SAND2012-2659P

Developing, Conducting, and Maintaining a Hazard Inventory

Instructor Guide

Sandia National Laboratories
International
BIOLOGICAL THREAT REDUCTION

CBEP

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

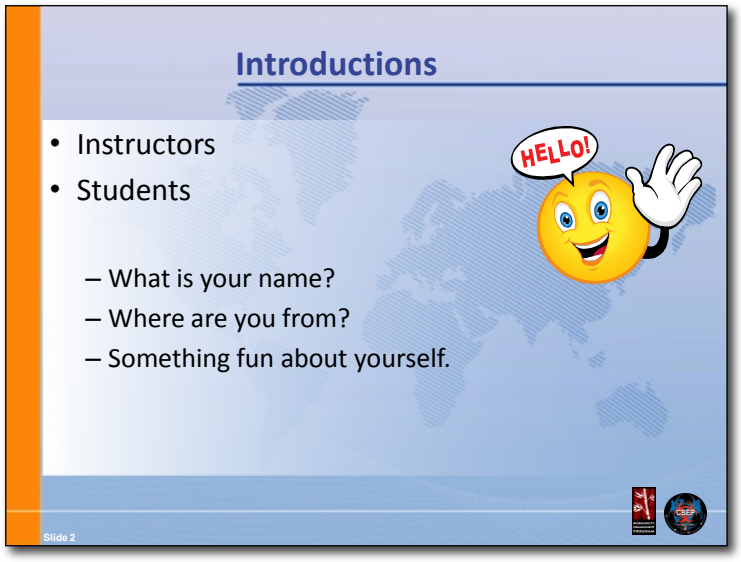
Relevancy of the Course to your experience

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

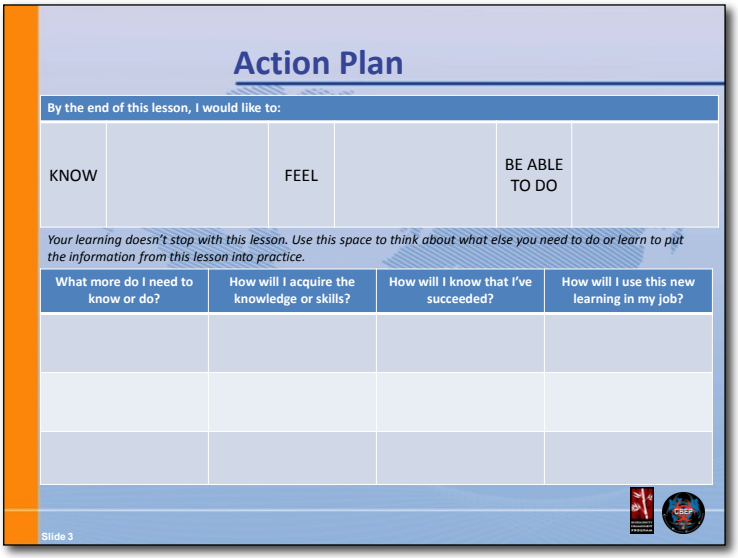
Welcome & Introductions

Key Messages for Instructor

1. Biological hazards are agents or toxins (including sources) that have a potential for causing harm to laboratory staff or the surrounding community
2. Biological hazards can be grouped according to risk group schemes, but these are only general guides to assist in risk assessment
3. Hazard identification is a critical component of risk assessment
4. Biological hazard identification and inventory are important aspects of a laboratory's risk-based material control and accountability (MC&A) system
5. The PCDA management cycle is a way that an inventory control system can be planned, implemented, checked, and improved.
6. Managerial leadership is a cornerstone of an effective hazard inventory system that communicates the need for continual hazard identification and inventory maintenance.
7. There are unique roles and responsibilities when working with the hazard inventory.
8. Based on risk, the inventory system should capture enough information about each hazard to effectively track the hazard. In addition, the system should be reviewed regularly and allow for continual improvement.
9. A hazard inventory can be a useful tool to investigate laboratory incidents, whether or not they result in actual harm or damage
10. Hazard inventory information should be protected according to risk

Welcome & Introductions

Slide 3

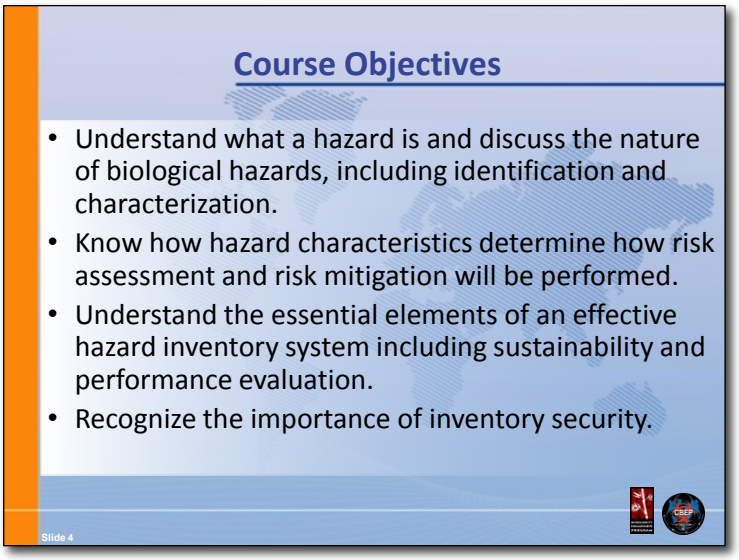


Instructions for the Action Plan handout:

- 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

Welcome & Introductions

Slide 4



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

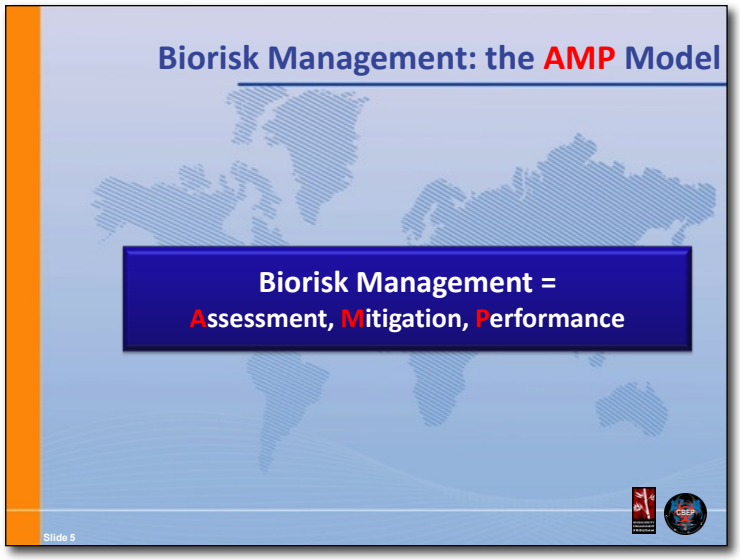
Capture any learning goals that will supplement course objectives and address any that are outside the scope of the course.

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.

Transition to Biorisk Management Touchstone

Biorisk Management

Slide 5

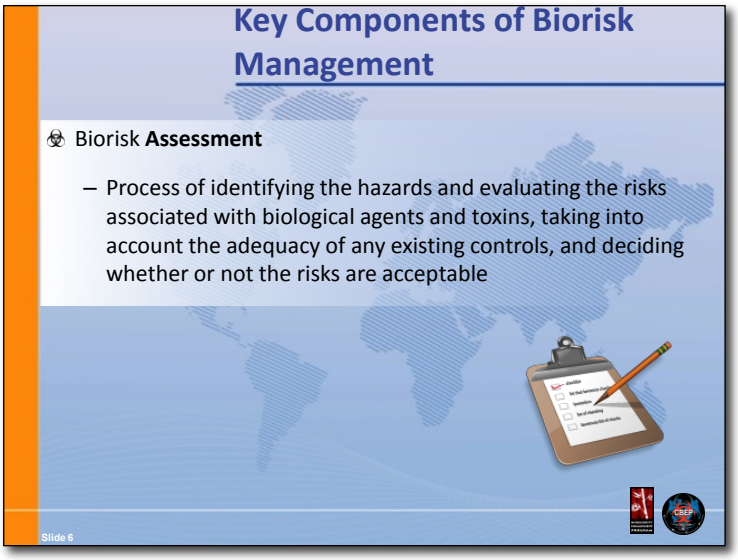


Background Information for Instructor

- Review the AMP model of Biorisk Management with the participants.
- The following three slides provide specific definitions for A, M, and P.
- Integration of laboratory biosafety (protect people from pathogens) and laboratory biosecurity (protect pathogens from people)

Biorisk Management

Slide 6



Background Information for Instructor

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

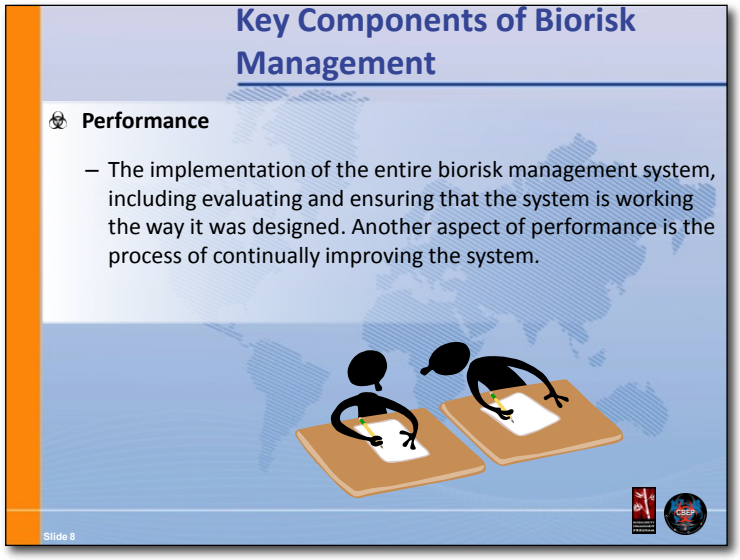
Slide 7

Biorisk Management

Background Information for Instructor

The instructor uses this slide and following slide (Performance) to define key components of biorisk management

Slide 8

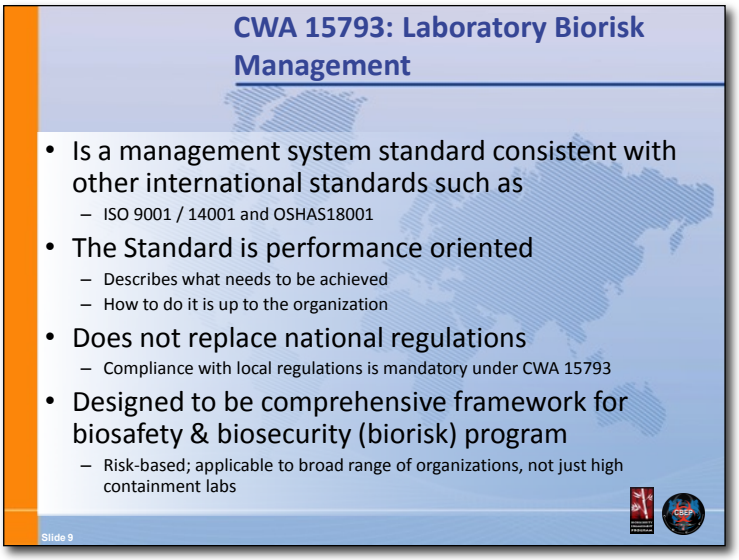


Lecture

Taken together, the three elements of AMP constitute a complete biorisk management system. The elements of the AMP model also underpin CWA 15793:2011 – Laboratory Biorisk Management Standard

Biorisk Management

Slide 9



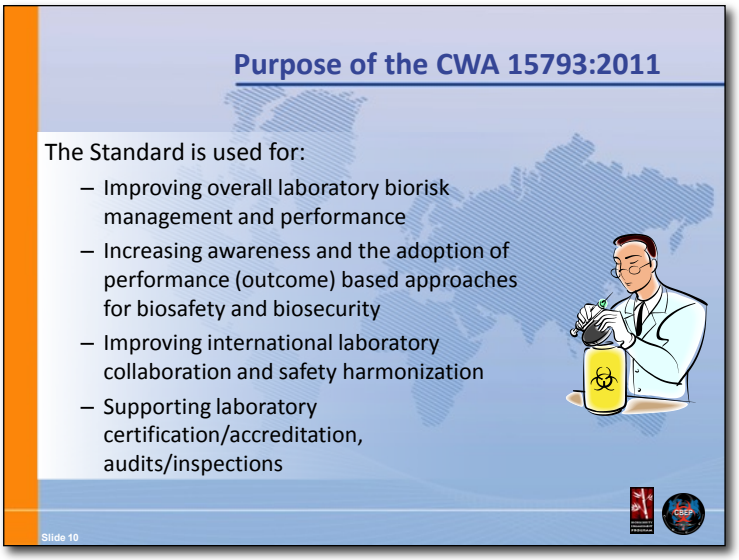
Biorisk Management

Background Information for Instructor:

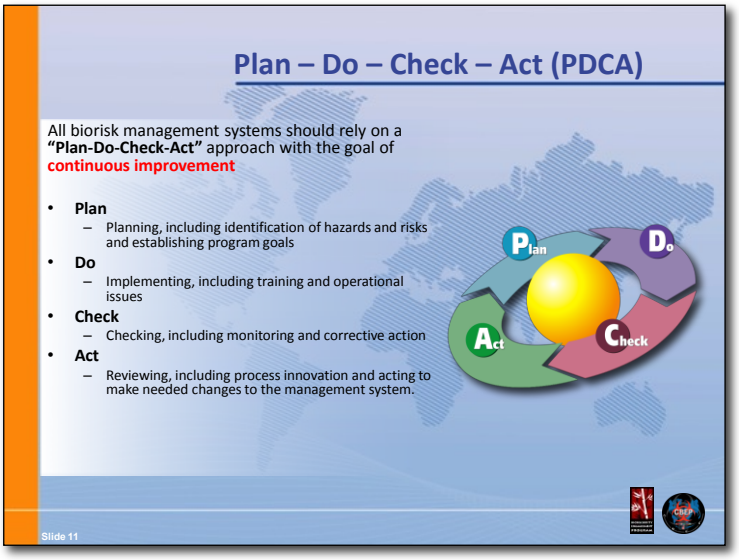
- The Laboratory Biorisk Management standard was developed through a joint action between EBSA, the American Biosafety Association (ABSA) and Det Norske Veritas (DNV) with funding from the EC. The CEN Workshop process was used to develop a CEN Workshop Agreement (CWA). Seventy-two participants from 24 countries ensured a truly international input.
- The scope was 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.

Biorisk Management

Slide 10



Slide 11



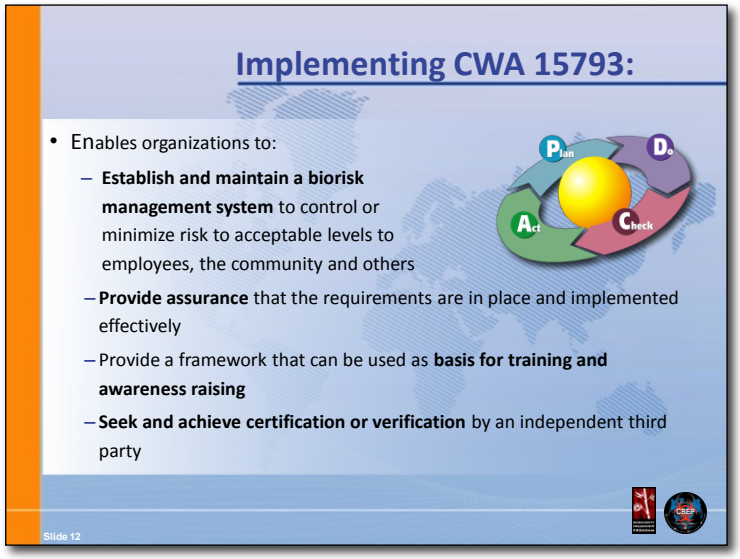
Biorisk Management

Background Information for Instructor

The CWA applies a common management system approach, called PDCA or Plan Do Check Act, to biorisk management.

A key objective of the CWA, and any PDCA-based management system, is to strive for continual improvement through a cycle of planning, implementing, checking, review and evaluation. Importantly, the process of reviewing and evaluation should lead into a new PDCA cycle. This cyclical process gives rise to continual management system improvement.

Slide 12



Biorisk Management

Lecture

- Using a PDCA approach to biorisk management as outlined in the CWA, organizations can accomplish a number of important objectives.
- The CWA provides important guidance on establishing an effective biorisk management system to control biorisks facing laboratory workers, the surrounding community outside the laboratory, and even people beyond the immediate vicinity of the laboratory.
- Because a PDCA-based biorisk management system has policies and procedures in place to check and evaluate performance, laboratory leaders have greater assurance that the biorisk management system is accomplishing its goals and objectives.
- The CWA also provides a useful framework for designing training for employees, by organizing individual elements of the biorisk management system (such as specific mitigation measures) into a holistic framework.
- Ultimately, it is hoped that the CWA will provide the basis for a universal system of laboratory biorisk management system certification or accreditation, that will provide independent third-party verification of laboratory conformance with the standard (or biorisk management standards like it)

Slide 13

Take a Break (10-15 minutes)

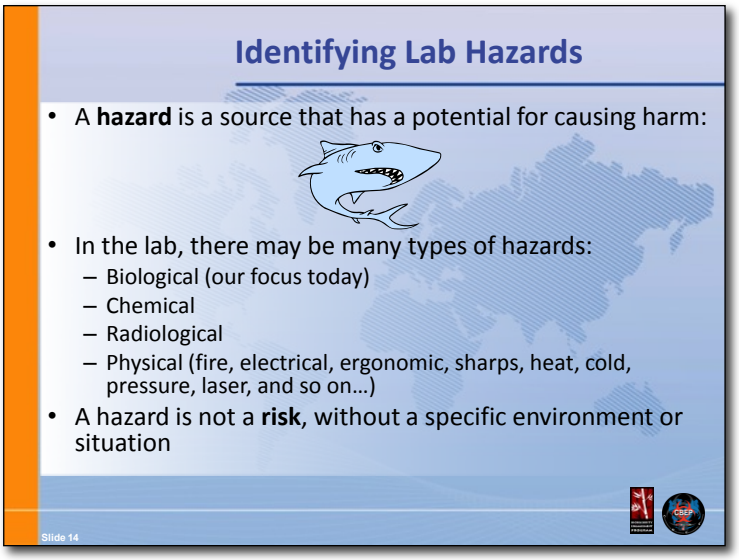
Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.

Transition to Biological Hazards

Identifying Lab Hazards

Slide 14



Background Information for Instructor

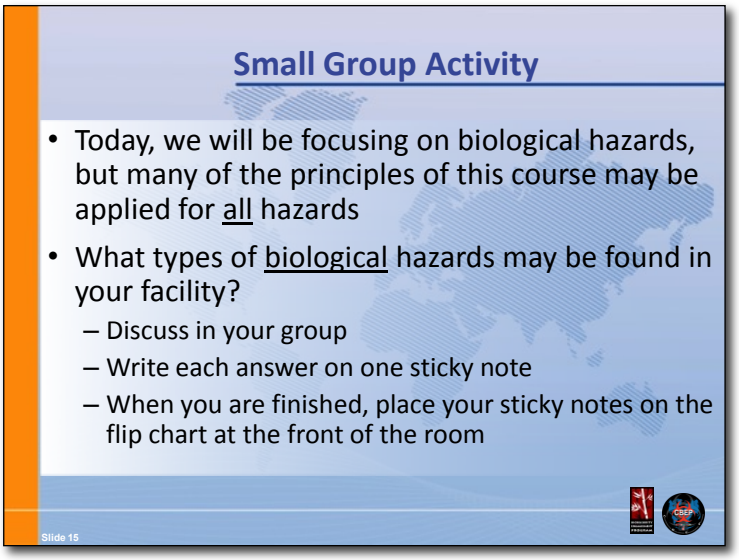
Note: This should still be a review for the students. (2 minutes)

Key points:

- Define what a hazard is
- Note that there are many types of hazards in the laboratory
- For this course, the focus will be on biological hazards (biological agents and toxins that have a potential for causing harm in some way), but many of the principles discussed during the course may be applied to other hazards as well.
- Remind students that a hazard in and of itself does not constitute a risk, in the absence of a specific environment or situation where the risk can be evaluate. A shark in the water with you may be a higher risk to your health than a shark in the ocean 100 km away, for example.

Identifying Lab Hazards

Slide 15



Identifying Lab Hazards

Small group activity (15 minutes).

Activity Instructions (to students)

1. In your groups, discuss this question: What types of biological hazards may be found in your laboratory facility?
2. Take about 10 minutes to discuss your answers.
3. Write EACH ANSWER on a SEPARATE sticky note.
4. When you are finished, place each sticky note on the flip chart at the front of the room.

You have 15 minutes to complete this activity

Directions for Instructor:

- Make sure each table has a different color sticky pad for this exercise.
- Remind students that we will be focusing on biological hazard identification and inventory today, but many of the principles of this course may be applied for all hazards
- Allow about 15 minutes total for this exercise. Circulate among the groups and answer questions. Try to make sure that the group discussions are proceeding down the right track.
- After the groups finish, note the distribution of sticky note colors.
- Read the answers provided to the group, noting overlaps (reinforcement).
- Time allowing, following the activity, identify any additional types of potential biological hazards that the students did not identify. After completing the exercise, remove the flip chart page with the sticky notes and place (or hang) in a visible location for future reference.

Identifying Lab Hazards

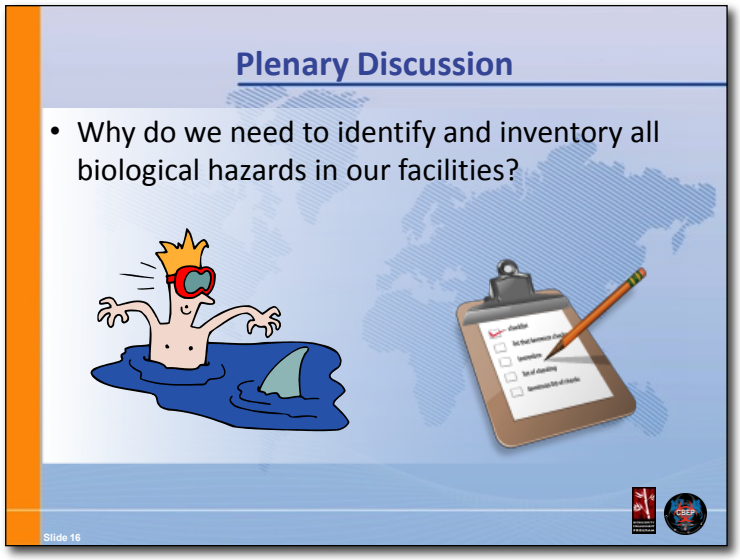
Expected Responses

- Cultures of pathogenic organisms
- Reference strains
- Cell culture lines
- Epidemiological isolates
- Vaccine strains
- GMOs
- Samples
- Clinical samples
- Veterinary samples
- Toxins
- Infectious waste
- Animals, vectors
- Contaminated equipment and/or consumables, including PPE
- Genetic elements (DNA, RNA)
- Proteins

New Responses from Students:

Identifying Lab Hazards

Slide 16



Plenary Discussion (10 minutes).

Question to consider:

Why do we need to identify all the biological hazards in our laboratories?

Directions for Instructor:

Provide example from Expected Responses list below to initiate discussion, if necessary. Record any answers not captured in the anticipated answers for future use

Capture on a flip chart:

- Capture unique answers on the flip chart set in the front of the room.
- After soliciting responses, move to the next slide.

Identifying Lab Hazards

Expected Responses

- Protect workers, visitors
- Know how to reduce/eliminate hazards
- Determine which materials should be subject to stricter controls and accountability measures
- Help determine who should be allowed to use/handle/access these materials, and how
- Help determine who should be responsible for these materials
- Help determine what additional staff training is required
- Financial reasons
- Efficiency improvements, GLP
- Liability reasons
- First step in determining biological risks (and therefore developing a biorisk management program)

New Responses from Students

Identifying Lab Hazards

Slide 17

Background Information for Instructor

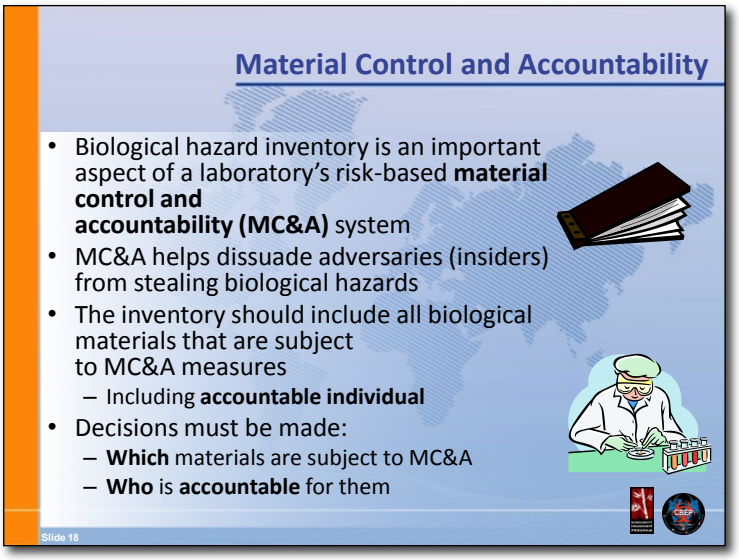
Instructor should summarize exercise. (2 minutes)

Exercise summary and key points:

- **What**: There are many reasons for performing systematic hazard identification; hazard identification is necessary in order to perform a proper assessment of the risk posed by the biological hazards in the laboratory.
- **So What**: As we know from the AMP model, risk assessment forms the foundation for effective biorisk management systems
- **Now What**: We need processes to identify and categorize biological hazards!

Identifying Lab Hazards

Slide 18



Identifying Lab Hazards

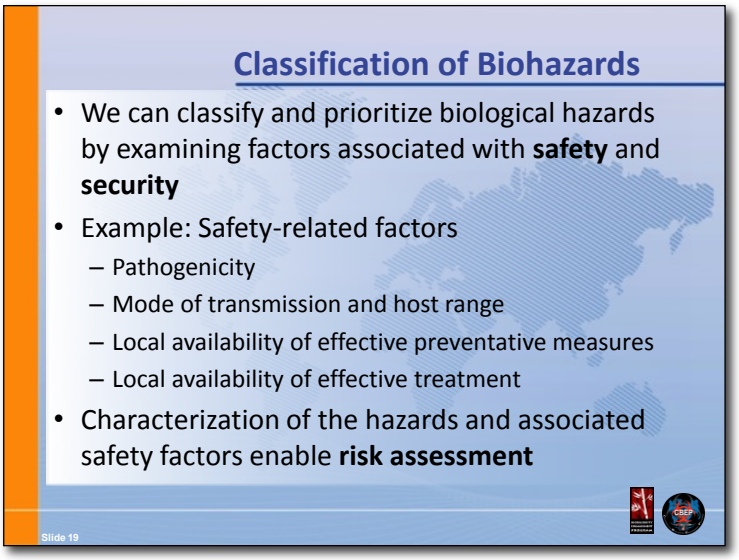
Lecture

Key Points:

- In addition to its central role in risk assessment, the hazard identification and hazard inventory process is an essential aspect of laboratory biosecurity, because it helps you keep track of exactly what hazardous biological materials are present at the facility, how and where the materials are stored and handled, and WHO is responsible for it.
- This is all important information from a material control and accountability (MC&A) perspective
- The objective of MC&A measures is to dissuade adversaries (especially insiders) from stealing or misusing the hazardous biological materials at your facility.
- Control – ensures that material is confined to known, legitimate use
- Accountability – ensures oversight by formally associating materials with people and information records
- The hazard inventory is an important tool for accountable individuals (those responsible for biological hazards) in your laboratory to ensure complete accountability for hazardous biological materials.
- The hazard inventory can be used to track relevant categories of information for accountable hazardous materials. We will discuss what those categories of information are later on in the course.
- Of course, as we just discussed, there are many types of hazardous materials potentially present in the laboratory. Deciding which of these materials is subject to MC&A, including hazard inventory procedures, is an important consideration in establishing an MC&A system, and will depend on the nature of your lab's work and the risk.

Identifying Lab Hazards

Slide 19



Identifying Lab Hazards

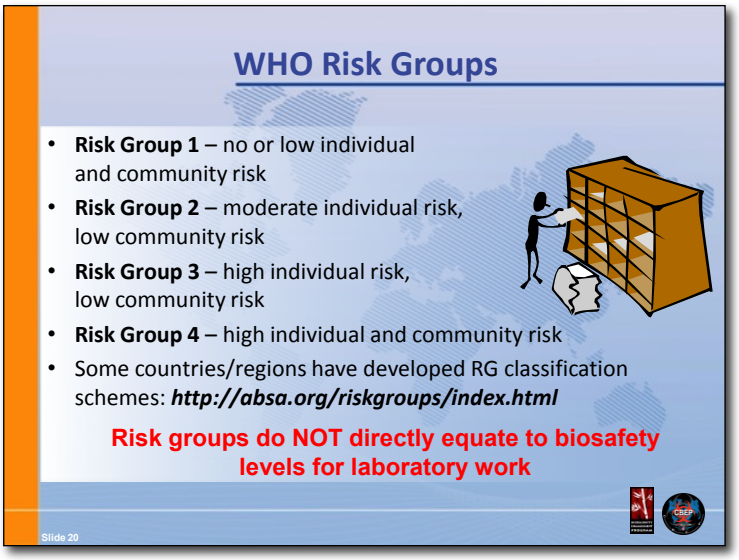
Lecture (4 slides, 10 minutes)

Key Points:

- Now that we know why hazard identification is important, let's talk about how to classify them.
- We can categorize biological hazards according to their characteristics.
- Certain characteristics are commonly associated with biosafety, others are associated with biosecurity, and some impact on both biosafety and biosecurity.
- On this slide, for example, are noted several hazard characteristics commonly associated with assessing biosafety risks, such as pathogenicity, mode of transmission and host range, and the local availability of preventative measures and/or effective treatments:
- By examining these factors for each hazard, we can create categories of hazards that are useful for biosafety and biosecurity risk assessments. It is important to remember, though, that risk assessment includes an examination of a number of risk factors, not just those factors associated with the hazards. These issues are covered in greater detail in courses devoted to risk assessment.

Identifying Lab Hazards

Slide 20



Identifying Lab Hazards

Lecture

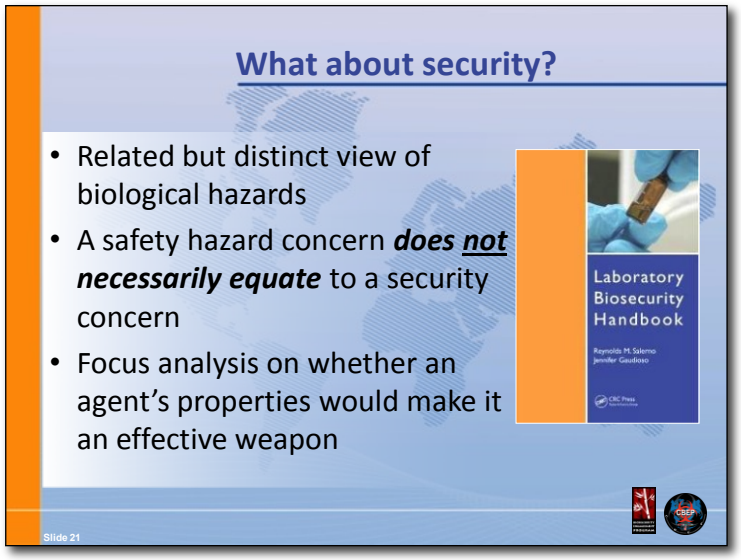
Key Points:

- The WHO has developed guidelines on biosafety "risk groups."
    - RG1 – a microorganism that is unlikely to cause human or animal disease
    - RG2 – A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection but effective treatment and preventative measures are available and the risk of spread of infection is limited
    - RG3 – A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventative measures are available.
    - RG4 – A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventative measures are not usually available.
- The WHO recommends that countries develop national classification of microorganisms by risk group.
- Risk groups DO NOT EQUATE TO BIOSAFETY LEVELS – BSL depends on risk assessment. RGs serve as a useful guide.
- Also note CWA guidance:

CWA: "Where hazardous materials are classified into hazard or risk groups based on international and/or foreign country classification schemes local diverging need and constraints should be considered."

Identifying Lab Hazards

Slide 21



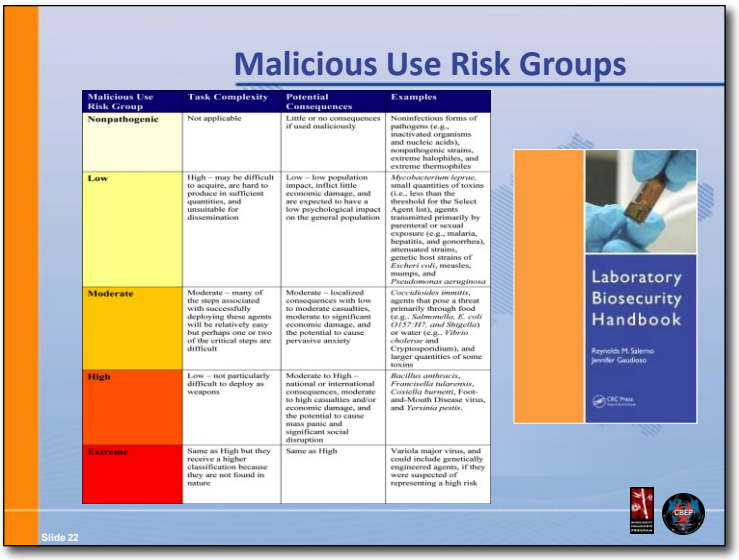
Lecture

Key points:

- We can also characterize biological hazards based on biosecurity-related characteristics.
- This method of hazard characterization is closely related to hazard characterization based on biosafety, but there are differences as well. A biological hazard that may pose a serious biosafety concern in the laboratory may not pose an equivalent biosecurity concern.
- In general, hazard characterization based on biosecurity-related characteristics is focused on analyzing those agent properties, which could make it an effective weapon in the hands of a malicious person or group.
- Examples of factors biosecurity-related (from Lab Biosecurity handbook)
    - Ease of production
    - Modes of dissemination
    - Environmental stability

Identifying Lab Hazards

Slide 22



Lecture

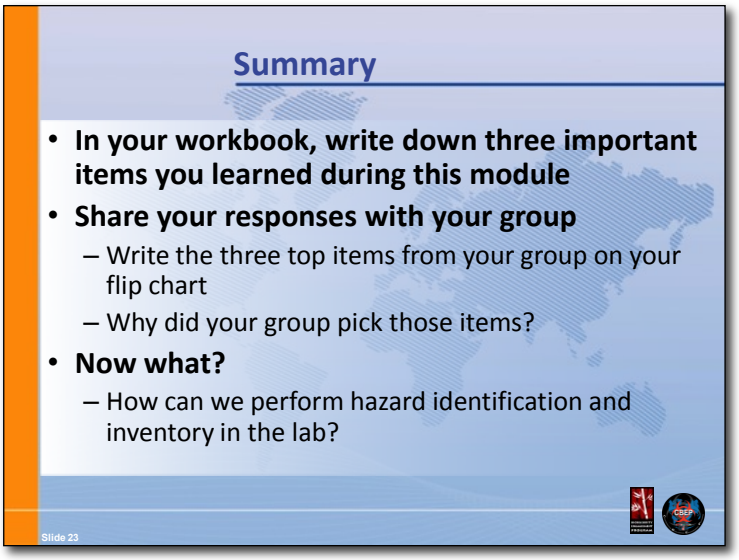
Key points:

- Risk groups related to biosecurity can be created as well.

For example, SNL developed a “malicious use” risk group classification system for biological hazards, ranging from “nonpathogenic” to “extreme.” These RGs can be used to assist in performing a biosecurity risk assessment. These risk groups were published in the *Laboratory Biosecurity Handbook*.

Identifying Lab Hazards

Slide 23



Ask students to REFLECT individually on the following question/statement (20 minutes):

Take 5 minutes and write down three important items you learned during this module in your workbook (WHAT?)

Take 10 minutes and share your thoughts with your group. See if you can agree upon the top three most important items, and be prepared to explain why you picked those three items.

Notes to instructor:

- After 10 minutes, begin with one group and solicit their three top items. Make sure that they provide an explanation for each item. Move from group to group in a plenary discussion.
- It is anticipated that the different groups will identify more than 3 items.
- Note that there are no "right" or "wrong" answers. The important thing is that the items selected are well justified. This discussion should take about 5 minutes.

Identifying Lab Hazards

Expected Responses

- There are many different types of biological hazards that may be found in the laboratory
- A hazard is not a risk, without a specific environment or situation
- If we know what hazards we have, we can properly assess risk
- Hazards can be classified into biosafety and biosecurity risk groups
- Risk groups are guides, they do not equate to biosafety levels
- Risk groups can help facilitate risk assessments
- Biosafety and biosecurity risk groups are based on related, but not identical, hazard characteristics

New Responses from Students:

Identifying Lab Hazards

Slide 24

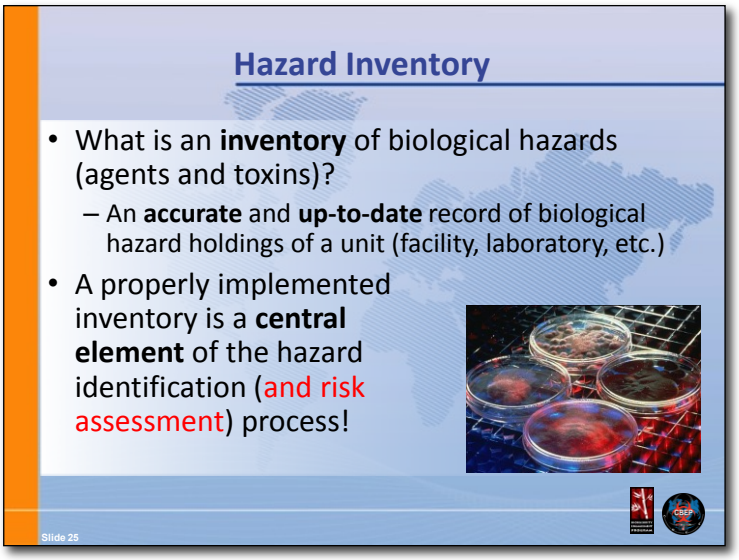
Take a Break (10-15 minutes)

Time Check

You should be approximately __ hour and __ minutes into the course.
You have 3 hours of the course remaining.

Hazard Inventory

Slide 25



Lecture

Key points:

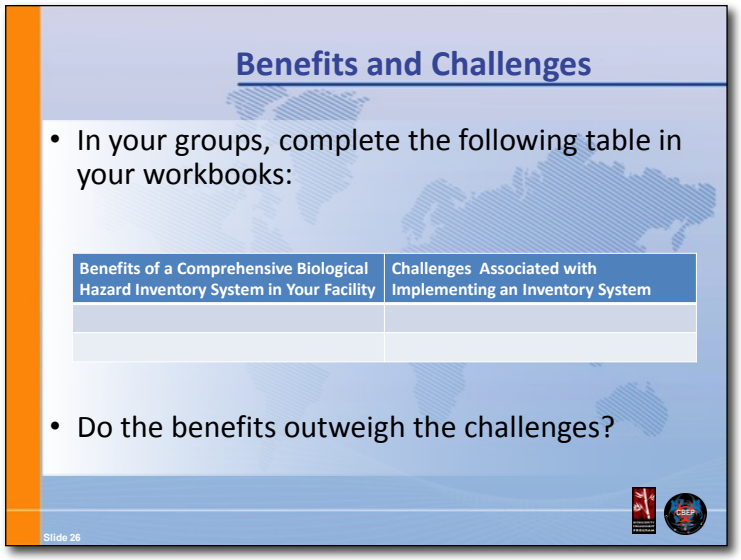
Our next course module will focus on building a hazard inventory.

What do we mean when we talk about a biological hazard inventory?

- A biological hazard inventory is an accurate and up-to-date record of biological hazard (biological agent and toxin) holdings of a unit, such as a facility, laboratory, or even an individual freezer.
- A biological hazard inventory is part of a larger inventory of facility holdings, but may contain different information based on the level of risk. Because biological hazards may pose greater risks to your lab staff or the surrounding community, you may wish to (or be required to) collect and track more detailed information about these holdings than other holdings in your facility, such as supplies.
- A properly implemented inventory is a central element of the hazard identification (and risk assessment) process!

Hazard Inventory

Slide 26



Small group activity (15 minutes).

Activity Instructions (to students)

1. Let's think about the benefits of building and maintaining a hazard inventory, versus the challenges associated with this type of undertaking.
2. Working with your group, complete the following table (not page #) in your workbooks.
3. You have 15 minutes to complete this exercise, and then we will discuss as a larger group.

You have 15 minutes to complete this activity

Directions for Instructor:

- Have the students work on the table in their workbooks.

Hazard Inventory

Expected Responses

Benefits (possible answers):

- Effective tracking of usage, transfer, shipment, disposal of biological agents and toxins
- Obtain detailed, current knowledge of facility assets, including (but not limited to) biological hazards
- Inform risk assessment
- Detect loss and/or diversion of materials (e.g., theft)
- Minimize overages and waste (avoid duplicative ordering, aging/expiring materials, etc.)
- Save time – avoid wasteful searching
- Conserve space (ID and properly dispose of obsolete materials)
- Conserve resources – improve budget outlook
- Contribute to overall laboratory quality management
- Enable implementing effective risk-based biosafety and biosecurity measures in each laboratory, based on the hazards actually present
- Enable restricting access to biological agents and toxins to authorized persons with a legitimate need

New Responses from Students:

Hazard Inventory

Expected Responses

Challenges (possible answers):

- Time (=money)
- Lack of information
- Assigning responsibility
- Checking accuracy
- Maintaining the system
- Consistent record-keeping
- Present in many locations within the lab*
- Freezers, incubators, working stocks, wastes, animals*
- Volumes and concentrations constantly increasing and decreasing*
- Accounting of pathogens difficult*

** From DTRA BSL-3 training module – Bioethics and Biosecurity*

New Responses from Students:

Hazard Inventory

Plenary Discussion (2 minutes).

Question(s) to consider:

1. Do the benefits outweigh the costs?
2. What? So What? Now What?

Directions for Instructor:

Instructor will lead a brief plenary discussion.

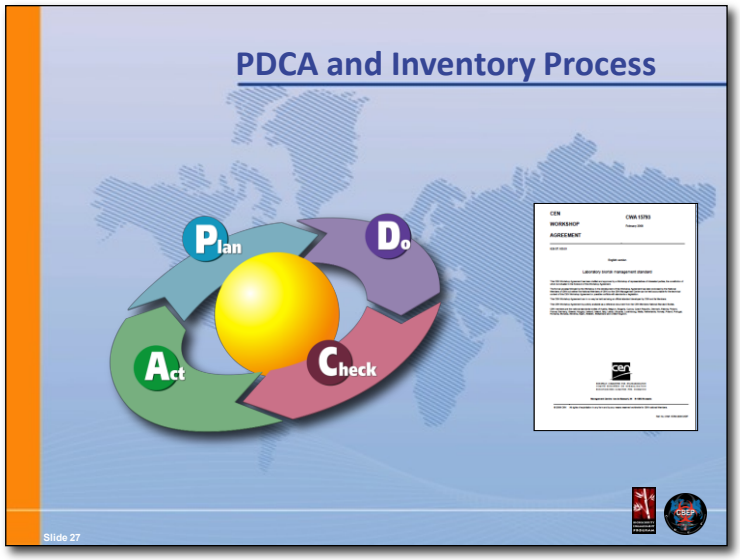
Expected Responses

- The benefits of robust hazard inventory outweigh the costs
- Management must communicate the need for a hazard inventory system that is well-maintained to staff
- Management must put forth the leadership effort to oversee the design of an effective hazard inventory and control system that makes sense for YOUR facility

New Responses from Students:

Hazard Inventory

Slide 27



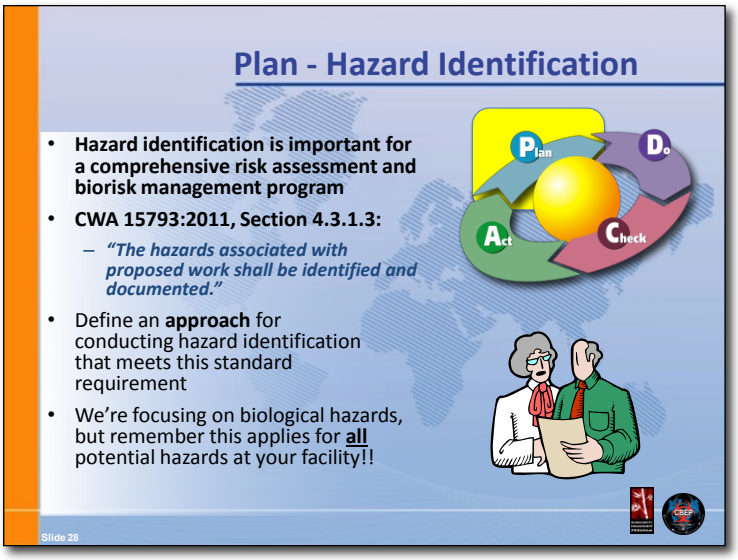
Lecture (2 slides, 5 minutes)

Key points:

- Like other systems, a hazard inventory control process can be designed, implemented, evaluated, and optimized using the PDCA process.
- During the next module of the course, we will use the PDCA framework as a basis for discussion of hazard inventory systems in the laboratory.

Hazard Inventory

Slide 28



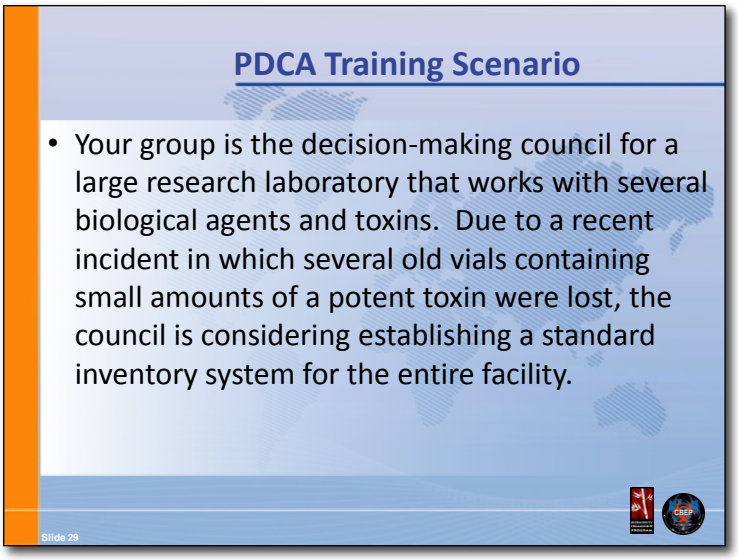
Lecture

Key points:

- The first step of the PDCA cycle is Planning.
- In order to plan a practical and effective hazard inventory system, we must have some sense of what the biological hazards are that we will be dealing with.
- Of course, we have the same initial requirement for performing an adequate risk assessment, so it makes sense to be thinking about hazard inventory from the outset.
- It is important to devise a systematic, reproducible, and reliable approach to hazard identification in the laboratory. This is imperative in order to compare data over time and measure process improvements (or degradation).

Hazard Inventory

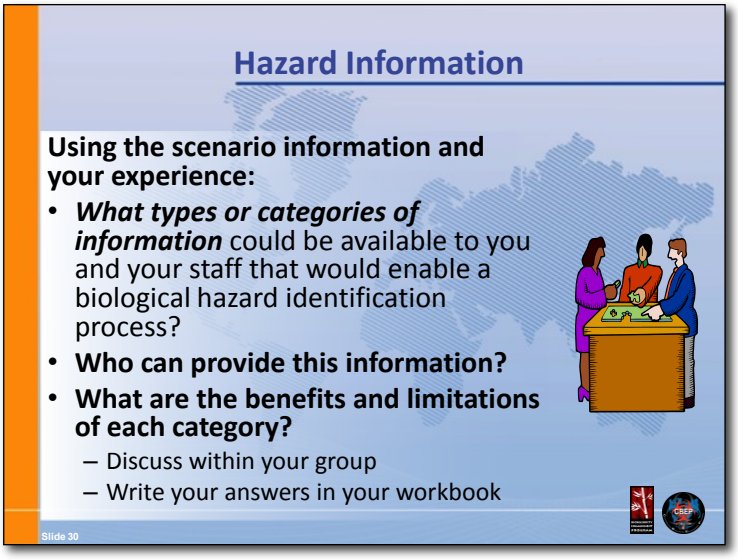
Slide 29



Background Information for Instructor

- Distribute scenario to the students.
- Display scenario on the screen.
- Explain that students will work in groups, using the scenario to complete a series of exercises designed to help them think through important hazard inventory issues.

Slide 30



Hazard Inventory

Small group activity (20 minutes).

Activity Instructions (to students)

1. We will now begin our scenario exercise.
2. In your groups, take 20 minutes to discuss the following questions:
    a. What types or categories of information could be available to you and your staff that would enable a biological hazard identification process? For example, one answer could be, "prior inventory lists."
    b. Think about who in your laboratory could provide this information. Identify their roles in the laboratory.
    c. Finally, not all sources of information will necessarily give you everything you need. Hazard identification involves putting together pieces of information from multiple sources to create the most comprehensive picture possible. Think about the benefits and limitations of the information types that you listed.
3. Write down your answers in your workbooks. We will discuss as a class after everyone is finished.

You have 20 minutes to complete this activity

Directions for Instructor:

- Re-create workbook columns on a flip chart(s) in the front of the classroom while the students are working on this small group activity.

Hazard Inventory

Plenary Discussion (10 minutes).

Directions for Instructor:

- Beginning with one group, ask for one type/category of information, along with who can provide it and its benefits/limitations.
- Ask the other groups,
    - Did they also come up with this category?
    - Did they list the same people as potential sources for this category?
    - Did they have the same benefits and limitations?
- After discussion, proceed to the next group and ask for another category of information, and associated answers.
- Time allowing; solicit at least one category from each group.
- Display the slide, which shows potential information sources based on CWA 15793. Note alignments, as well as other important information sources.

Capture on a flip chart:

- Re-create the workbook table columns while students are working on their workbook.

Expected Responses

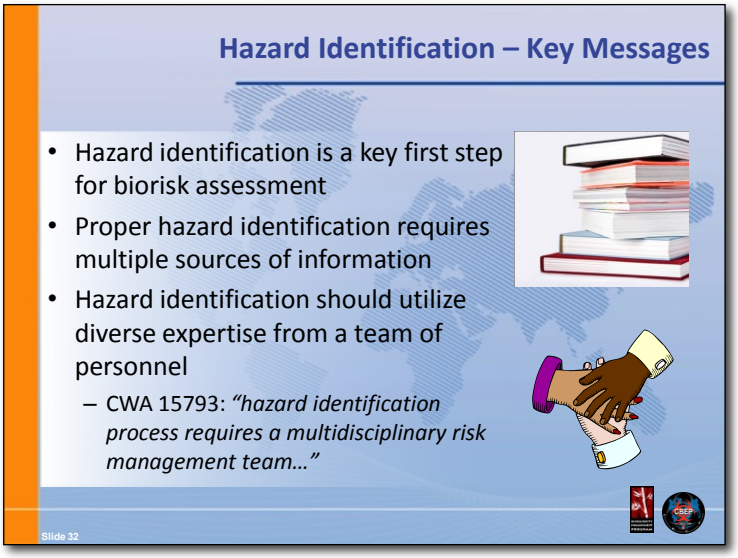
- The following slide lists the expected responses.

New Responses from Students:

Hazard Inventory

Slide 31

Slide 32



Hazard Inventory

Lecture (2 minutes)

Exercise Recap:

- **What**: Hazard identification requires that your team consult multiple sources of information.
- **So What**: In order to do this effectively, you will have to assemble a team of individuals with specific knowledge to fill those information gaps.
- **Now What**: Once you, as a laboratory leader, have considered this and have assembled a team, you are now in a much better position to assemble a comprehensive biological hazard inventory.

Slide 33

Take a Break (10-15 minutes)

Time Check

You should be approximately __ hours and __ minutes into the course.
You have __ hour, __ minutes of course remaining.

Hazard Inventory

Lecture

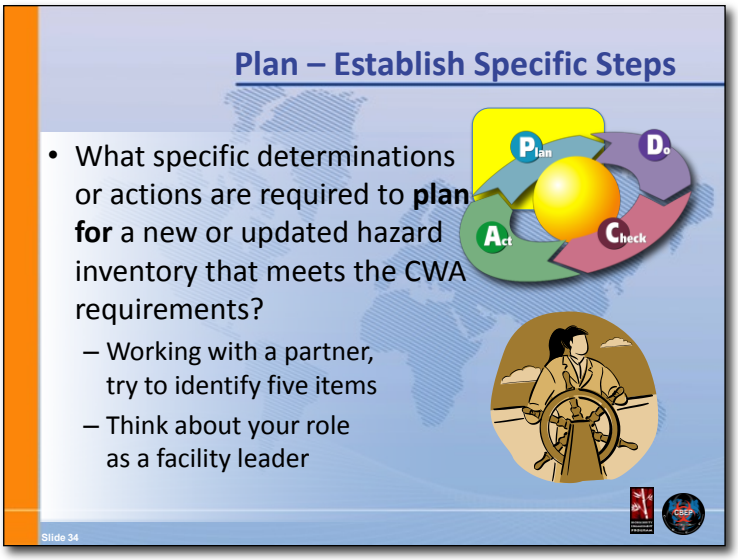
We are now ready to talk about the steps we need to take to plan for a hazard inventory. As we proceed with this part of the course, I(we) will try to show how the PDCA process is a useful way to guide your thinking on creating, maintaining, and improving your laboratory's hazard inventory.

- The CEN Workshop Agreement has described very specific requirements for inventory information pertaining to biological agents and toxins (a biological agent, as defined by the CWA, is "any microorganism including those which have been genetically modified, cell cultures and parasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants).
- Our focus today will be to think together about how an inventory system may be designed to meet these requirements.
- Because each laboratory is different, your laboratories may have different specific requirements and associated implementation strategies for a hazard inventory.
- Our goal today is to develop some common approaches to inventory system management that everyone can draw upon in their unique situations.
- THE INVENTORY PROCESS SHOULD BE BASED ON RISK
- Materials that could be controlled – seed stocks, working stocks, infected animals.

Let's take some time to think about what some practical steps might be, and how you, in your roles as laboratory leaders and managers, can help lead those steps.

PLAN Hazard Identification

Slide 34



Small group activity (10 minutes).

Activity Instructions (to students)

1. In your workbooks, you will find the CWA requirements for "biological agents and toxins inventory and information."
2. Working with a partner at your table, discuss what specific steps can you take in planning stage for a new or updated hazard inventory that meets the CWA requirements? Try to identify 5 steps or so.
3. Write your answers in your workbooks.

You have 10 minutes to complete this activity

Directions for Instructor:

- Circulate and provide guidance as necessary. Check on each group to ensure that discussions are on track and that responses are being generated. The students should focus on the planning stage at this point.
- After 10 minutes, continue on to the Plenary Discussion

PLAN Hazard Identification

Plenary Discussion (25 minutes).

Directions for Instructor:

- Select one group and elicit one response.
- Write the response on the instructor flip chart.
- Elicit unique responses from each group, and write them on your flip chart in front of the class.
- Supplement student responses with additional potential responses after all unique responses have been elicited. (10 minutes)
- Provide feed forward if a response better addresses another aspect of PDCA.

Capture on a flip chart:

- Prepare a flip chart at the front of the room while the students are performing the exercise.

PLAN Hazard Identification

Expected Responses

- Communicate necessity for hazard inventory
- Assign responsibilities for inventory
- Determine what the facility needs to have
    - Less may be more! Are there safer alternatives?
- Determine what types of materials should be included in the hazard inventory
    - Seed stocks, working stocks, infected animals, etc.
- Determine what information should be captured in the inventory for these materials based on the risk
    - Design forms and logs to capture this information
- Determine who will have access to the hazardous materials, and to the inventory itself
- Determine training requirements for staff to implement hazard inventory process
- Determine storage requirements for hazard inventory – how should biological agents and toxins in the inventory be stored?
    - Determine how inventory will be organized based on storage requirements
- Determine how the inventory will be updated and maintained.
- Determine how the inventory will be checked.

PLAN Hazard Identification

Expected Responses

Potential Leader-specific Responses

- Decide to perform a hazard identification – who is authorized to make a decision to develop and perform a hazard ID process at your facility? Does anyone else have to approve this course of action?
- Establish any necessary policy that supports and funds the expectation that the institution (or laboratory) establish inventories and conduct hazard identification – as management, what institutional policies must be enacted/developed to conduct a hazard ID process? Is an institutional policy already in place to guide the hazard ID process?
- Allocate any necessary resources (staff time) – what type(s) of resources do you (management) need to set aside?
- Assign roles and responsibilities – who needs to be involved?
    - Institutional leadership/management
    - Laboratory (scientific) management
    - Biosafety Officers
    - Laboratory staff (scientists, technicians, other regular staff)
    - Environmental health and safety officials
    - Security officials
    - Emergency response officials
    - Maintenance personnel (equipment, animal husbandry, housekeeping)
    - Outside hazard identification/risk assessment experts

PLAN Hazard Identification

Expected Responses

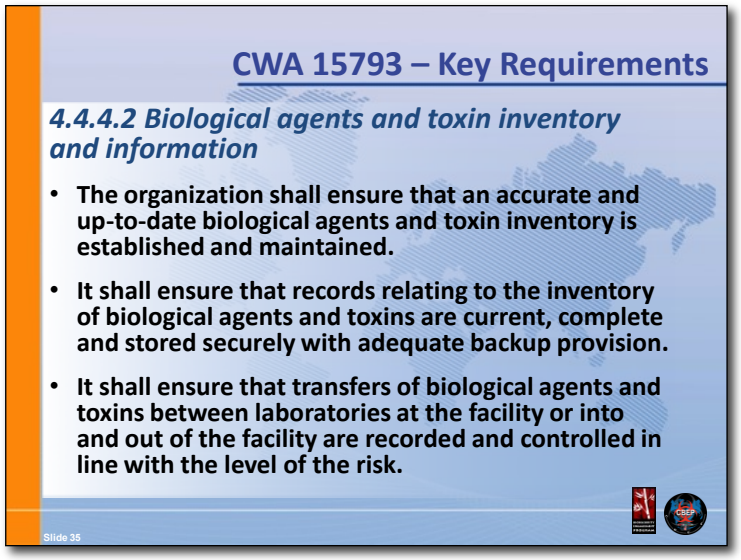
- Communicate expectations, roles, responsibilities for hazard identification process to your staff – how will you (management) communicate your expectations/instructions for the hazard ID process?
- Develop a Hazard ID Process SOP – possible sub-procedures could include:
    - Information/Document collection
    - Document review (SOPs, legal/regulatory requirements, standards and guidelines, codes of practice, prior hazard ID assessments, incident/accident reports, etc.)
    - "Baseline" data
    - Laboratory Inventory
    - "New" data
    - Staff interviews/surveys/questionnaires
    - "New" data
    - Internal review
    - Outside expert review
- Prepare hazard ID assessment
- Inform risk assessment
- Develop recommendations
- Document Hazards
- Deliver report and brief leadership on hazard ID/risk assessment findings and recommendations

Archive and store report securely

New Responses from Students:

PLAN Hazard Identification

Slide 35

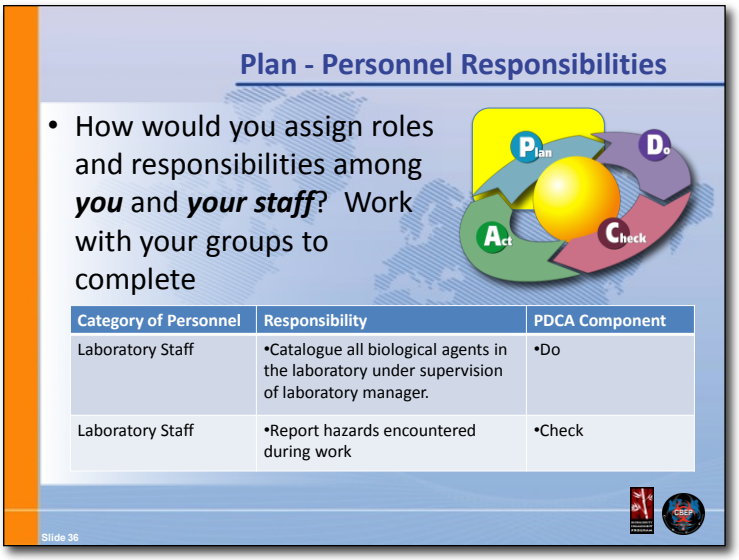


Background Information for Instructor

This slide contains some expected responses from the previous activity.

PLAN Roles and Responsibilities

Slide 36



Lecture

Key Points:

- As laboratory managers and leaders, it is unlikely that you will undertake all of the planning for the hazard inventory yourselves.
- You will rely on the input and expertise of a group of staff, and potentially experts from outside your facility, to plan, implement, and check the hazard inventory system.
- As managers, you may be responsible for determining the roles and responsibilities for members of this group throughout the PDCA cycle

PLAN Roles and Responsibilities

Small group activity (20 minutes).

Activity Instructions (to students)

1. This next exercise is designed to help you think through planning for the various roles and responsibilities inherent in establishing, maintaining, and improving a hazard inventory system.
2. Working with your group, take 15 minutes and complete the table in your workbooks.
3. Refer back to the categories of personnel we discussed earlier when we talked about hazard identification, and for each major category of laboratory or external personnel, assign specific hazard inventory responsibilities to them.
4. For each responsibility you come up with, try to categorize it in terms of the PDCA cycle. On the screen are a couple of examples.
5. There are no right or wrong answers for this exercise, but it is designed to help you think through and discuss how responsibilities for a laboratory's hazard inventory MAY BE shared.

You have 20 minutes to complete this activity

Directions for Instructor:

- Allow students to complete the table in their workbook.
- After 15 minutes, receive responses and record if necessary.

PLAN Roles and Responsibilities

Expected Responses

Categories of Personnel and Responsibilities (this list is not intended to be comprehensive but may be used to provide examples or guide group discussions – actual answers may vary)

- Top Management – assign responsibilities (PLAN) oversight (CHECK), address significant problems (ACT)
- Lab Manager – maintain hazard inventory records (DO), (potentially) accountable for biological hazards (DO), ensure staff follow hazard inventory procedures (CHECK)
- Scientific Management (PI) - ensure laboratory staff are properly trained to follow hazard inventory procedures (DO), supervise staff including their compliance with hazard inventory procedures (CHECK), advise superiors and BRMA on possible improvements to hazard inventory system (ACT)
- Research Laboratory Staff – report biological hazards encountered (DO), catalog all biological hazards in the laboratory (DO), follow hazard inventory procedures (DO)
- Technicians – follow hazard inventory procedures (DO)
- Biosafety Officer – advise lab management on proper hazard inventory procedures (PLAN), assist lab staff in developing hazard inventory procedures (PLAN), perform periodic checks to ensure hazard inventory procedures are being followed (CHECK)

New Responses from Students:

PLAN Roles and Responsibilities

Slide 37

PLAN Roles and Responsibilities

Lecture (3 minutes)

Key Points:

- During the last exercise, you had an opportunity to think about your leadership role, and the roles of your staff, as it pertains to hazard inventory systems in the laboratory.
- Hazard inventory is not only a responsibility for laboratory scientists and technicians; it requires active support by laboratory leadership as well.
- On this slide are some responsibilities that you, as leaders and managers may undertake in your own facilities.
- As you can see, there are a number of essential functions that you can play, including:
- Leading the establishment or upgrade of a hazard inventory system
- Creating or updating relevant lab policies
- Allocating necessary resources, including financial resources, training resources, and staff time, to hazard inventory functions
- Assigning roles and responsibilities, which we have practiced today
- Communicating these expectations to your staff clearly and consistently

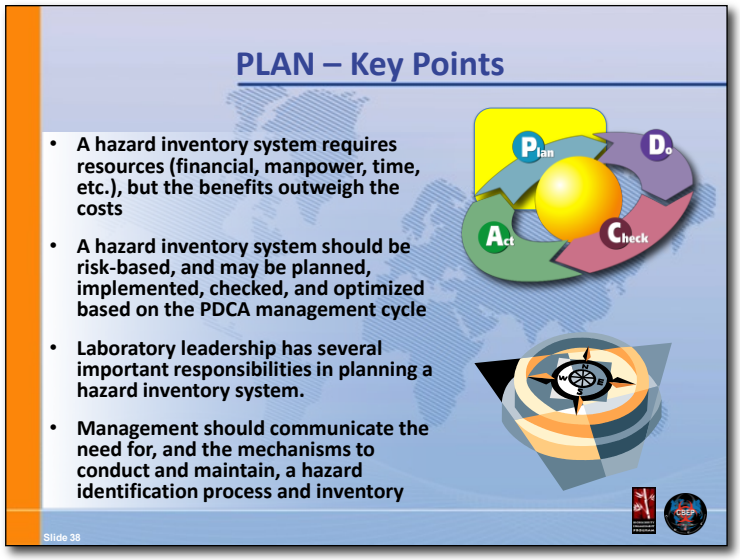
Monitoring and reviewing the progress of the system, with the goal of continuous improvement

Background Information for Instructor

This slide is intended to serve as a summary of the "Plan" section by reinforcing the role of management in the hazard inventory process.

PLAN Roles and Responsibilities

Slide 38



Lecture (2 minutes)

Recap of PLAN

Key Points:

- A hazard inventory system requires resources (financial, manpower, time, etc.), but the benefits outweigh the costs – as we saw earlier, there are numerous benefits to establishing a PDCA-based hazard inventory system, including a safer and more secure laboratory operation.
- A hazard inventory system should be risk-based, and may be planned, implemented, checked, and optimized based on the PDCA management cycle - – not all biological hazards in the inventory will necessarily have the same controls applied
- Laboratory leadership has several important responsibilities in planning a hazard inventory system.
- Management should communicate the need for, and the mechanisms to conduct and maintain, a hazard identification process and inventory – as leaders, YOU are responsible for laying the foundation for acceptance of a robust hazard inventory system within your workforce

PLAN Roles and Responsibilities

Slide 39

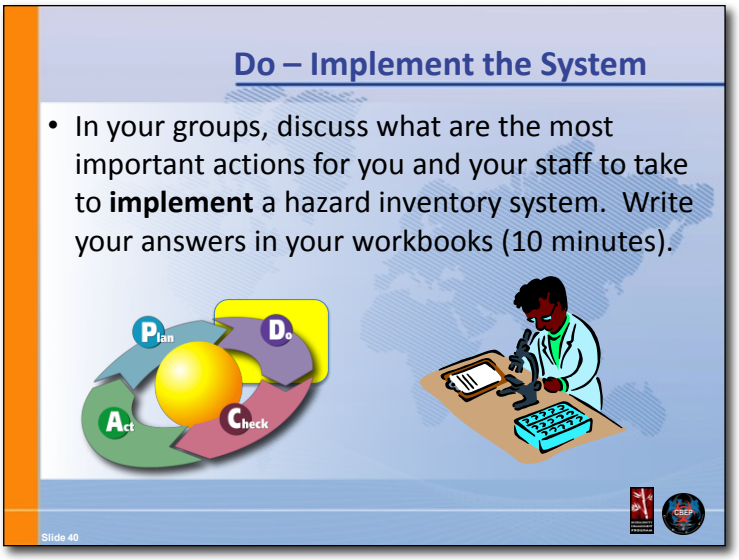
Take a Break (10-15 minutes)

Time Check

You should be approximately __ hours and __ minutes into the course.
You have __ hour, __ minutes of course remaining.

DO Implement the System

Slide 40



DO Implement the System

Small group activity (10 minutes).

Activity Instructions (to students)

1. In your groups, discuss what are the most important actions for you and your staff to take to translate plans into "Do." In other words, what actions are required to implement a hazard inventory system based on plans developed during the first stage?
2. Write your answers in your workbooks.

You have 10 minutes to complete this activity

Directions for Instructor:

- Place flip chart page from PLAN on wall or other visible surface.
- Circulate and provide guidance as necessary.
- After 10 minutes, elicit unique responses from each group, and write them on your flip chart in front of the class (Plenary Discussion).

DO Implement the System

Plenary Discussion (10 minutes).

Directions for Instructor:

- Elicit unique responses from each group, and write them on your flip chart in front of the class.
- If desired, use a different color marker for each group.
- Give a prize to the group with the most unique answers.
- Compare to expected responses and provide suggestions for additional actions. (5 minutes)
- Provide feed forward if response better addresses another aspect of PDCA.
- Note any connections between the answers provided during this exercise, and the roles/responsibilities exercise performed in the "plan" section. There should be some internal consistency.

Capture on a flip chart:

Place flip chart page from PLAN on wall or other visible surface.

DO Implement the System

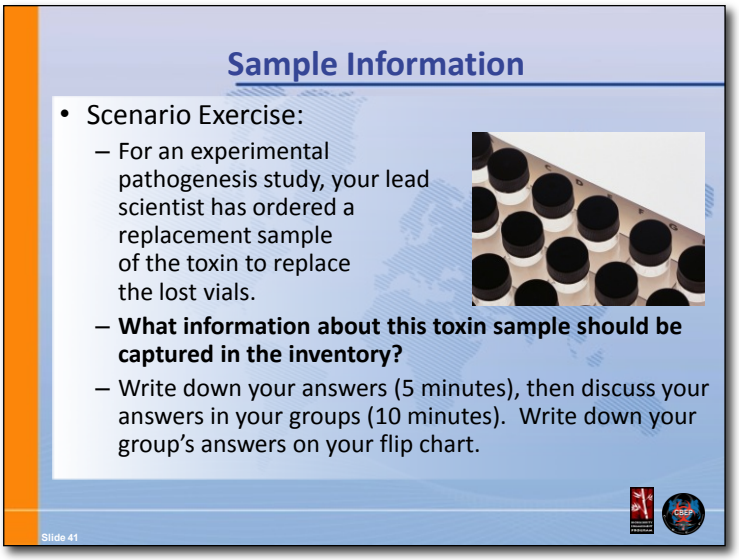
Expected Responses

- Input hazard data into inventory, whether electronic or paper-based system
- Back up information as necessary
- Implement a sample identification system to track samples easily
- Complete usage logs when using materials in the inventory
- Complete required forms (receiving, shipping, etc.)
- Update inventory whenever required (samples received, samples used/expired, samples destroyed, samples shipped elsewhere)
- Restrict storage area access to authorized persons
- Provide inventory training to laboratory staff
- Immediately report any major discrepancies between actual laboratory holdings and inventory records to appropriate contact.
- Ensure that any inventory-related responsibilities are transferred if an employee leaves or transfers to another position.

New Responses from Students:

DO Implement the System

Slide 41



DO Implement the System

Small group activity (25 minutes).

Activity Instructions (to students)

1. For this next exercise, let's go back to our toxin scenario. Let's assume that the new hazard inventory system has been planned out, and that implementation (DO) has begun. Your lead scientist has just requested a replacement sample of the toxin to replace the lost vials. The toxin will be used in a pathogenesis study. These will be the first toxin samples entered into the new biological hazard inventory.
2. Take 5 minutes, and think about what information about this toxin sample should be captured in the inventory.
3. Write down your answers (5 minutes),
4. Discuss your answers in your groups (10 minutes).
5. Write down your group's answers on your flip chart. (15 minutes).

You have 25 minutes to complete this activity

Directions for Instructor:

- This exercise is designed to utilize the scenario to probe important details of implementation ("DO") more deeply. The focus of the exercise is on eliciting the necessary sample information to construct a useful hazard inventory database; a key aspect of the hazard inventory process.
- Solicit one unique answer from each group.
- Have all groups "cross off" similar answers as they are announced (including the group that announces the answer).
- Continue until all unique answers are identified.

DO Implement the System

Expected Responses

- Identity of biological agent
- Source of biological agent
- Identifier/identification number
- Seed stock
- Working stock
- Culture
- Specimens
- Other sources (e.g. infected tissues, samples, and/or animals)
- Date received/generated
- Matrix type(s) or information
- Quantity(ies), and units (tubes, vials, petri dishes, etc)
- Condition(s)
- Storage and/or usage location(s) (e.g. freezer in lab XX) – risk-based segregation with appropriate access controls
- Status (consumed, destroyed, removed, transferred, shipped, lost, etc.)
    - Must be updated immediately upon change, ie transfer to another facility or laboratory
- Names and contact information for responsible person(s) for each biological agent or toxin in the facility's or laboratory's possession that requires inventory tracking
- Change management – transfer responsibility upon permanent departure of personnel from facility

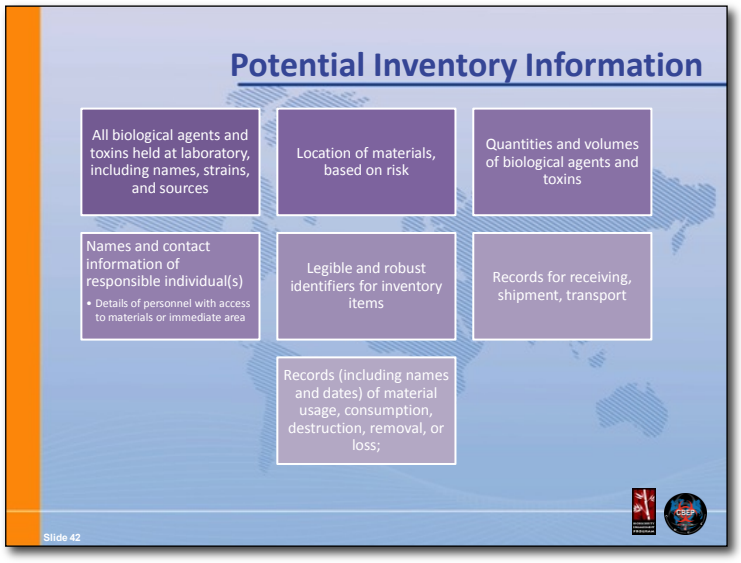
DO Implement the System

Expected Responses

- Names and contact information of persons with access for each biological agent or toxin in the facility's or laboratory's possession that requires inventory tracking
    - Change management – ensure removal of access privileges once personnel depart facility permanently
- Projects or project record locators (identifiers) for which the agents are to be used Biosafety and/or biosecurity risk group(s)

New Responses from Students:

Slide 42



DO Implement the System

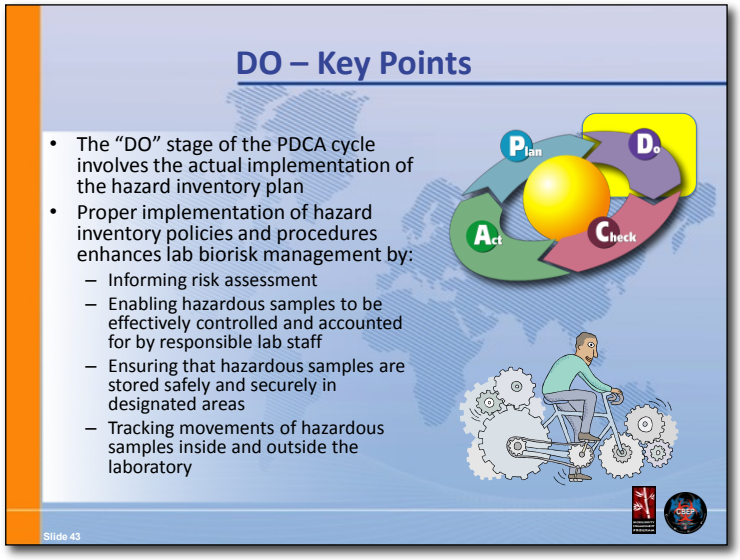
Lecture (2 minutes)

CWA 15793 and other guides (Laboratory Biosecurity Handbook) have identified some specific types of information regarding biological agents and toxins that should be captured in the inventory.

- Note: It is likely that the participants will have identified most or all of these in the previous exercise. Highlight any items that were not identified during the exercise.

Note: actual information captured in inventory should be based on combination of best practices, requirements, and laboratory risk assessment. Not all information may need to be captured for every biological hazard. For example, it may not be practical to quantitatively track quantities and volumes of all biological agents, depending on the circumstances of use and storage.

Slide 43



Background Information for Instructor

This slide may be displayed following completion of the group activity

DO Implement the System

Lecture

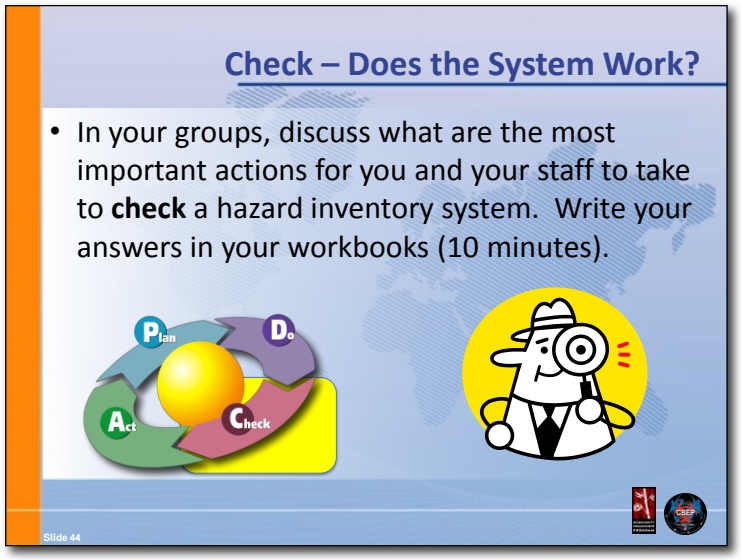
Recap of DO

Key Points**:**

- The “DO” stage of the PDCA cycle involves the actual implementation of the hazard inventory plan
- Proper implementation of hazard inventory policies and procedures enhances lab biorisk management by:
    - Informing risk assessment
    - Enabling hazardous samples to be effectively controlled and accounted for by responsible lab staff
    - Ensuring that hazardous samples are stored safely and securely in designated areas
    - Tracking movements of hazardous samples inside and outside the laboratory

CHECK Does the System Work?

Slide 44



Small group activity (10 minutes).

Activity Instructions (to students)

1. In a well-designed hazard inventory system, implementation ("DO") should naturally proceed from Planning. Now, let's talk about how we can check to make sure that the system we implement performs as expected.
2. We'll take the same approach here as we have for the previous PDCA elements.
3. In your groups, discuss what are the most important actions for you and your staff to take to check a hazard inventory system.
4. Write your answers in your workbooks (10 minutes).

You have 10 minutes to complete this activity

Directions for Instructor:

- Circulate and provide guidance as necessary.
- Place flip chart page from DO on wall or other visible surface next to the PLAN page (for Plenary Discussion).

CHECK Does the System Work?

Plenary Discussion (10 minutes).

Directions for Instructor:

- After 10 minutes, elicit unique responses from each group, and write them on your instructor flip chart in front of the class. If desired, use a different color marker for each group.
- Compare to expected responses and provide suggestions for additional actions.
- Provide feed forward if response better addresses another aspect of PDCA. (10 minutes)

Capture on a flip chart:

- Place flip chart page from DO on wall or other visible surface next to the PLAN page

CHECK Does the System Work?

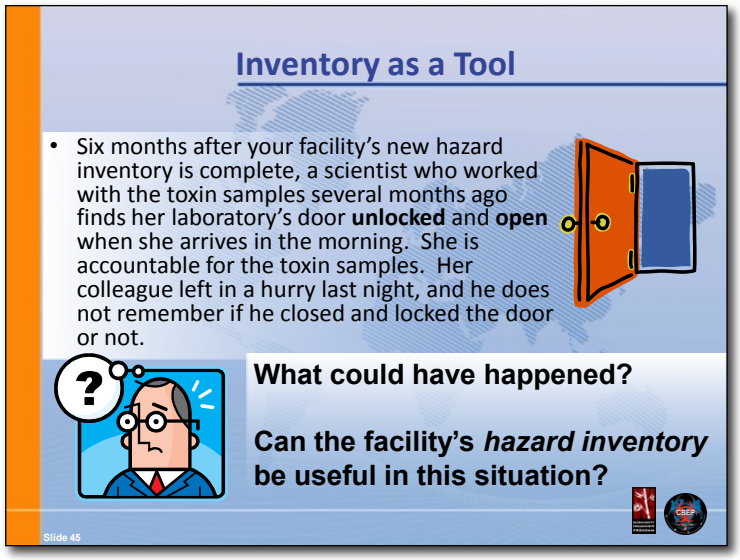
Expected Responses

- Ensure that accountable individual(s) have maintained current and complete inventory-related records of hazardous biological materials
- Ensure that any inventory-related reports are complete and on-time
- Perform a regular internal audit of the hazard inventory
- How often? It depends on the level of risk and risk acceptance!
- What to check during a review/audit?
- Inventory records are complete
- Records are consistent with actual holdings
- Any discrepancies were promptly corrected/reported/investigated
- Log books are complete, and that personnel had appropriate authority to sign out/in hazard materials
- Staff knowledge of inventory requirements
- Compliance with SOPs
- Perform periodic inspections of laboratory areas to ensure compliance with inventory procedures
- Commission an external audit of the inventory system to get a second opinion
- Gather feedback from employees on effectiveness/burden of inventory system
- Take corrective actions as warranted based on checking and documented procedures

New Responses from Students:

CHECK Does the System Work?

Slide 45



Lecture

Let's examine another scenario related to the toxin scenario we have been discussing.

- Six months after your facility's new hazard inventory is complete, a scientist who worked with the toxin several months ago finds her laboratory's door unlocked and open when she arrives in the morning.
- She is accountable for the toxin samples.
- Her colleague left in a hurry last night, and he does not remember if he closed and locked the door or not.

Plenary Discussion (5 minutes).

Questions to consider:

What could have happened?

Can the facility's hazard inventory be useful in this situation?

Directions for Instructor:

- Receive answers from the class as a whole.
- Recording is not necessary.

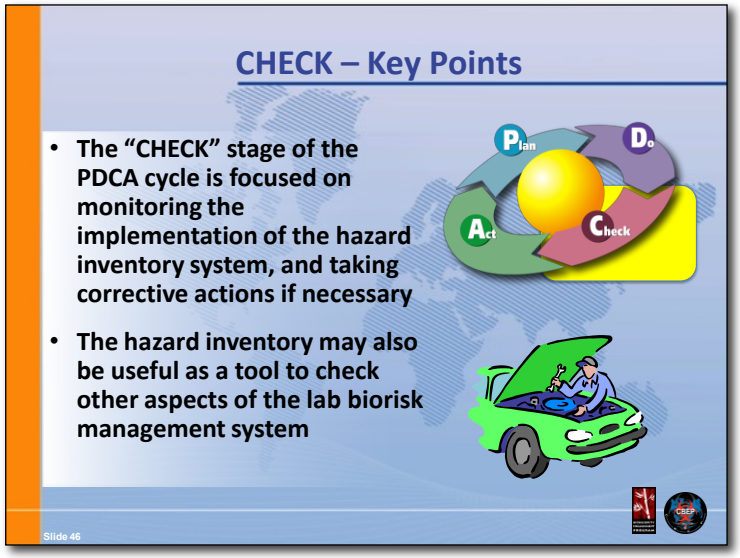
CHECK Does the System Work?

Expected Responses

- YES the hazard inventory can be useful in this situation to help determine what could have happened.
- The complete and up-to-date hazard inventory can be used to quickly compare the holdings in the lab to what should be in the lab.
- If something is missing, this may be an indication that there was a break-in.
- Importantly, the inventory must be complete and up-to-date.
- We cannot count on the scientist's memory from a few months ago to determine exactly how much toxin should be in the lab.

New Responses from Students:

Slide 46



CHECK Does the System Work?

Lecture (2 minutes)

Recap of CHECK

Key Points:

- The “CHECK” stage of the PDCA cycle is focused on monitoring the implementation of the hazard inventory system to ensure proper function, and taking corrective actions if necessary
- The hazard inventory may also be useful as a tool to check other aspects of the lab biorisk management system

ACT How to Get Better

Slide 47

Small group activity (10 minutes).

Activity Instructions (to students)

1. Finally, let's talk about the steps that you, as lab leaders, need to take to realize our goal of continuous process improvement with respect to hazard inventory.
2. In your groups, discuss what are the most important actions to take to review, innovate, and act to improve a hazard inventory system.
3. Write your answers in your workbooks (10 minutes).

You have 10 minutes to complete this activity

Directions for Instructor:

- Circulate and provide guidance as necessary. (10 minutes)
- Place flip chart page from CHECK on wall or other visible surface next to the DO page (for Plenary Discussion).

ACT How to Get Better

Plenary Discussion (10 minutes).

Directions for Instructor:

- Place flip chart page from CHECK on wall or other visible surface next to the DO page.
- Elicit unique responses from each group, and write them on your instructor flip chart in front of the class. If desired, use a different color marker for each group.
- Give a prize to the group with the most unique answers. (5 minutes)
- Compare to expected responses and provide suggestions for additional actions. (5 minutes)
- Provide feed forward if response better addresses another aspect of PDCA.

ACT How to Get Better

Expected Responses

- Perform a periodic management review of results of inspections, audits, and other information to identify areas for improvement of inventory control system
    - How often? It depends on risk/risk acceptance – but is a management decision
    - Develop recommendations for inventory process improvement
- If discrepancy, implement process to recommend improvements to prevent recurrences
- Decide on concrete steps to take to improve the inventory control system
- Communicate results of review to laboratory staff, along with rationale for changes in inventory control system
- Provide resources necessary to implement planning and implementation of improvements of inventory control system

New Responses from Students:

ACT How to Get Better

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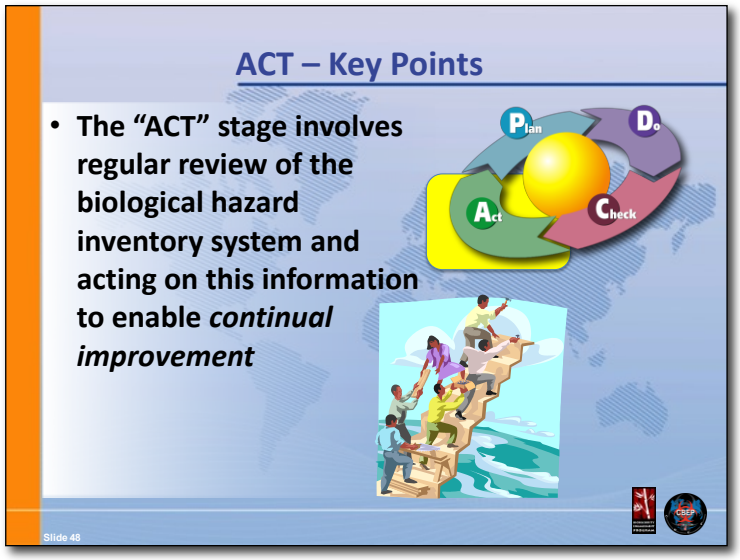

Lecture (2 minutes)

Key Points:

- The "ACT" stage involves regular review of the biological hazard inventory system and acting on this information to enable continual improvement
- The findings of your inventory system review should flow directly into PLANNING for process improvements.

ACT How to Get Better

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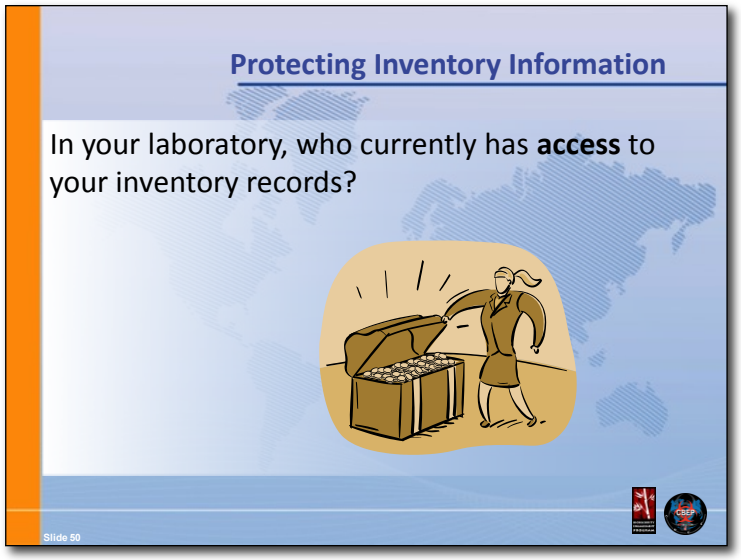
Take a Break (10-15 minutes)

Time Check

You should be approximately __ hours and __ minutes into the course.
You have __ hour, __ minutes of course remaining.

Protecting Information

Slide 50



Lecture

Protecting hazard inventory-related information is also a key component of a hazard inventory. This information may be valuable and warrant protection.

Plenary Discussion (5 minutes).

Questions to consider:

In your laboratory, who currently has access to your inventory records?

Follow-up:

ASK:

- Do other personnel who don't need access as part of their functions, such as maintenance staff or visitors, have access to records?
- Would it be possible for unauthorized individuals to access inventory-related information in your facility?

Directions for Instructor:

- Write down answers on the instructor flip chart in the front of the room.

Protecting Information

Expected Responses

- Managers
- Scientists
- Technicians
- BSO
- Follow Up response
    - Yes, at least for some participants

New Responses from Students:

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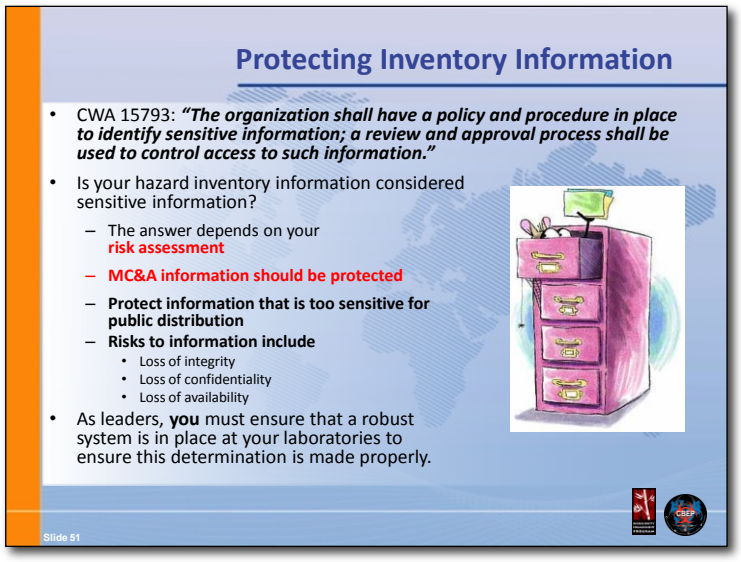

Protecting Information

Lecture (2 slides, 5 minutes)

Key Points:

- According to the CWA, organizations should have policies and procedures in place to identify sensitive information, and a review and approval process shall be used to control access to this information.
- Whether or not the information contained in the hazard inventory constitutes “sensitive information” is dependent on several factors, including the risk assessment.
- As leaders, you must ensure that a robust system is in place at your laboratories to ensure this determination is made properly.

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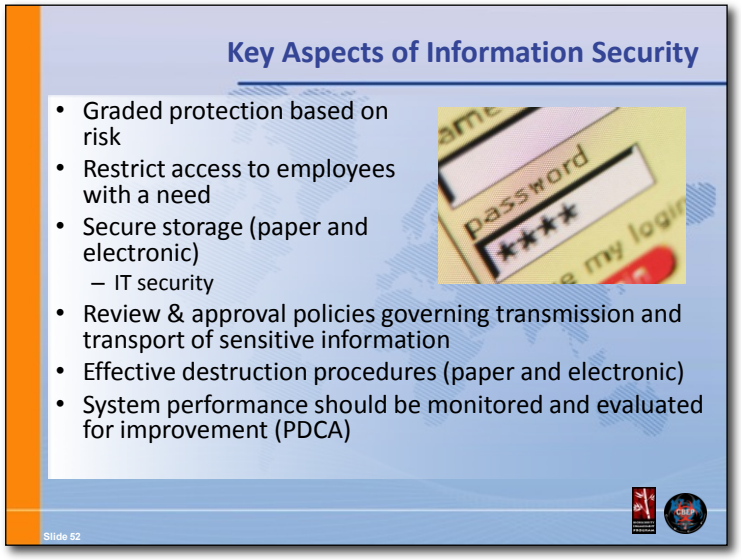

Protecting Information

Lecture (5 minutes incl. previous)

Key Points:

- A risk assessment will help determine what level of protection your hazard inventory information warrants.
- The level of protection applied should be risk-dependent. In other words, more sensitive information should be protected more rigorously than less sensitive information.
- Some key principles and procedures common to information security systems include:
- Restrict access to sensitive information to those who need to access it for job-related functions
- Store your hazard inventory information securely, whether the information exists in electronic or physical forms (or both)
- It may be necessary to share sensitive inventory information with others on occasion, so policies and procedures governing how sensitive information is shared with others, including transmission and transport, should be established
- When sensitive information is no longer required, it should be destroyed in a secure fashion. This is true for both physical and electronic records
- Finally, as with all elements of the lab biorisk management system, the performance of your lab's information security procedures should be monitored, evaluated, corrected, and improved over time

Protecting Information

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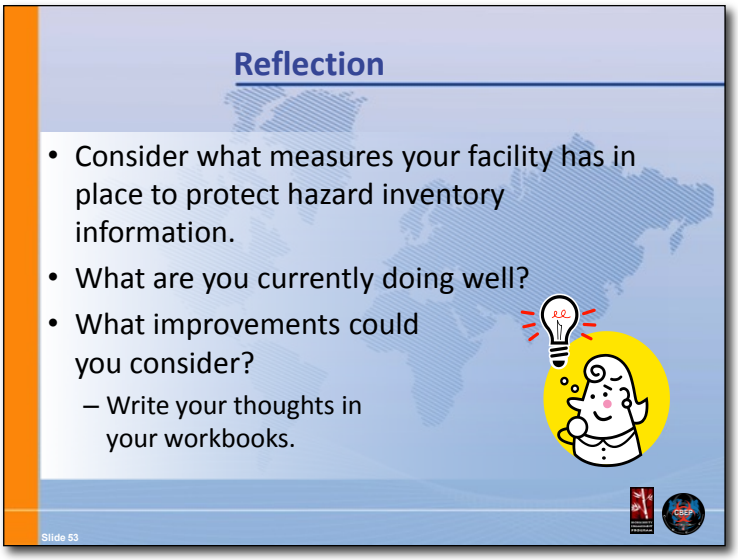

Ask students to REFLECT individually on the following question/statement (5 minutes):

1. In the next 5 minutes, consider what measures your facility has in place to protect hazard inventory information.
2. What are you currently doing well?
3. What improvements could you consider?
4. Write your thoughts in your workbooks.

After 5 minutes, if desired and time allowing, solicit voluntary feedback from 1-2 participants.

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.

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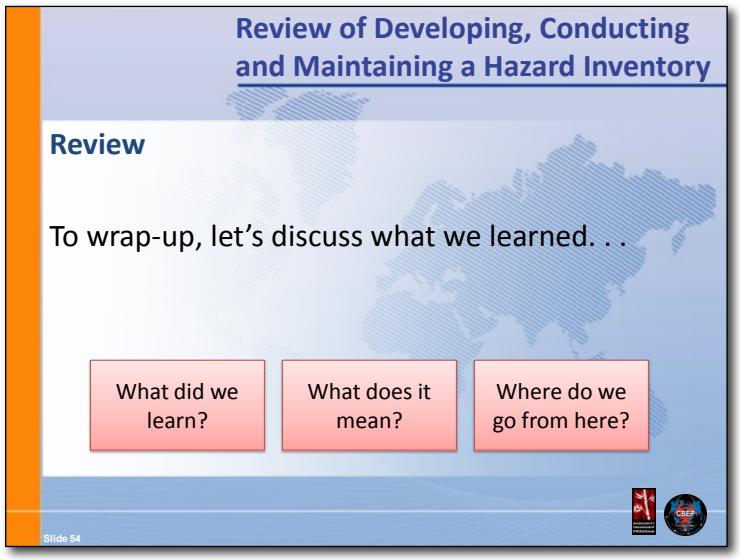

Review

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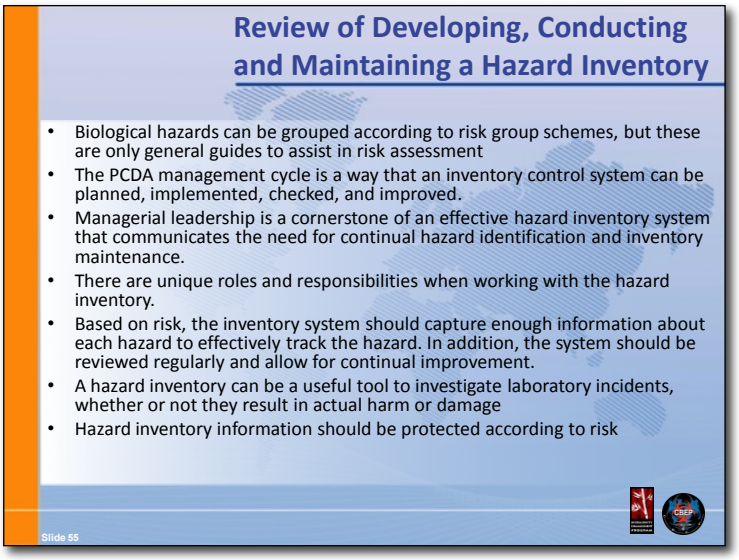


Review

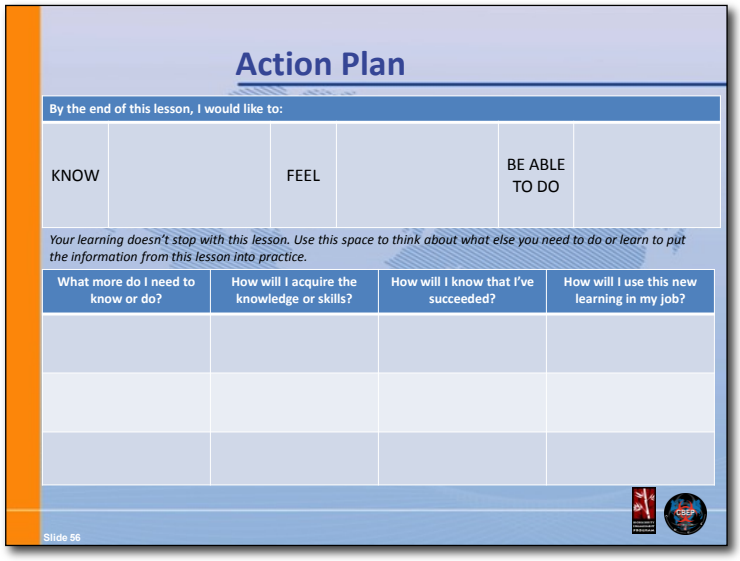
Review Key Messages

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

- Biological hazards can be grouped according to risk group schemes, but these are only general guides to assist in risk assessment
- The PCDA management cycle is a way that an inventory control system can be planned, implemented, checked, and improved.
- Managerial leadership is a cornerstone of an effective hazard inventory system that communicates the need for continual hazard identification and inventory maintenance.
- There are unique roles and responsibilities when working with the hazard inventory.
- Based on risk, the inventory system should capture enough information about each hazard to effectively track the hazard. In addition, the system should be reviewed regularly and allow for continual improvement.
- A hazard inventory can be a useful tool to investigate laboratory incidents, whether or not they result in actual harm or damage
- Hazard inventory information should be protected according to risk

Review

Slide 56



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

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Review

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).