SAND2014-4143P

Orientation to Biorisk Management

Student Guide

Welcome to Orientation to Biorisk Management!

Introductions

- Instructors
- Students
  - Your name?
  - Where are you from?
  - What do you hope to gain from the course?

Action Plan

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

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

- Understand: biorisk, biosafety, biosecurity, biorisk management system
- To use AMP (Assessment, Mitigation, and Performance) as a simple model for managing biorisks
- Implementing a comprehensive biorisk management system is critical to reduce both the safety and security risks associated with handling, storage and disposal of biological agents
- Dual use is an issue relevant to all researchers
- All researchers have a role in upholding a high standard for the responsible conduct of research.
- Some of the key factors in establishing and implementing a successful biorisk management system include commitment by top management and a focus on continual improvement

Orientation to Biorisk Management

Group Activity

- Split into groups:
- In your group, take 10 minutes to discuss and answer the following question:
- ***What are the risks of working in a laboratory with biological materials?***
- Write down your answers and be prepared to report to the class

What are the risks of working in a laboratory with biological materials?

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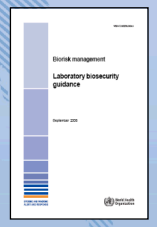
Definitions

- **Laboratory biosafety**: containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]
- **Laboratory biosecurity**: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. [2]

[1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)

[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)



Laboratory biosafety definition:

Laboratory biosecurity definition:

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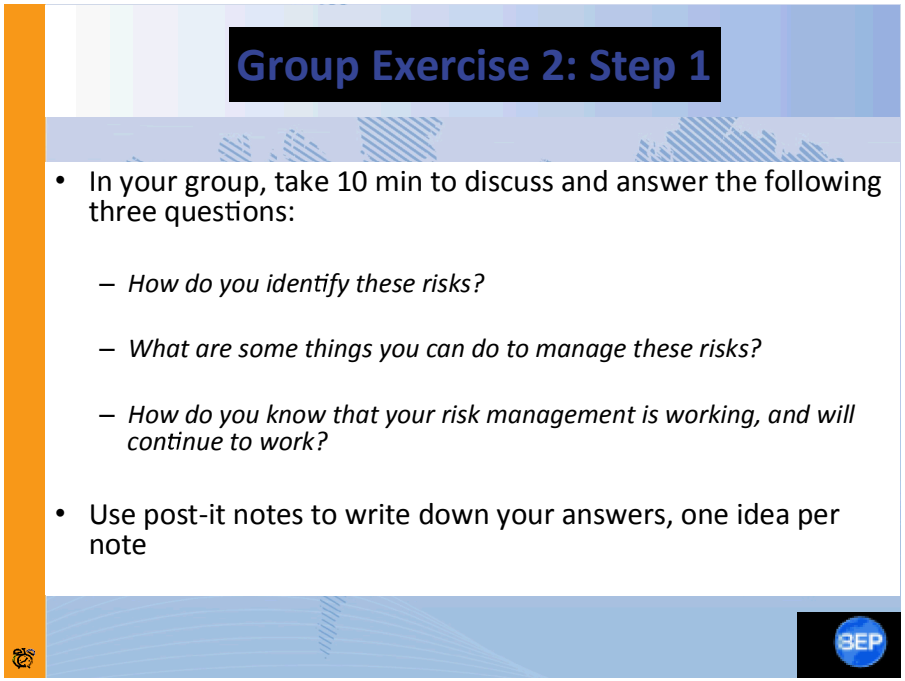
Biorisk

- The risk associated with biological materials in the laboratory
- Biorisk encompasses biosafety and biosecurity

Define Biorisk:



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How do you identify these risks?

What are some things you can do to manage these risks?

How do you know that your risk management system is working and will continue to work?

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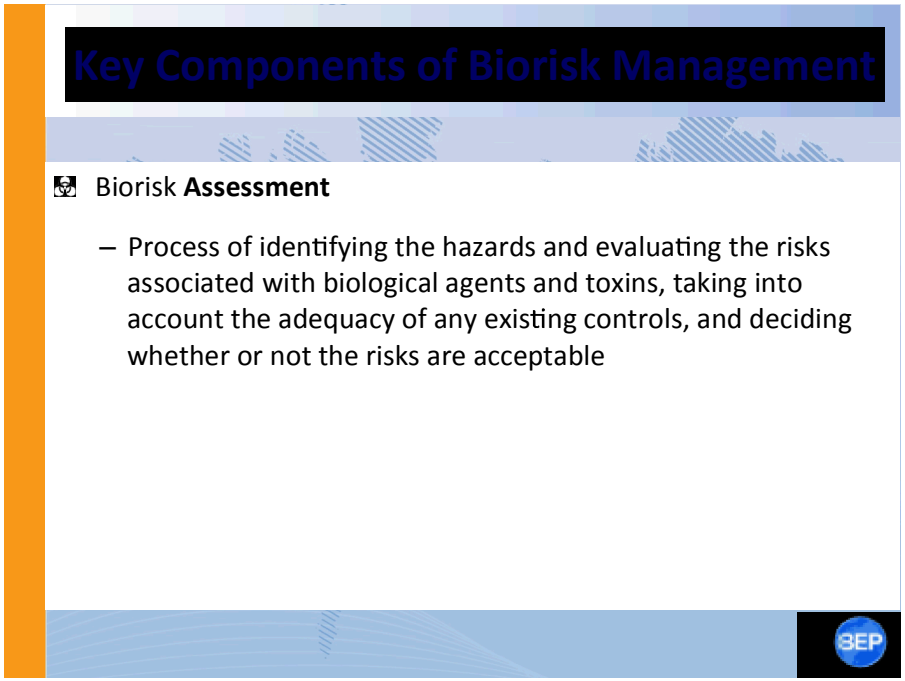

Define Biorisk Assessment:

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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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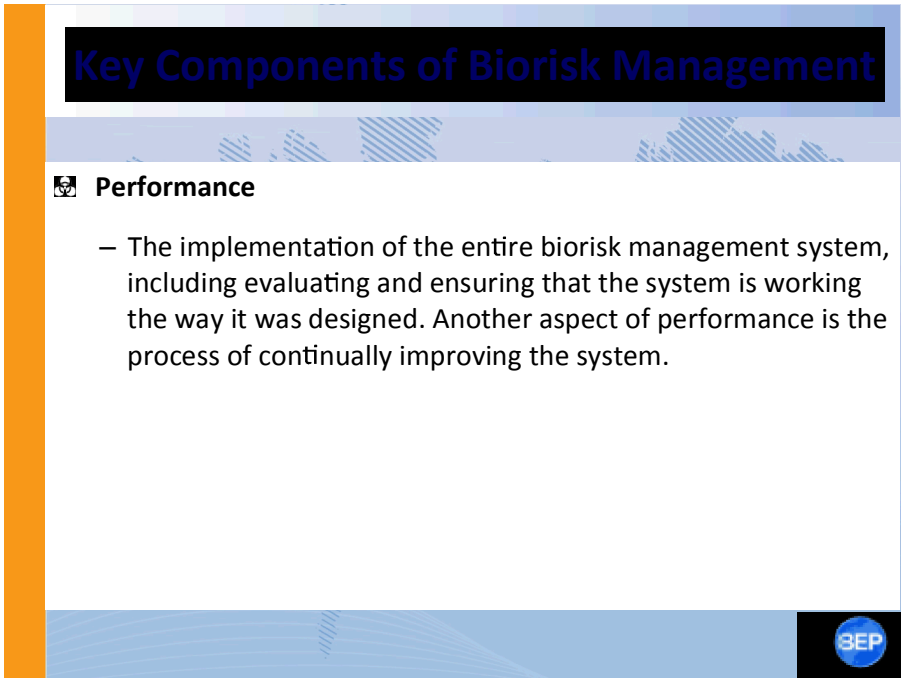

Define Performance:

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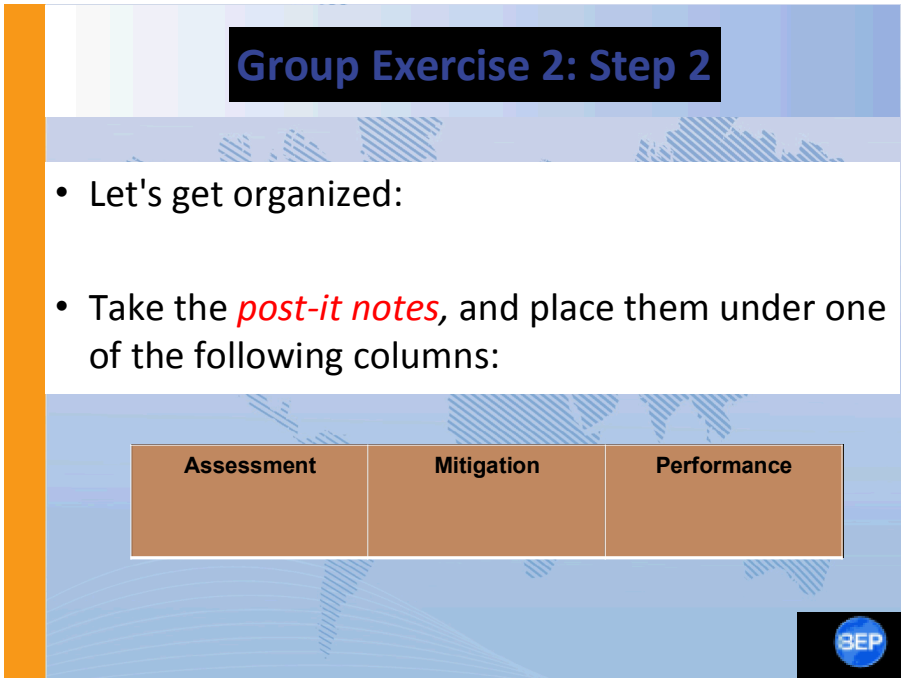

Assessment

Mitigation

Performance

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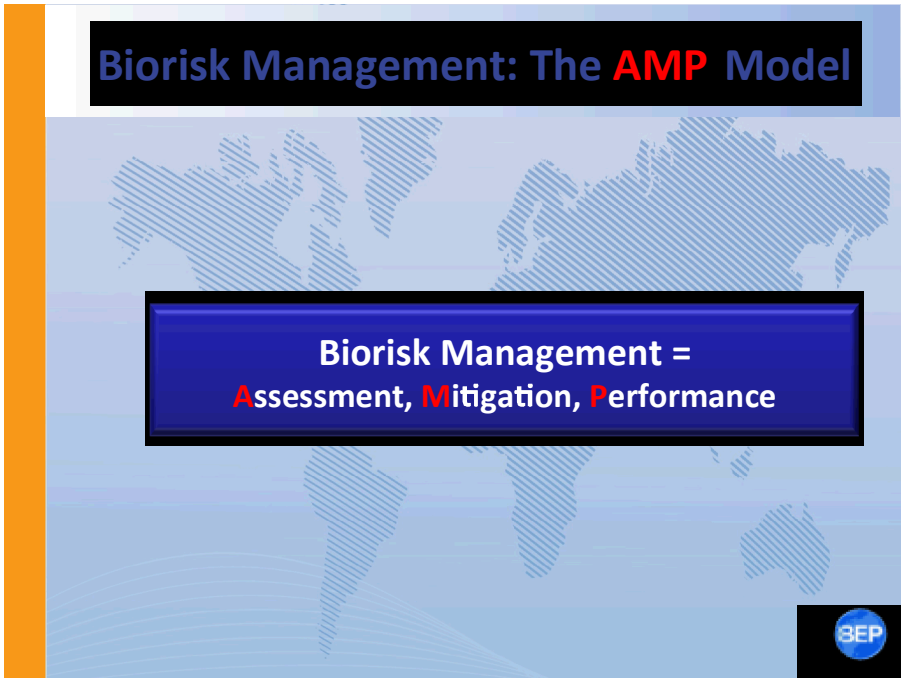

Define biorisk management system (the next activity may help you construct your definition):

Describe an AMP model:

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Management System

- In your group, take 10 minutes to discuss and answer the following questions:

What is a "management system"? And why is it important?

- Develop a definition for a management system and write it down.
- Be prepared to report to the class

A "management system" is…

Benefits of a management system include…

Record the definition of a management system that is agreed upon.

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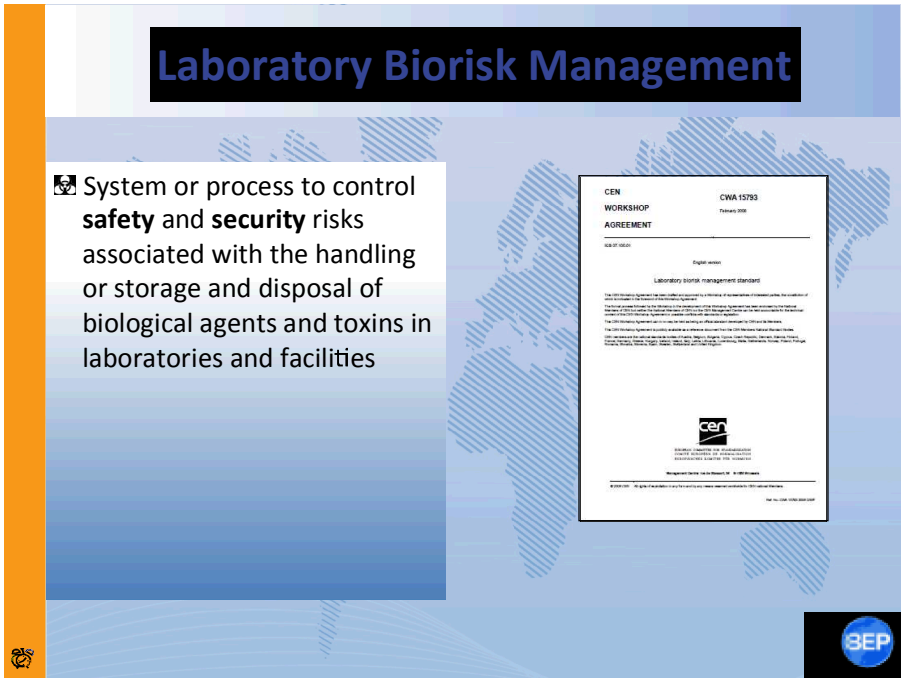

CEN Workshop Agreement (CWA): a comprehensive framework for managing biorisks developed through international collaboration.

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CWA 15793: Laboratory Biorisk Management

- Is a management system standard consistent with other international standards such as
  - ISO 9001 / 14001 and OSHAS18001
- The Standard is performance oriented
  - Describes what needs to be achieved
  - How to do it is up to the organization
- Does not replace national regulations
  - Compliance with local regulations is mandatory under CWA 15793
- Designed to be comprehensive framework for biosafety & biosecurity (biorisk) program
  - Risk-based; applicable to broad range of organizations, not just high containment labs

The CWA('s):

- Is a management system
- Standards outlined are performance oriented
- Does NOT replace national regulations
- Is designed to be comprehensive framework for biorisk programs

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Purpose of the CWA 15793:2011

The Standard is used for:

- Improving overall laboratory biorisk management and performance
- Increasing awareness and the adoption of performance (outcome) based approaches for biosafety and biosecurity
- Improving international laboratory collaboration and safety harmonization
- Supporting laboratory certification/ accreditation, audits/inspections

The purpose of the CWA is to improve, increase, and support safety and security (when applicable) of biolabs.

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International Approach

- Extensive definition section
- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- Derived from the current WHO Biosafety and Biosecurity Guidelines

How does the CWA have the ability to be accepted internationally?

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CWA 15793:2011 Examples of Topics Covered:

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

Topics of the CWA

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Group Exercise

- Individually, carefully read the *Cataract University* exercise
- Split into groups
  - Identify ***problems*** with Biorisk Management. These problems could be associated with assessment, mitigation or performance
  - Use post-it notes, one for each problem
  - Place post-it notes on your flip chart
- How have these problems affected the university?
- Report out results to full group

Problems found in the biorisk management system of Cataract University:

1.

2.

3.

4.

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The Role of Ethics for Biosecurity

Potential for misuse of biological agents

- Theft, diversion, weaponizing an agent, dual-use

Possible Solution:

- Know what you don't know
  - Understand the risk
  - Consider how otherwise benign biological research may be misused
  - **Utilize Bioethics Principles**

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Dual Use Traditional Definition

- What is **Dual Use**?
  - **Traditional Definition**
    - "Goods and technologies are considered to be dual-use when they can be used for both civil and military purposes."
      - » European Commission – Trade Website http://ec.europa.eu/trade/creating-opportunities/trade-topics/dual-use/
    - "'Dual-Use items' shall mean items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices"
      - » Council Regulation (EC) No 428/2009

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Dual Use Research of Concern

- **National Security Advisory Board for Biosecurity** (NSABB):
  - It can be argued that virtually **all life sciences** research has dual use potential.
  - Research that has the **highest potential** for misuse is classified as **Dual Use Research of Concern**.

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Instilling Positive Bioethics

Codes of Conduct/Ethics

- Institutional
- These may involve **punitive measures**, and/or be upheld through **behaviorally enforced** and **peer-regulated** means rather than things like audits
- **Opportunity for application to manage Dual Use Research of Concern**

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Code of Conduct Activity

Exercise:

Individually, spend **5 minutes** to think about the **factors that make a successful code of ethics** and how they are implemented, or could be implemented, at **your institution**.

To help with this task, consider the answers to the following questions:

- Is there a code of conduct at your institution?
- If you had to create a code of ethics what specific factors would you include?

Write your answers in your student guide.

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Code of Conduct Activity

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Bioethics - Individual Role

- Each individual is **responsible** for their own behavior.
- While "**do no harm**" is important, it is more critical to "**do good while minimizing harm**."
- Each individual has a responsibility to **report** or **formally address** ethical violations to preserve their personal integrity, and protect the integrity of their institution
- **Address ethical dilemmas**
  - In the absence of legal recourse, the society will benefit from ethically conduct research

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Bioethics - Institutional Role

- **Each institution is responsible** for ensuring proper oversight and training to manage dual use research of concern
- The institution is **required to address any ethical dilemmas** brought to its attention by one of its researchers in a discrete and timely manner

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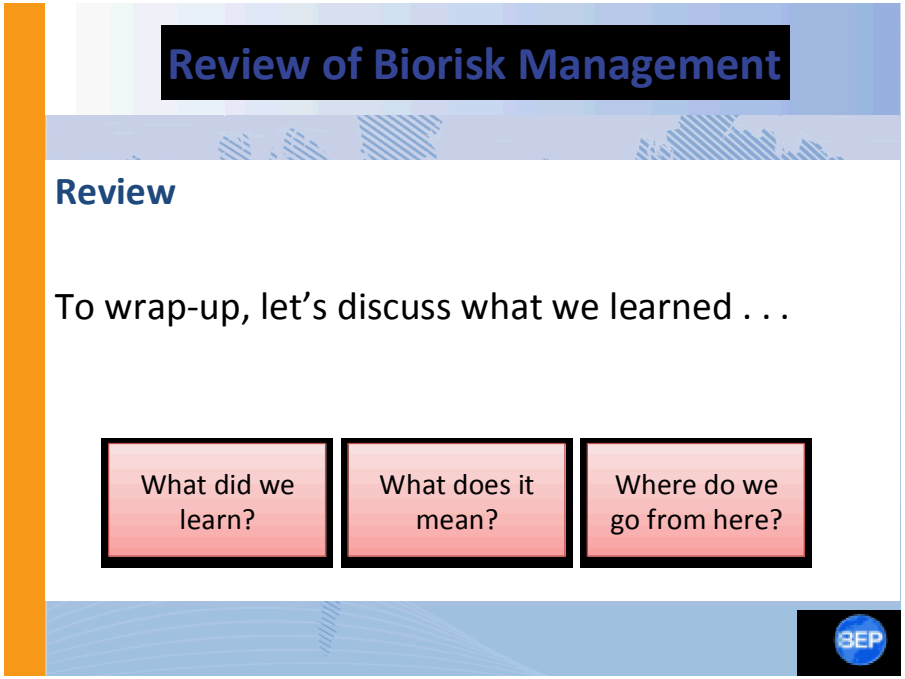
Review of Biorisk Management
Review
To wrap-up, let's discuss what we learned . . .
What did we learn?
What does it mean?
Where do we go from here?

Review of Biorisk Management

- Biorisk Management = Biosafety + Biosecurity
- Biorisk Management System is a means to reduce Biorisk
- AMP = Assessment, Mitigation, Performance
- CWA 15793 outlines a comprehensive, international biorisk management system framework

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