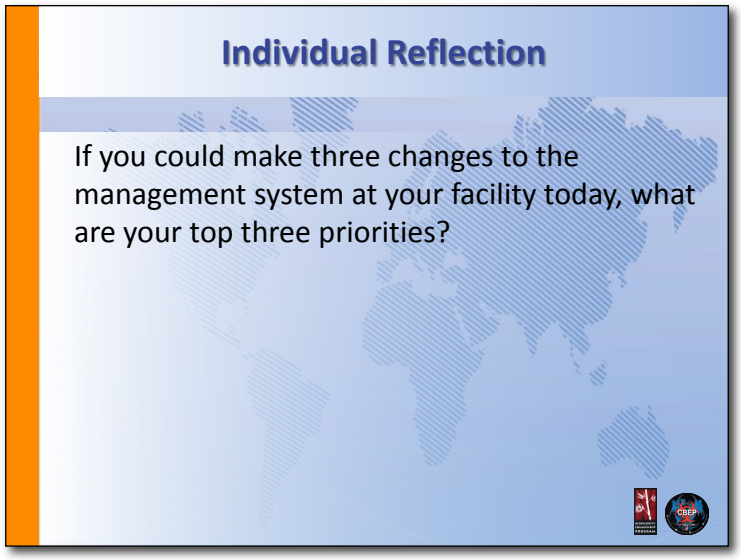
- Allow each group to discuss their answers (3 to 5 factors) to the following question and write them down in their workbooks or on their group's flipchart.
    - What are the key challenges or factors to consider in establishing and implementing a biorisk management system?
- Capture all the unique challenges/factors on a flip chart.

Expected Responses

- Commitment from top management
- Buy in from those who will implement the system
- Must be able to show results and improvement
- Financial considerations
- Overcoming old habits
- Resistance to change
- Continual improvement (never satisfied with the status quo)
- Having a clearly defined path or system
- Training and communication
- Making sure everyone understands the direction we want to go

New Responses from Students:

Slide 27



Ask students to REFLECT individually on the following question/statement (5 minutes):

If you could make three changes to the management system at your facility today, what are your top three priorities?

Ask if there is anyone who would be willing to share one or two with the rest of the class.

Transition to Review

Review

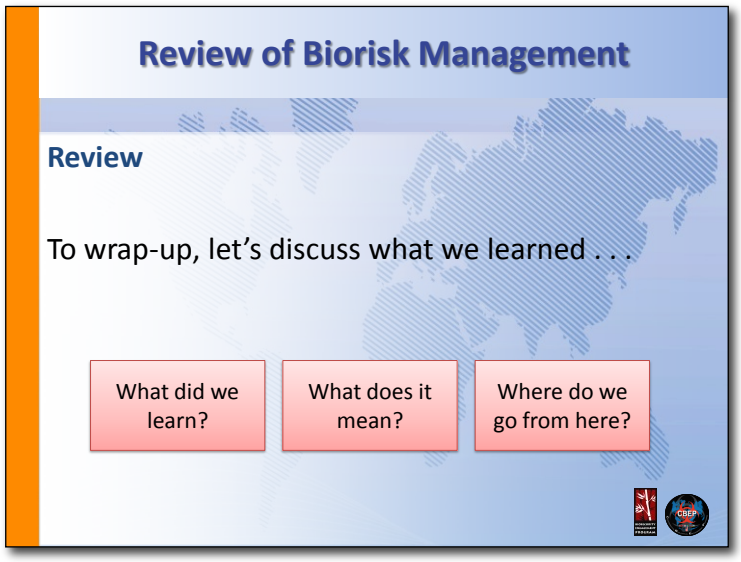
Goal

The purpose and goal of this module is to recap the key messages of the course and to conduct a “What? So What? Now What?” review of the course and key messages.

Time

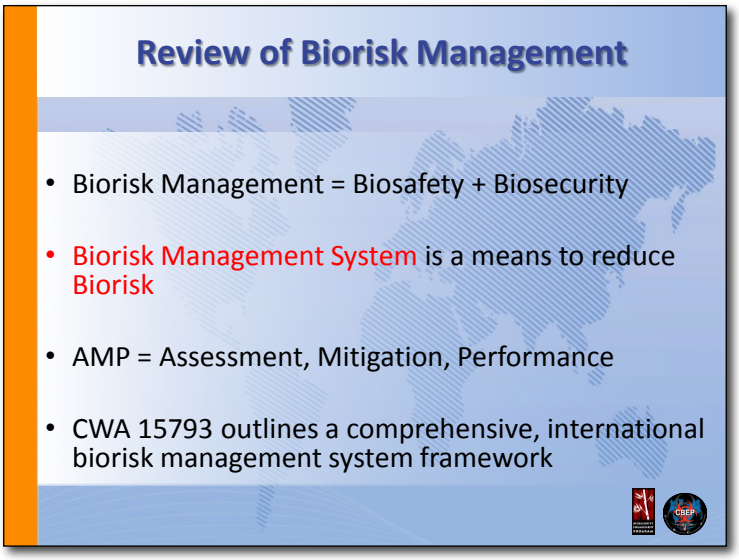
Allow 20 minutes to get through the Review section.

Slide 28



Review

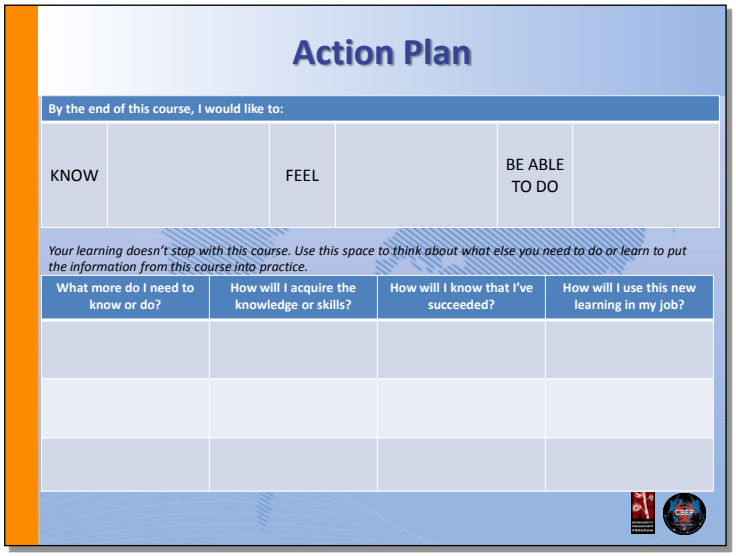
Slide 29



Review Key Messages

Include discussion on how activities/examples relate to the Key Messages of the course and how the messages can be applied.

Slide 30



Review

Ask students to spend a few minutes reviewing and completing their action plan.

Slide 31

Level 1 Evaluation

- Ask students to complete the course evaluation and to put it in the evaluation box (alternately, give students instructions for completing the evaluation on-line).