



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

Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins

Welcome & Introductions



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



Introductions

- Instructors
- Students
 - What is your name?
 - Where are you from?



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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?



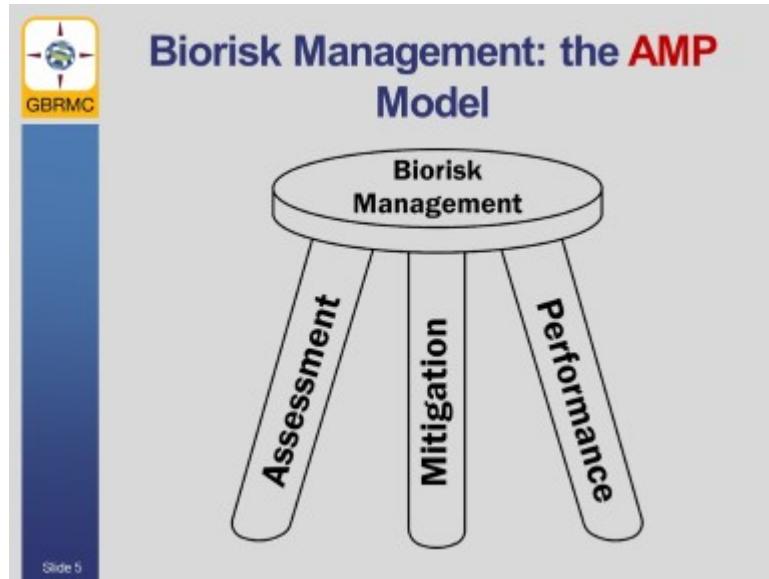
Key Messages

- 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.

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Risk-Based Access to, Control of, and Accountability for Biological Agents and Toxins

Biorisk Management



Record refresher notes on the AMP model and biorisk management.



Key Components of Biorisk Management

- Biorisk Assessment**

- Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable



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Define Biorisk Assessment:



Key Components of Biorisk Management

- **Biorisk Mitigation**
 - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins



Define Biorisk Mitigation:

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Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



Define Performance:

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Access Requirements & Risk



Access and Risk

Group Exercise

In your group, identify groups of people that need authorization for access to the laboratory.

Categorize these groups of people according to the level and/or parameters for access to the laboratory. This is the **Access Category**.

- Write each answer on a **sticky note**, categorize them and record answers in your **workbooks**.

Consider, what groups of people should not have authorization for access to any part of the laboratory?

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?

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Access Requirements & Risk



Access and Risk

Group Exercise:

For each **Access Category**, list:

- The potential risks to the **people** from the laboratory
- The potential risks to the **laboratory** from the people



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

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Access Requirements & Risk



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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Laboratory Access Controls



How Do We Control Who Has Access?

Control Access Through Mitigation Measures:

- Engineering Controls
- Administrative Controls
- Practices and Procedures
- Elimination



Notes:



Definition and example of Engineering Controls:

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Laboratory Access Controls



Definition and example of Administrative Controls:

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Laboratory Access Controls



Definition and example of Practices and Procedures:

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Laboratory Access Controls



Granting Access - Responsibilities

Group Exercise

In your group, identify **responsibilities** that you could assign to each group of authorized people as a condition for granting access?

What are some responsibilities for each group of authorized people?

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



Maintaining and Revoking Access

- What steps should **laboratory leadership** take to control access privileges for staff and visitors?
- What happens to an employee's access privileges when he or she **departs their position** at your facility?
 - How is this change managed?



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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?



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

Notes:

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Material Control & Accountability



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

 **Material Control & Accountability Overview**

The Objective of MC&A is to:

- Ensure the complete and timely knowledge of:
 - What materials exist
 - Where the materials are
 - Who is accountable for them
- Objective is NOT to detect whether something is missing. This could be impossible. The objective is to create an environment that discourages theft and misuse by establishing oversight.
- Most laboratories already control and track their samples for scientific reasons. The emphasis here is that this is also important from a security perspective.

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



 **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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Material Control & Accountability

Material Control & Accountability

Material Control & Accountability

What information should we keep track of?

Agent	Quantity	Form	Detail	Scope
Which agents?	Any amount of a replicating organism can be significant.	Repository Stocks, Working Samples, yes...	Materials as items	Laboratory Strains? Wild-type?
Only viable organisms? Whole org. or just DNA?	For toxins, must define a threshold amount.	What about: In host? Contamination?	Each vial as a separate inventory record?	Clinical Samples?

Note some of the key issues for Material:

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Material Control & Accountability

Material Control & Accountability

Material **Control** & Accountability

- **Control is either...**
 - Engineered / Physical
 - Administrative
- **Containment is part of material control**
 - Containment Lab / Freezer / Ampoule
- **Procedures are essential for material control**
 - For both normal and abnormal conditions



Note some of the key issues for Control:



Material Control & Accountability

All material should have an associated "accountable person" who is ultimately responsible for the material.

- The person best in a position to answer questions about the associated material
- Not someone to blame!
- Ensure that no material is "orphaned"



Note some of the key issues for Accountability:

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Accountability

Discussion

- What are some specific responsibilities that management could **assign** and **communicate** to an **accountable individual**?
- What are some ways management could ensure that responsibilities are met?



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

How can management ensure that these responsibilities are met?



Material Control & Accountability

Procedures should ensure accountability

- Experimental work: laboratory procedures
- Inventory: know what you have
- Reporting: document routine MC&A practices
- Audit/Assessment: is this working?
 - Ensures effective *implementation* of MC&A
- Training: personnel understand requirements

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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?

2



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.



MC&A Scenario

Group Exercise:

In your groups, please spend **10 minutes** to answer the following questions about the scenario.

1. What MC&A-related gaps and/or problems can you identify?
2. How could this have been prevented?
3. What should the role of leadership and/or management be to address these gaps and or problems?

Be prepared to report to the class.

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What are some MC&A problems?

How could they have been prevented?

What is the role of leadership/management?



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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Management's Role in MC&A

Group Exercise

- Effective MC&A requires that facility management define a number of parameters around:
 - Material
 - Control
 - Accountability
- In your groups, define what MC&A means to management.**
 - Give specific examples for Material, Control and Accountability.
 - Write each answer on a sticky note



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What does MC&A mean to management?

Material:

Control:

Accountability:

 **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?

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Notes:



Roles and Responsibilities

Scenario:

- We will now perform a **role playing exercise**
- **Read** the scenario
- Pick a **Role Card**
- Let's discuss:
 - What could go wrong from the perspective of the role you picked??



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What is your role?

What could go wrong from your perspective?



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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Assigning Roles and Responsibilities

 **Roles and Responsibilities**

Individual Exercise:

Work individually – for your role:

- What are your MC&A **responsibilities**?

Write down everything you can think of!

- Be sure to include **responsibilities** for Material, Control and Accountability.

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

Material:

Control:

Accountability:

 **Apply the AMP Model**

Group Exercise:

- Reorganize into groups based on your role
- Discuss with your group and organize each **responsibility** into the **AMP Model**
- Use the following format:

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

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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)		
	Responsibilities		
	Material	Control	Accountability
Assessment			
Mitigation			
Performance			

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

 **Exercise Recap**

Review
For **10 minutes**, let's reflect on the following statements:

- For the role that most closely fits your current position, determine the Plan Do Check Act (PDCA) for one responsibility under that role.
- Think about the communication requirements for that responsibility and how these responsibilities can be assigned and controlled.

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A circular diagram divided into four quadrants labeled P (Plan), D (Do), C (Check), and A (Act). Each quadrant contains small, colorful icons representing various elements of the process.

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

Plan:

Do:

Check:

Act:



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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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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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?

Use space on back, if needed