



Establishing Work Program Review & Approval


Student Guide



GLOBAL BIORISK MANAGEMENT CURRICULUM




Welcome to Establishing Work Program Review and Approval



Introductions

- Instructors
- Students
 - 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	
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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?

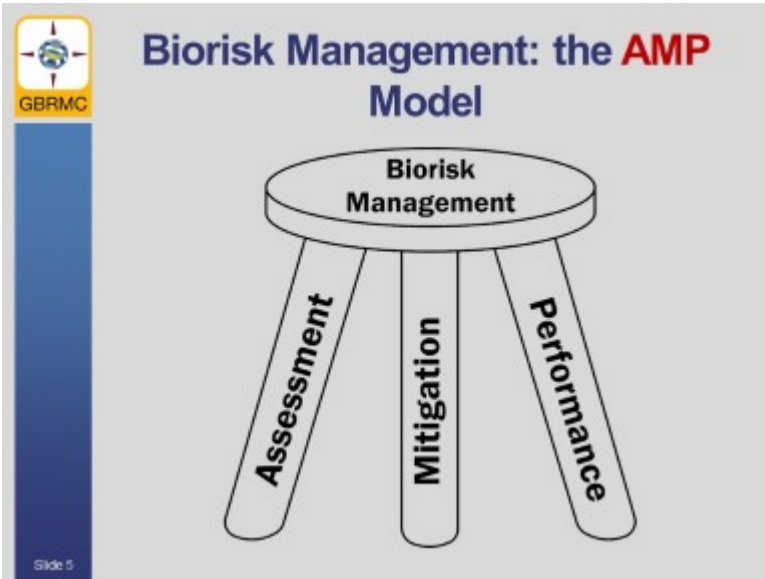
Use space on back, if needed




Key Messages

- The key to assessing priorities for the human capacity and physical infrastructure of a biorisk management system is to know what is occurring in the work program.
- Biorisk assessment relies on an accurate picture of the agents and situations in the work program.
- A transparent, robust, and reproducible peer-review process for defining, documenting, reviewing, and approving work helps identify “missing” hazards and issues.

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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



Slide 5

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




Slide 6

Define Biorisk Mitigation:



Key Components of Biorisk Management

- **Biorisk Performance**
 - The recording and evaluation of measurements to provide evidence that an organization is reliably and continuously conducting accurate biorisk assessments and implementing biorisk mitigation strategies that effectively reduce or eliminate identified biorisks to an acceptable degree.



Slide 8

Define Performance:



Exercise

Scenario:

- A laboratory director emails you a request to hire two additional full-time scientists and to purchase two biological safety cabinets.
- Another lab makes a request to send 4 staff members to a week-long biosecurity training course, out of country.
- Yet another lab requests hiring a consultant to evaluate laboratory SOPs on biosafety and biosecurity.

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Notes:



Exercise, continued

Exercise:

How do you juggle these requests? What information do you need to determine the **validity** and **importance** of the request to the individual lab's goals and to those of the organization, especially in the context of biorisk management.

In your groups, take **5 minutes** to write down the **questions** you would ask each lab. Write the questions in your **workbook**.

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What are some questions:



CWA 15793:2011

4.4.4.3 – Work programme, planning and capacity

- The organization shall ensure that the **programme of work** for the facility is **defined, documented, and reviewed**
- The organization shall establish **criteria** for work that requires prior approval
- It shall ensure there is sufficient **resource** capacity and capability to manage workflow, whether planned or unplanned.

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Notes:



Roundtable Exercise

Exercise Part 1:

Round 1:

Each small group is assigned a component of **work program assessment** (as specified in CWA 15793 4.4.4.3):

- Define
- Document
- Review
- Approve

In your groups, take **15 minutes** to discuss and answer the questions on the following slides for that component.

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What component of the work program assessment did your group choose?



Defining the Work Program

- Why is **defining** the work program important to biorisk management?
- What are the **data** necessary help define the work program?
- How can these data be **collected**?
- Who should be **involved**?



Slide 12

Notes:



Documenting the Work Program

- Why is **documenting** the work program important to biorisk management?
- What should be **documented**?
- Who should be **involved**?



Slide 13

Notes:



Reviewing the Work Program

- Why is **reviewing** the work program important to biorisk management?
- What **criteria** should be used to review the work?
- By what **process** is the work compared with the review criteria?
- Who should be **involved**?



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Notes:



Approving the Work Program

- Why is **approving** the work program important to biorisk management?
- What **criteria** should be used to approve the work?
- By what **process** is the work approved?
- Who should be **involved**?



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Notes:



Roundtable Exercise

Exercise Part 2:

- Rounds 2 to 4
 - Each group will rotate to the left.
 - Read the answers from the other group(s).
 - Discuss **in your small group** if any additional thoughts should be added to the existing answers.
 - **Take 5 minutes.**

Note: there will be overlap between answers for the four steps – these will be reconciled later in the exercise.

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Notes:



Roundtable Exercise

Exercise Part 3:

- Go back to your original table.
- Read the additional thoughts from the other groups.
- **As a class, develop a matrix** for work program assessment using the answers from Parts 1 and 2 of this exercise.
- Use the matrix in your **workbook** and the matrix cells provided by the instructor.
- **Take 15 minutes.**

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What comments did you receive?

Roundtable Exercise, Part 3

	Using what data or criteria?	By what process?	Who is involved?
Define			
Document			
Review			
Approve			





CWA 15793:2011

4.4.1.3 Biorisk management committee [BRMC]

- A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management, the committee shall:
 - Have documented terms of reference;
 - Include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken;
 - Ensure issues addressed are formally recorded, actions allocated, tracked and closed-out effectively;
 - Be chaired by a senior individual;
 - Meet at a defined and appropriate frequency, and when otherwise required.

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Is a BRMC also Called an IBC?

- In many institutions, especially in the U.S., a committee with similar responsibilities to those specified in CWA 15793:2011 is called an **Institutional Biosafety Committee** (IBC).
- The name is not important. The **responsibilities** and **function** of the committee ARE important.



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BRMC Membership

[T]he committee shall include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken

- Why does review by a **committee**, rather than an **individual**, promote effective biorisk management?
- Why is a **diversity** of members important?
- **Make a list of members** that might be appropriate for BRMC membership. Put each role on a **sticky note**.

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What are the advantages of a committee?

What members would be useful to have?




CWA 15793: 2011, continued

4.4.1.3 Notes

- Functions of the committee should include:
 - Contributing to the development of institutional biorisk management **policies and codes of practices**;
 - **Approving proposals for new work or significant modifications** to the potential risk associated with existing activities;
 - **Reviewing and approving protocols and risk assessments** for work involving biological agents and toxins;
 - **Reviewing** information relating to significant **accidents/incidents**, data trends, associated local/organizational actions and associated communication needs.

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Notes:



BRMC and Work Program Assessment

Exercise:
Look at the **Work Program Assessment** process you created:

- Which aspects of this process are appropriately assigned to a BRMC? Why?
- Which are NOT appropriate for BRMC assignment? Why not?

As necessary, **revise** the **Work Program Assessment** to reflect the **responsibilities of the BRMC**.

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What aspects of the Work Program Assessment process could be assigned to a BRMC?

Which are not appropriate for a BRMC?




Terms of Reference

- **Terms of Reference** describe the purpose and structure of a project, committee, meeting, negotiation, or any similar collection of people who have agreed to work together to accomplish a shared goal.
- **Terms of Reference** define the:
 - Vision, objectives, scope and deliverables (i.e. what has to be achieved)
 - Members and stakeholders, roles and responsibilities (i.e. who will take part in it)
 - Resource, financial and quality plans (i.e. how it will be achieved)
 - Work breakdown structure and schedule (i.e. when it will be achieved)

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What are the benefits of terms of reference?



BRMC Terms of Reference

Exercise:

Create a draft **BRMC Terms of Reference**.

- Each group will work on one aspect and write their answers in their **workbook**:
 - Vision, objectives, scope and deliverables
 - Members and stakeholders, roles and responsibilities
 - Resource, financial and quality plans
 - Work breakdown structure and schedule
- **Take 10 minutes.**

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Draft BRMC Terms of Reference:



Summary

- For appropriate assessment, mitigation, and performance measurements of biorisk management systems, the organization needs to have information on the work occurring.
- Work program information should be collected in a consistent, comprehensive, and transparent manner.
- Using a peer group, like a biorisk management committee, to review and approve a work program is an effective way to assure that a diversity of elements of biorisk management have been considered and address.

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Notes:



Review

To wrap-up, let's discuss what we learned about **Establishing Work Program Review & Approval?**

What did we learn?

What does it mean?

Where do we go from here?

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Action Plan

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Slide 3

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