SAND2014-17109PE

Orientation to Biorisk Management

Introductions

- Instructors
- Students
  - What is your name?
  - Where are you from?
  - What do you hope to gain from this course?

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?

Use space on back, if needed

Key Messages

- “Biosafety”, “biosecurity”, “biorisk”, and “biorisk management system” are common biorisk terms that relate to and support each other.
- AMP (Assessment, Mitigation, and Performance) is a simple but powerful model for managing biorisks.
- Implementing a comprehensive biorisk management system is critical to reduce both the safety and security risks associated with biological agents.
- Some key factors for establishing and implementing a successful biorisk management system include commitment by top management and a focus on continual improvement.
- CWA 15793 is a comprehensive framework for managing biorisks developed through international collaboration.

Group Exercise

In your group, discuss and answer the following two questions:

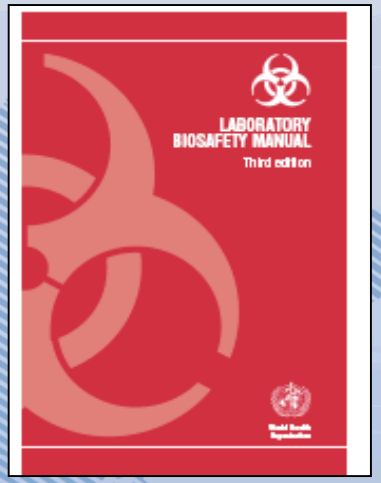
1. **What are the risks when working with biological materials?**

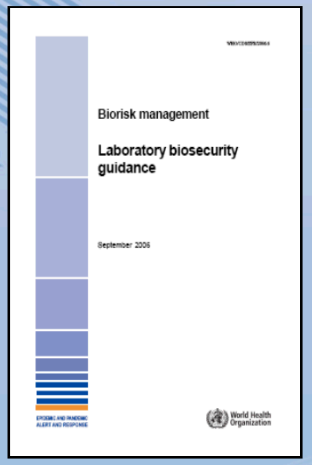
2. **Where does work with biological materials occur?**

Take **10 minutes** and write down your answers; be prepared to share your answers with 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)

Group Exercise

In your group, discuss and answer the following questions:

1. **What is one example of a biosafety measure?**

2. **What is one example of a biosecurity measure?**

Take **5 minutes** and write down your answers on post-it notes, **one idea per note**. Be prepared to share your answers with the class.

What is Biorisk?

Risk associated with biological materials

Biorisk = biosafety + biosecurity risks

Group Exercise: Step 1

In your group, discuss and answer the following three questions:

1. **How do you identify biorisks?**
2. **What are some things you can do to manage these risks?**
3. **How do you know that your risk management is working, and will continue to work?**

Take **10 minutes** and write down your answers on post-it notes, **one idea per note.**

Key Components of Biorisk Management

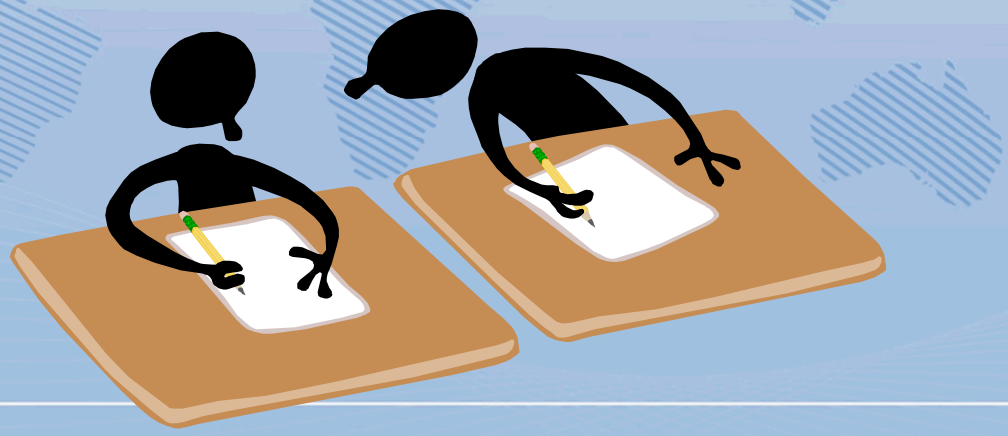
- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

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**
  - 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: Step 2

Let's get organized. Take the ***post-it notes***, and place them under the **appropriate category**:

Assessment	Mitigation	Performance

Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Management System

A management system is a set of interrelated elements used to establish policy and objectives and to achieve those objectives.[1]

Group Exercise:
In your group, discuss and answer the following question:

What results would you expect in a situation with a good management system in place versus no management system at all?

Take **10 minutes** and write down your answers; be prepared to share your answers with the class.

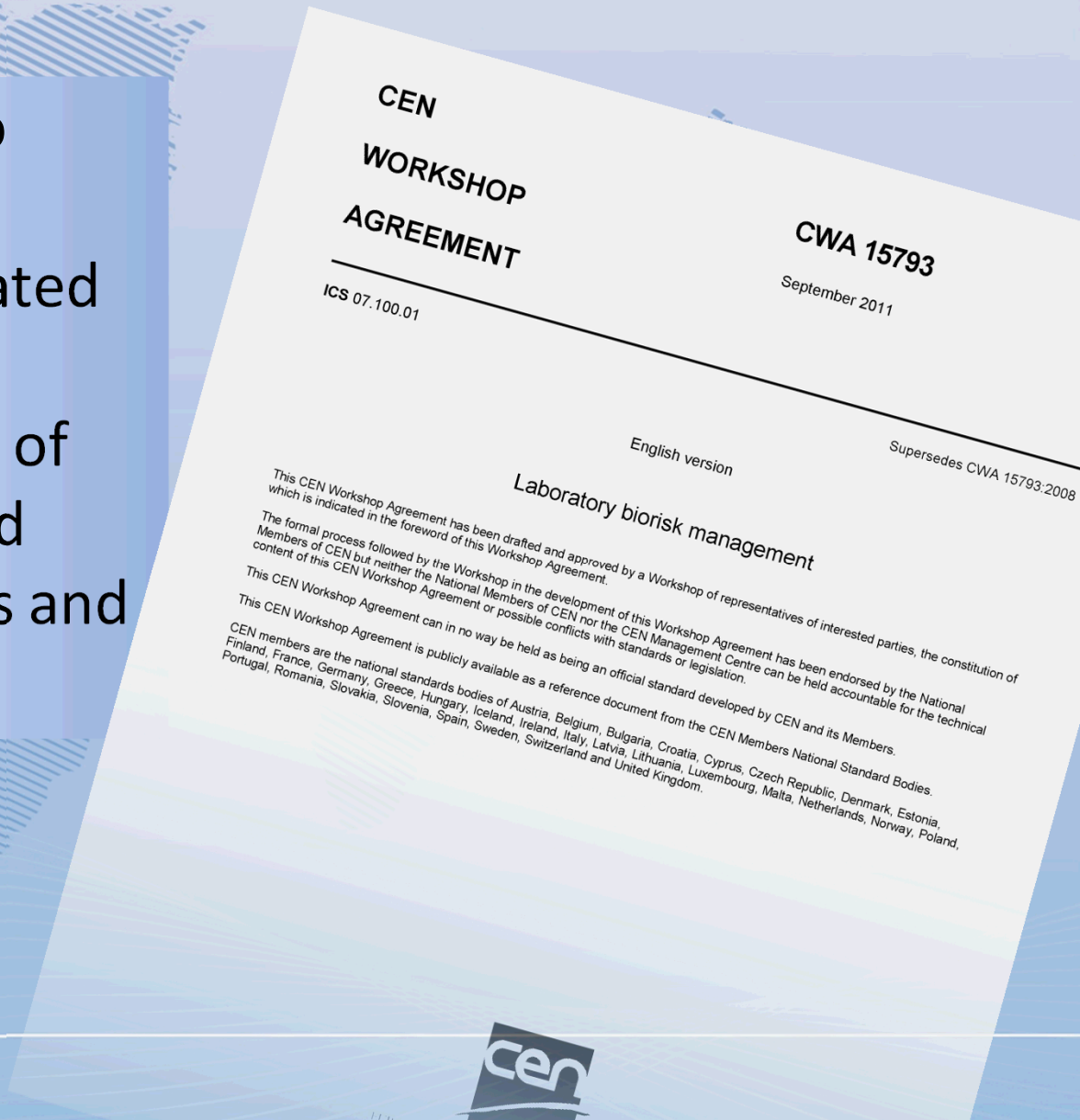
[1]CWA 15793 – Laboratory biorisk management (CEN, 2011)

Important Elements of a Management System

Teamwork and Communication

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

ICS 07.100.01

September 2011

English version

Supersedes CWA 15793:2008

Laboratory biorisk management

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

CWA 15793 – Laboratory Biorisk Management

- Comprehensive **framework** for a biosafety & biosecurity (biorisk) program
- Based on a management systems approach
- Designed for **all** laboratories that handle biological materials
- **Freely available** on the CEN website:

  ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf

CWA 15793 – International Approach

- Derived from the current **WHO Biosafety and Biosecurity Guidelines**
- Consistent with other international standards such as
  - ISO 9001/14001 and OSHAS18001
- **Not country specific**
  - **Local solutions possible**
  - Compliance with national and local regulations mandatory

CWA 15793 – Major Sections

4.1 General Requirements

4.2 Policy

4.3 Planning

4.4 Implementation and Operation

4.5 Checking and Corrective Action

4.6 Review

- **Assessment**
  - Hazard Identification
  - Risk Assessment
- **Mitigation**
  - Good microbiological technique
  - Waste management
  - Physical security
- **Performance**
  - Performance measurement and analysis of data
  - Management review

CWA 15793 is Performance-Oriented

- Describes ***what*** needs to be achieved
- Allows ***organizations*** to determine how best to achieve those objectives
- ***Not*** a technical document
- Example:

> 4.4.4.5.3 Waste Management
>
> The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins

Group Exercise: Step 1

1. Individually, carefully **read** the exercise.
2. 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 the post-it notes on your flip chart.
   - Discuss how these problems affected the institution.
3. Share your results with the class.

Group Exercise: Step 2

1. Choose **one** biorisk management **problem** from the previous exercise:

   - **Identify** the **specific paragraphs** in **CWA 15793** that apply to this problem. Is the organization in **conformance** with **CWA 15793**?

   - **Recommend** specific **changes** in biorisk management that the leadership can implement to address this problem.

2. Record your conclusions on a flip chart.

3. Share your results with the class.

CWA 15793 – Implementation

How to implement CWA 15793?

How would you eat a dinosaur?

CWA 15793 – Implementation

How to implement CWA 15793?

One bite at a time

Plenary Discussion

Process for the implementation of a biorisk management system

1. **What needs to be in place before starting?**
2. **Where would you start?**
3. **Are there past experiences that may provide guidance?**

Individual Reflection

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

1.?

2.?

3.?

Group Exercise

In your group, discuss and answer the following question:

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

Take **5 minutes** and write down at least 3 – 5 factors; be prepared to share your answers with the class.

Review - Introduction to Biorisk Management

For **10 minutes**, let's discuss what we have learned about **biorisk management**.

What did we learn?	What does it mean?	Where do we go from here?

Review - Key Messages

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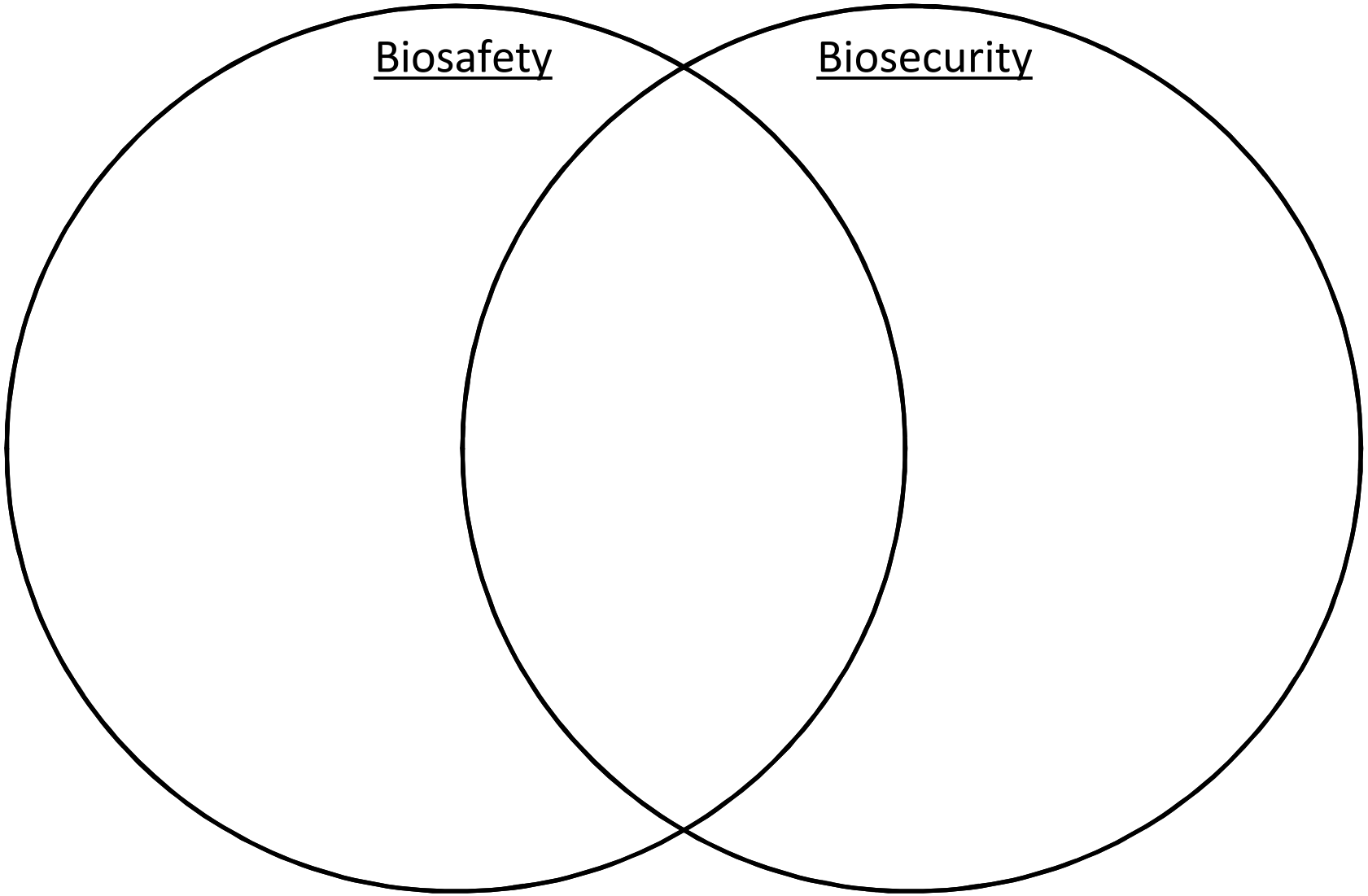
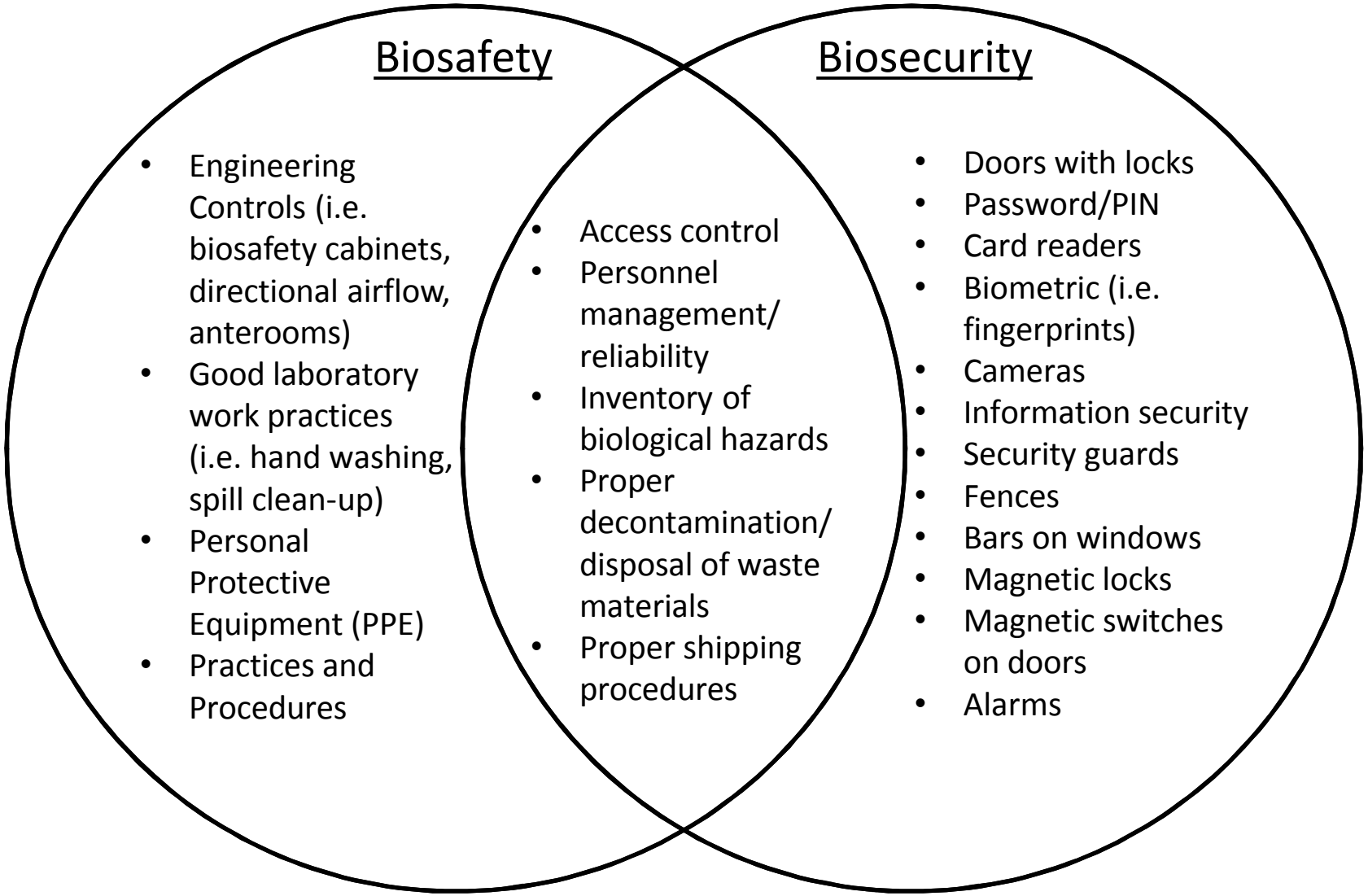
Thank You!

Don’t forget to complete your evaluation!


Biosafety
Biosecurity


Biosafety
Engineering Controls (i.e. biosafety cabinets, directional airflow, anterooms)
Good laboratory work practices (i.e. hand washing, spill clean-up)
Personal Protective Equipment (PPE)
Practices and Procedures
Access control
Personnel management/ reliability
Inventory of biological hazards
Proper decontamination/ disposal of waste materials
Proper shipping procedures
Biosecurity
Doors with locks
Password/PIN
Card readers
Biometric (i.e. fingerprints)
Cameras
Information security
Security guards
Fences
Bars on windows
Magnetic locks
Magnetic switches on doors
Alarms