SAND2012-0243C

Orientation to Biorisk Management

Module 1

BIOSECURITY ENGAGEMENT PROGRAM

CBEP

Module Objectives

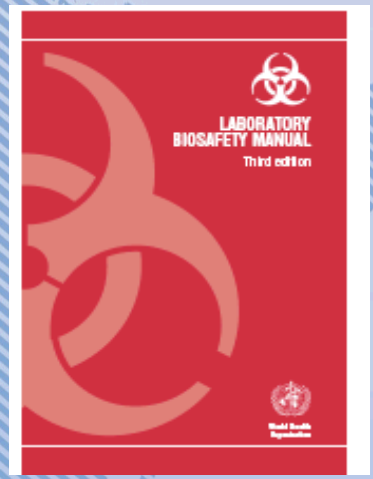
- Understand: biorisk, biosafety, biosecurity, biorisk management system
- To use AMP (Assessment, Mitigation, and Performance) as a simple model for managing biorisks
- Implementing a comprehensive biorisk management system is critical to reduce both the safety and security risks associated with handling, storage and disposal of biological agents
- CWA 15793 is a comprehensive framework for managing biorisks developed through international collaboration.
- 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

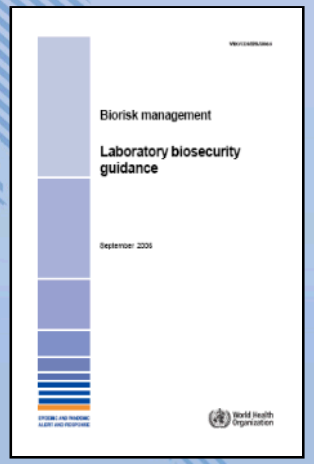
Group Activity

- 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

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)

Biorisk

- The risk associated with biological materials in the laboratory

- Biorisk encompasses biosafety and biosecurity

Group Exercise 2: Step 1

- In your group, take 10 min to discuss and answer the following three questions:
  - *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 is working, and will continue to work?*
- Use post-it notes to write down your answers, one idea per note

BREAK

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

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

Key Components of Biorisk Management

- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Group Exercise 2: Step 2

- Let's get organized:

- Take the *post-it notes*, and place them under one of the following columns:

Assessment	Mitigation	Performance

Biorisk Management: The AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Management System

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

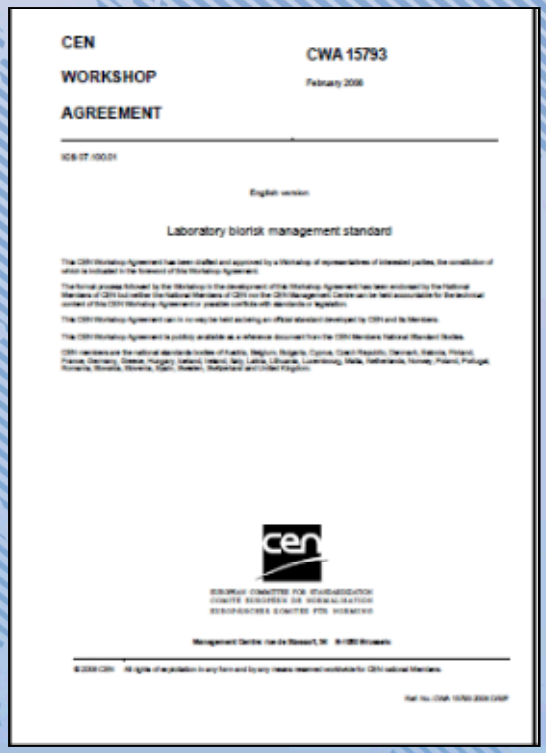
What is a "management system"? And why is it important?

- Develop a definition for a management system and write it down.

- Be prepared to report to the class

Laboratory Biorisk Management

- System or process to control **safety** and **security** risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities



CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2006

Laboratory biorisk management standard

BREAK

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

Purpose of the CWA 15793:2011

The Standard is used for:

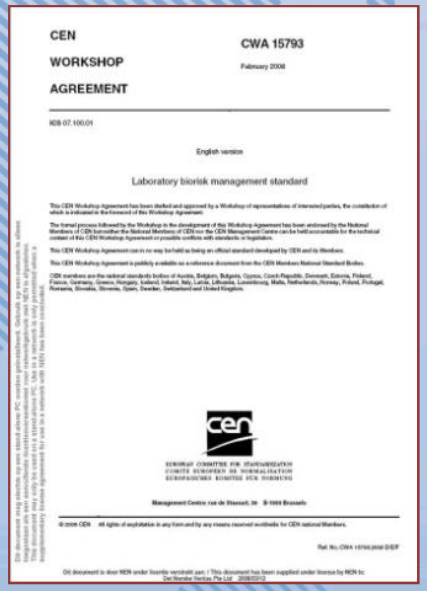
- Improving overall laboratory biorisk management and performance
- Increasing awareness and the adoption of performance (outcome) based approaches for biosafety and biosecurity
- Improving international laboratory collaboration and safety harmonization
- Supporting laboratory certification/accreditation,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

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

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



CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2008

Laboratory biorisk management standard

BIOSECURITY ENGAGEMENT PROGRAM

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Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- The standard is not a technical document
- Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives
  - **Provides Biorisk management framework for the day-to-day functions of the institute / organization during both normal operations and times of emergency**

Group Exercise 3, Step 1

- 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

Group Exercise 3, Step 2

- In the same groups, use the table of contents of the CWA15793 to develop recommendations for change at Cataract University
  - Choose one problem from the list
  - Recommend specific changes in Biorisk Management that the leadership at Cataract University can implement to address this problem
  - Identify the specific paragraphs in CWA 15793 that apply to your selected solutions
- Record your conclusions on a flip chart
- Report the results to class

Individual Reflection

If you could make three changes to the management system at your facility today, what are your top three priorities?

BREAK

Group Exercise

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

- ***What are the key challenges or factors to consider in establishing and implementing a biorisk management system?***

- Write down at least 3 – 5 factors and be prepared to report to the class

Individual Reflection

- How could you improve biorisk management at your own lab, short-term and long-term?
- What would be the benefits of implementing a more comprehensive standardized biorisk management system?
- Write your answers on a piece of paper; you only have to share your answers if you wish

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

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?

THANK YOU!