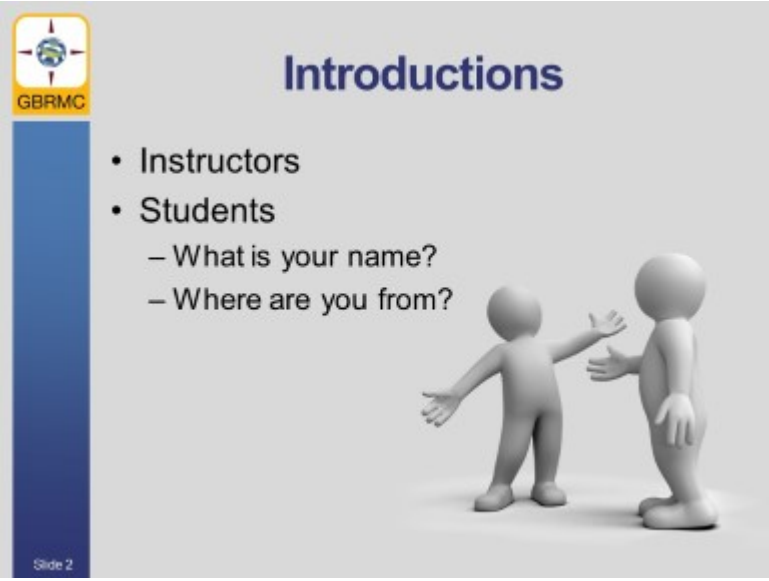
Developing and Maintaining Roles & Responsibilities for Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins

Student Guide

2012

GLOBAL BIORISK MANAGEMENT CURRICULUM

Welcome to Developing and Maintaining Roles & Responsibilities for Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins


GBRMC
Introductions
• Instructors
• Students
– What is your name?
– Where are you from?
Slide 2

Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

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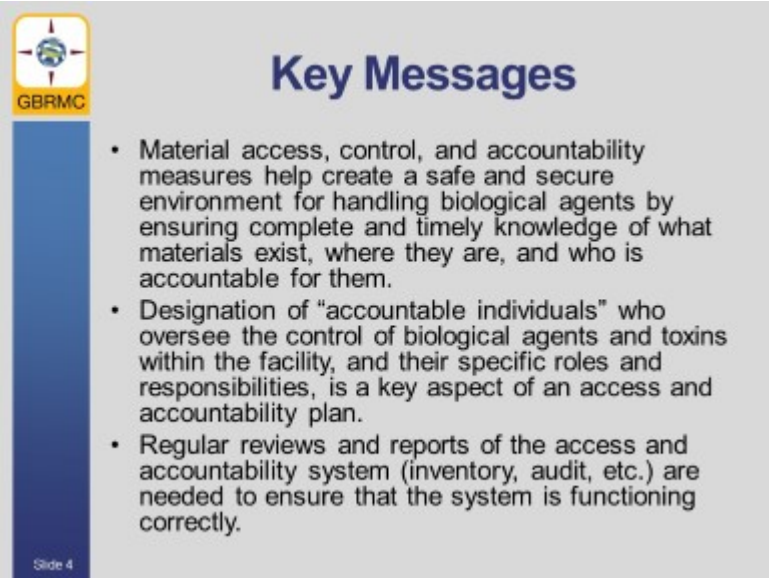
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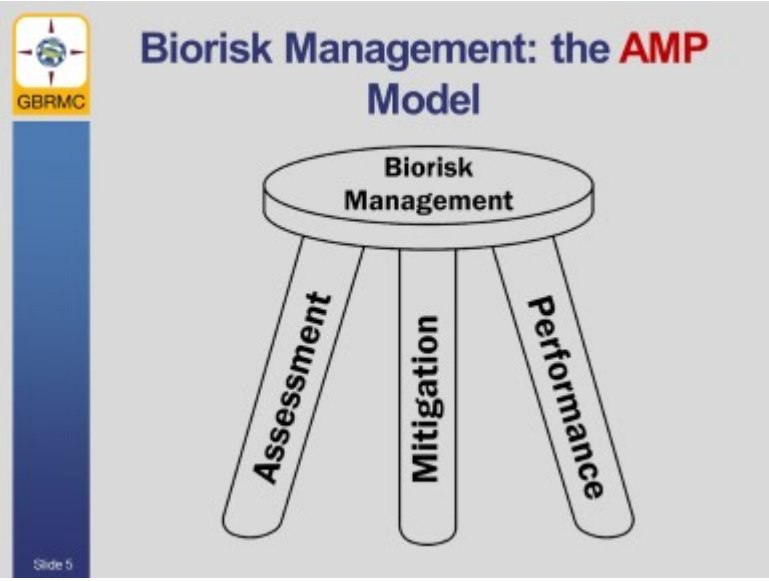
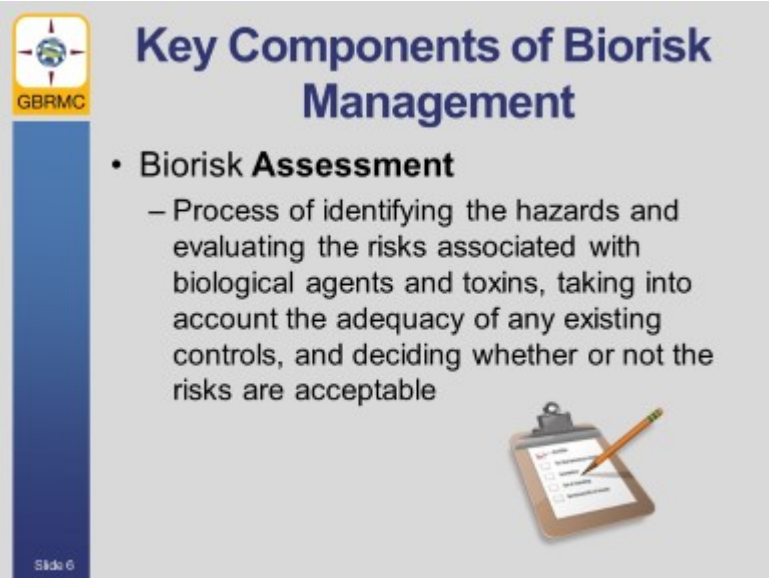
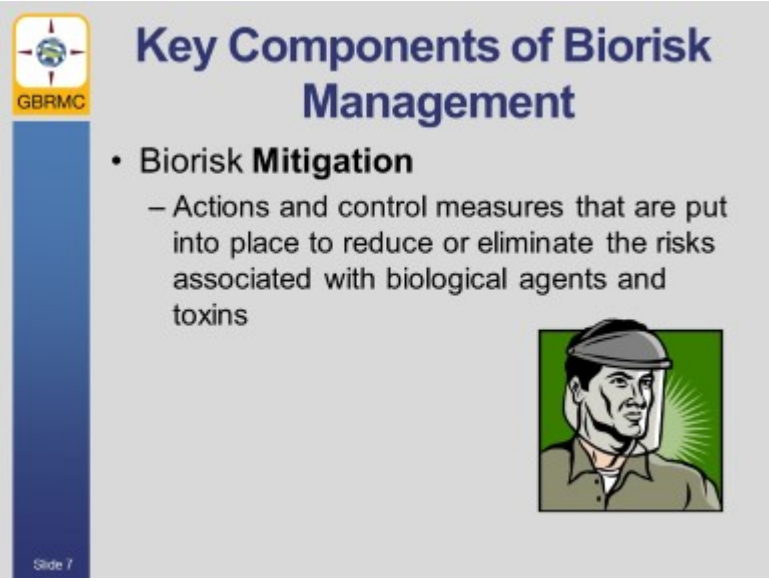
Key Messages
• Material access, control, and accountability measures help create a safe and secure environment for handling biological agents by ensuring complete and timely knowledge of what materials exist, where they are, and who is accountable for them.
• Designation of "accountable individuals" who oversee the control of biological agents and toxins within the facility, and their specific roles and responsibilities, is a key aspect of an access and accountability plan.
• Regular reviews and reports of the access and accountability system (inventory, audit, etc.) are needed to ensure that the system is functioning correctly.
Slide 4



Record refresher notes on the AMP model and biorisk management.

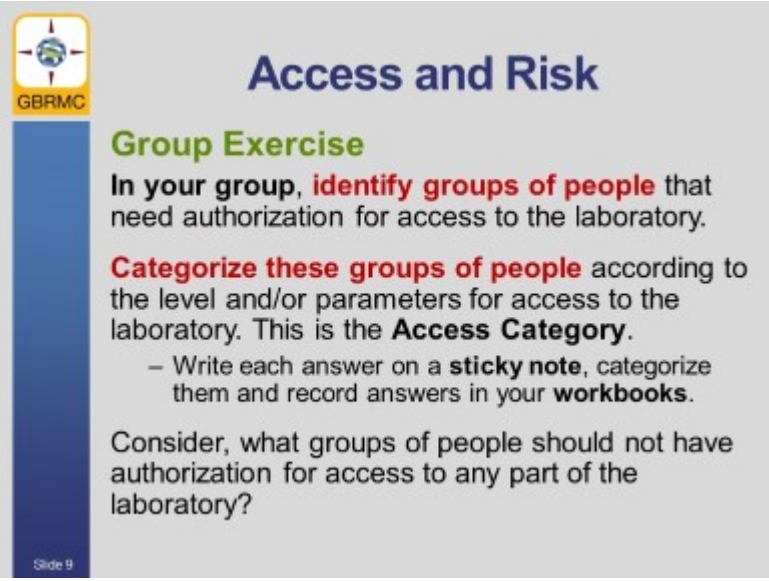


Define Biorisk Assessment:



Define Biorisk Mitigation:

Define Performance:



Groups of people that need authorization for access:

What are your Access Categories? How do these groups fit into each category?

What groups of people should NOT have authorization for access to any part of the laboratory?

Fill in the table on the following page.

Access Category	Group Examples	Potential Risks to the People from the Laboratory	Potential Risks to the Laboratory from the People

Are the access requirements the same for all groups?

Are the risks to all groups the same?

Are the risks from all groups the same?

How do we control access for those who need it?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How Do We Control Who Has Access?
Control Access Through Mitigation Measures:
– Engineering Controls
– Administrative Controls
– Practices and Procedures
– Elimination
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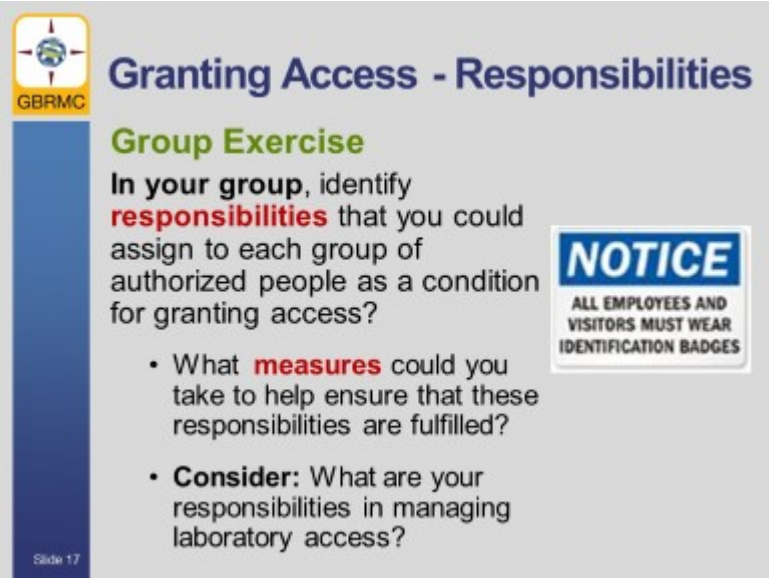
Slide 13

Notes:

Definition and example of Engineering Controls:

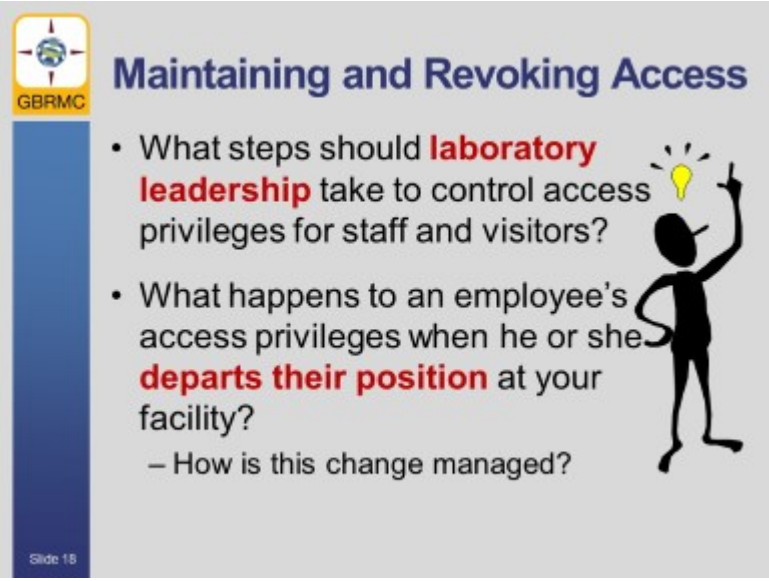
Definition and example of Administrative Controls:

Definition and example of Practices and Procedures:



What are some responsibilities for each group of authorized people?

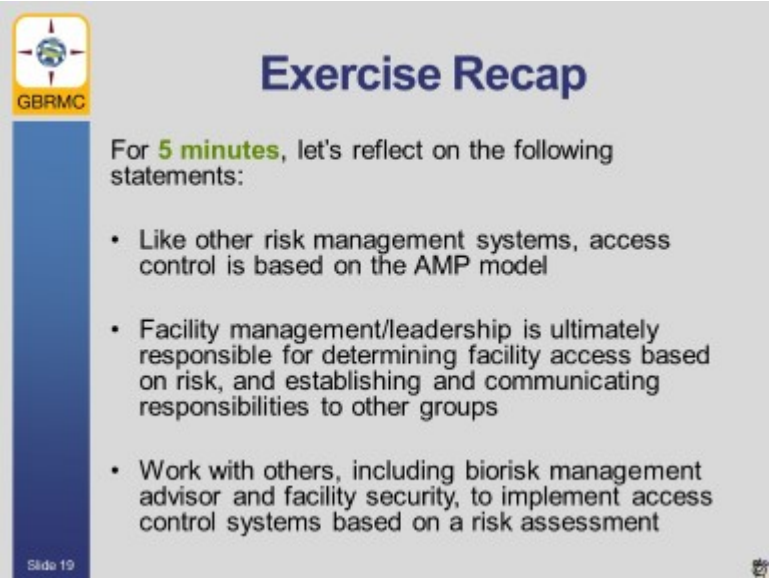
What measures could you take to ensure that these responsibilities are fulfilled?



What steps should laboratory leadership take to control access privileges for staff and visitors?

What happens to an employee's access privileges when they depart their position?

How are these changes managed?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Exercise Recap
For 5 minutes, let's reflect on the following statements:
• Like other risk management systems, access control is based on the AMP model
• Facility management/leadership is ultimately responsible for determining facility access based on risk, and establishing and communicating responsibilities to other groups
• Work with others, including biorisk management advisor and facility security, to implement access control systems based on a risk assessment
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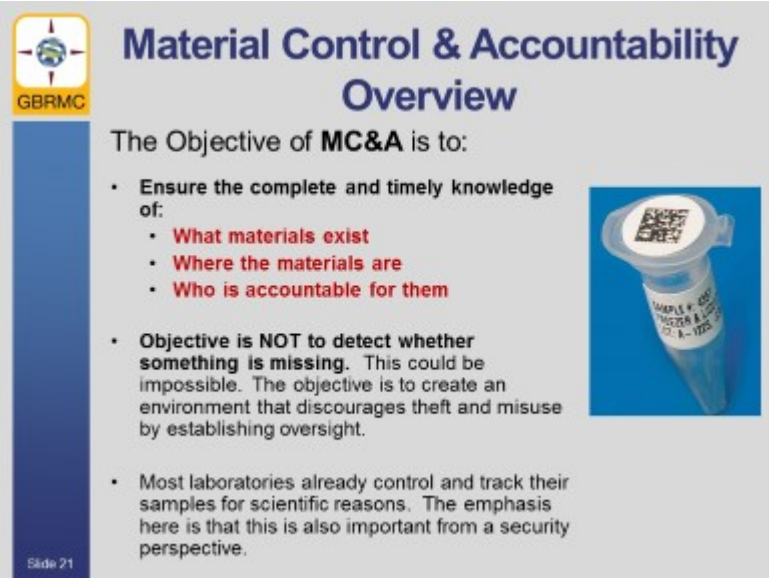
Notes:

Material Control & Accountability is one part of a complete biorisk management plan.



Remember, every risk mitigation policy and program must be designed based on a **robust risk assessment**.

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Material Control & Accountability Overview

Key Issues in **MC&A**

- What materials are subject to MC&A measures?
- What operating procedures are associated with the materials?
  - **Where can they be stored and used?**
  - **How are they identified?**
  - **How is inventory maintained?**
- What records need to be kept for those materials? What timeliness requirements are necessary for those records?
- What does accountability mean?
- What documentation and reporting requirements?

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MC&A - Elements

- **Material**
- **Control**
- **Accountability**

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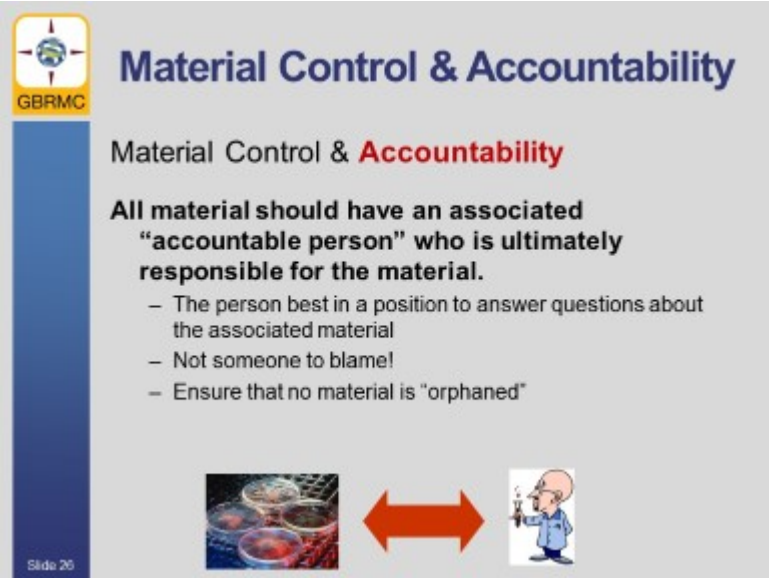
Note some of the key issues for Material:

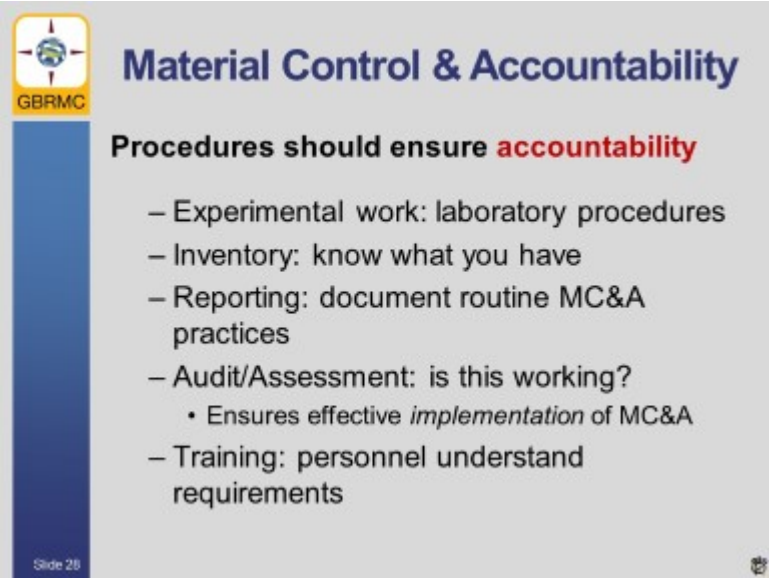
Note some of the key issues for Control:



Note some of the key issues for Accountability:

Examples of responsibilities that management could assign and communicate to an accountable individual?

How can management ensure that these responsibilities are met?



Note the safety and security benefits that come from adequate Procedures and Inventory Keeping:

List some examples of inventory:

Who needs to know? Who needs to know *what?*

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MC&A Scenario

Scenario:

3 vials of Equine Encephalitis Virus are reported missing from a high security facility. This virus infects horses, but can be spread to humans through mosquitoes, where it can be deadly in ~1 out of 100 cases. The vials were under the control of a senior scientist who had retired a few years ago and were first identified as missing when a new computer-based inventory system was implemented at the laboratory. The senior scientist thinks that there is a "strong possibility" that the samples were destroyed 8 years ago when one of the freezers in the facility broke down and everything in the freezer had to be destroyed. Unfortunately, a complete inventory of the destroyed samples was never performed. Investigators have not found any evidence of criminal activity.

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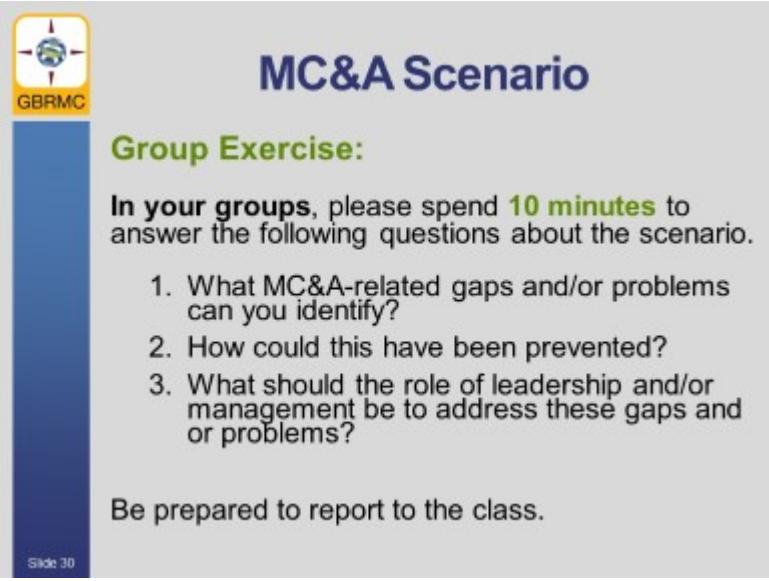
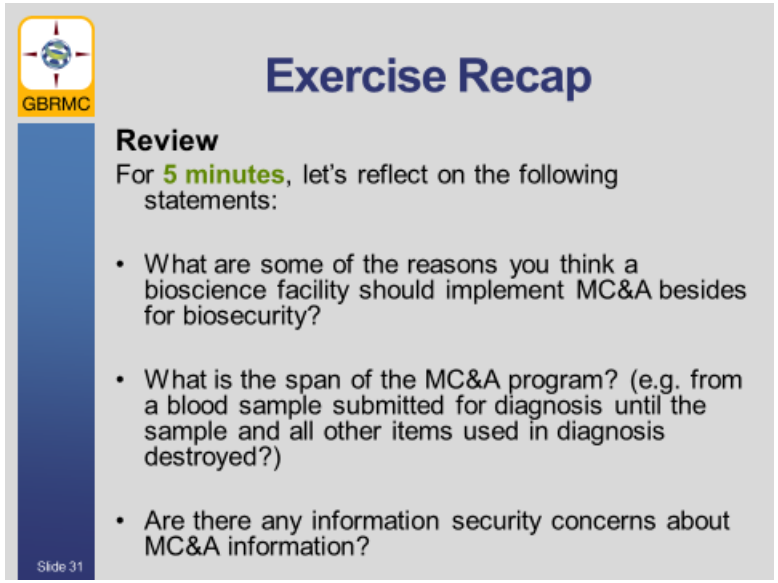


What are some MC&A problems?

How could they have been prevented?

What is the role of leadership/management?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Exercise Recap
Review
For 5 minutes, let's reflect on the following statements:
• What are some of the reasons you think a bioscience facility should implement MC&A besides for biosecurity?
• What is the span of the MC&A program? (e.g. from a blood sample submitted for diagnosis until the sample and all other items used in diagnosis destroyed?)
• Are there any information security concerns about MC&A information?
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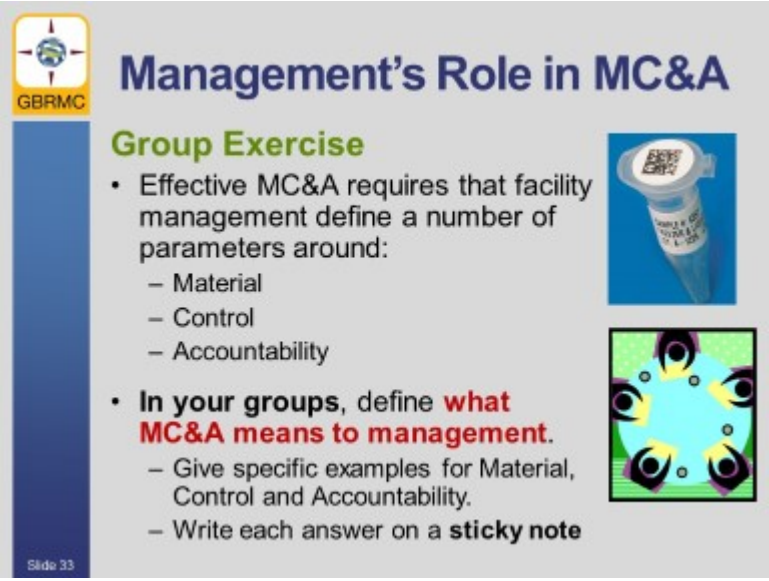
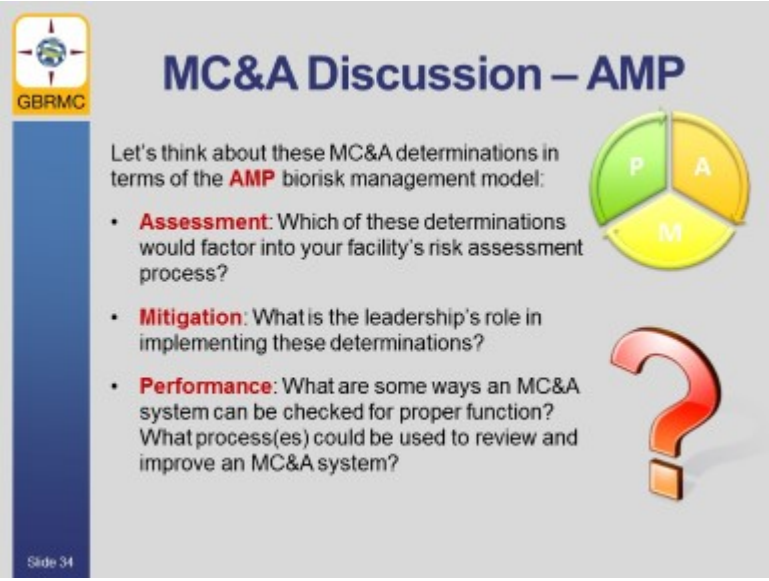


What does MC&A mean to management?

Material:

Control:

Accountability: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MC&A Discussion – AMP
Let's think about these MC&A determinations in terms of the AMP biorisk management model:
• Assessment: Which of these determinations would factor into your facility's risk assessment process?
• Mitigation: What is the leadership's role in implementing these determinations?
• Performance: What are some ways an MC&A system can be checked for proper function? What process(es) could be used to review and improve an MC&A system?
P
A
M
Slide 34

Notes:

What is your role?

What could go wrong from your perspective?

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Roles and Responsibilities

Scenario:

You and your colleagues work together at a small food-borne infectious disease research facility, which houses two BSL-2 laboratories. The research facility is overseen by a **director general (DG)**. The **PI** (who also serves as lab manager of Laboratory Number 1) has ordered a culture of *E. coli* O157:H7 for use in a study of pathogenesis mechanisms. The culture will be stored in a freezer shared by the two laboratories, which is located in a separate freezer room. The actual manipulation of the culture and research samples day-to-day to be performed by a **graduate student**, who works in Laboratory Number 1 and is directly supervised by the **PI**. The lab manager for the other BSL-2 laboratory (Laboratory Number 2) also serves as the facility's **biorisk management advisor**.

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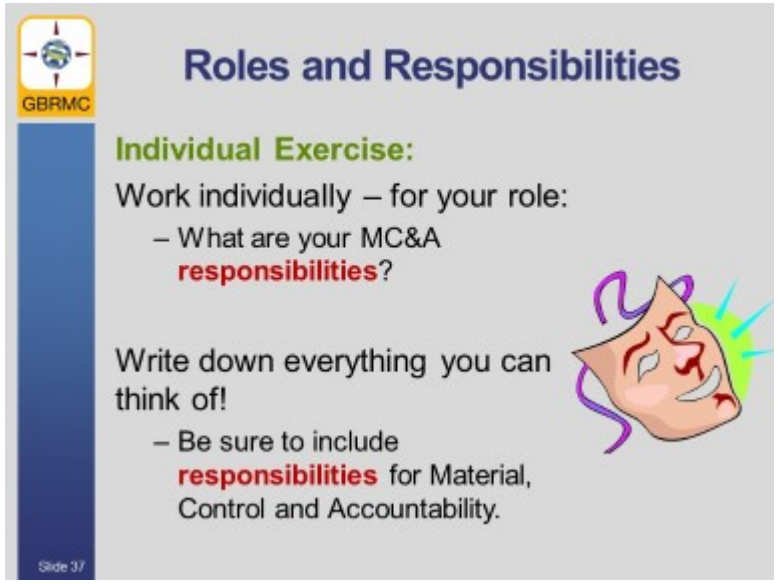
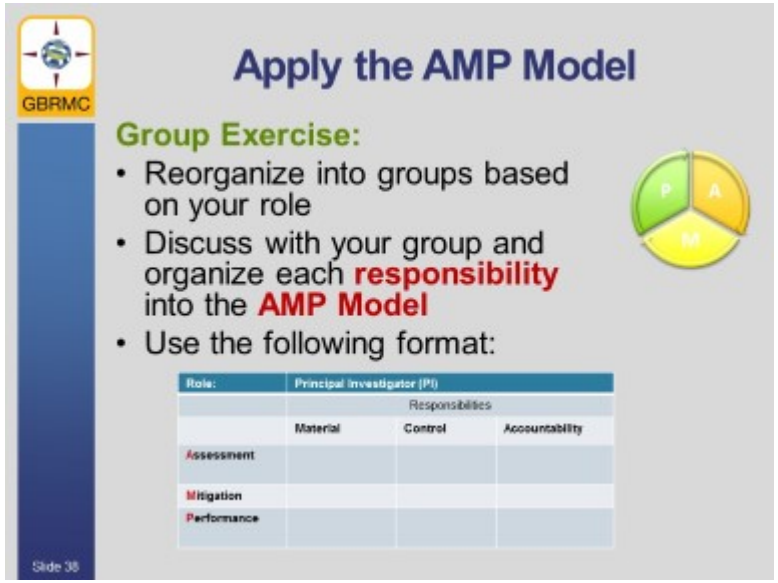


For your role, what are the MC&A responsibilities?

Material:

Control:

Accountability:



Fill in the table on the following pages.

Role:	Principal Investigator (PI)		
	Responsibilities		
	Material	**Control**	**Accountability**
Assessment			
Mitigation			
Performance			

Role:	Principal Investigator (PI)		
	Responsibilities		
	Material	**Control**	**Accountability**
Assessment			
Mitigation			
Performance			

Role:	Principal Investigator (PI)		
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Role:	Principal Investigator (PI)		
	Responsibilities		
	Material	**Control**	**Accountability**
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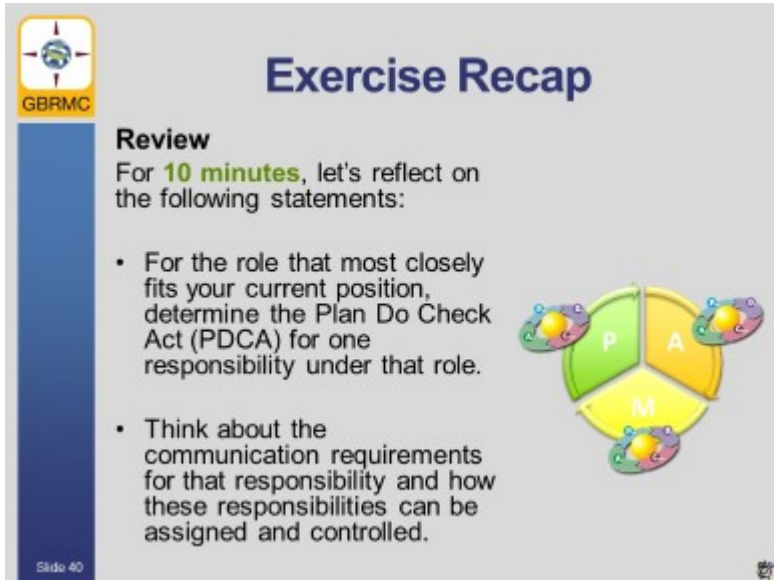
Mitigation			
Performance			



Apply the PDCA model for the role that most clearly fits your current position for at least one responsibility.

Plan:

Do:

Check:

Act: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Review
To wrap-up, lets discuss what we learned about Developing and Maintaining Roles & Responsibilities for Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins….
What did we learn?
What does it mean?
Where do we go from here?
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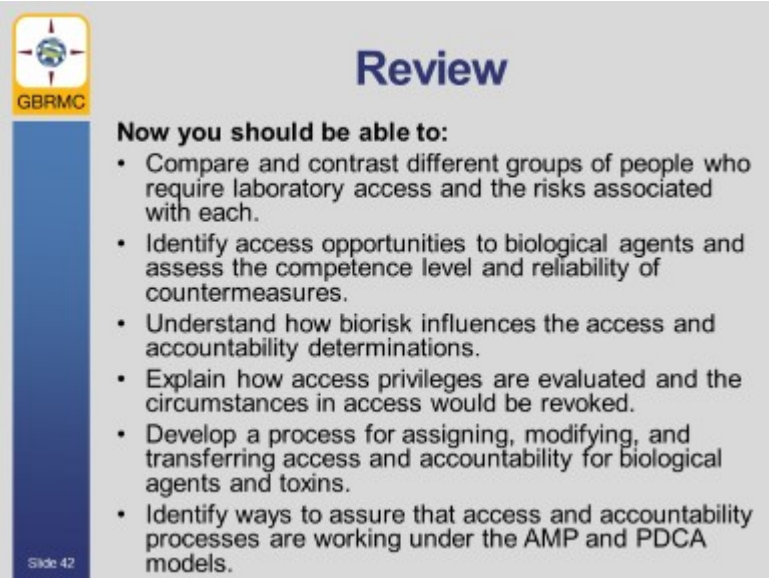
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Review
Now you should be able to:
• Compare and contrast different groups of people who require laboratory access and the risks associated with each.
• Identify access opportunities to biological agents and assess the competence level and reliability of countermeasures.
• Understand how biorisk influences the access and accountability determinations.
• Explain how access privileges are evaluated and the circumstances in access would be revoked.
• Develop a process for assigning, modifying, and transferring access and accountability for biological agents and toxins.
• Identify ways to assure that access and accountability processes are working under the AMP and PDCA models.
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Action Plan

By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

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Use space on back, if needed