

# Biosafety Risk Assessment

## *Student Guide*



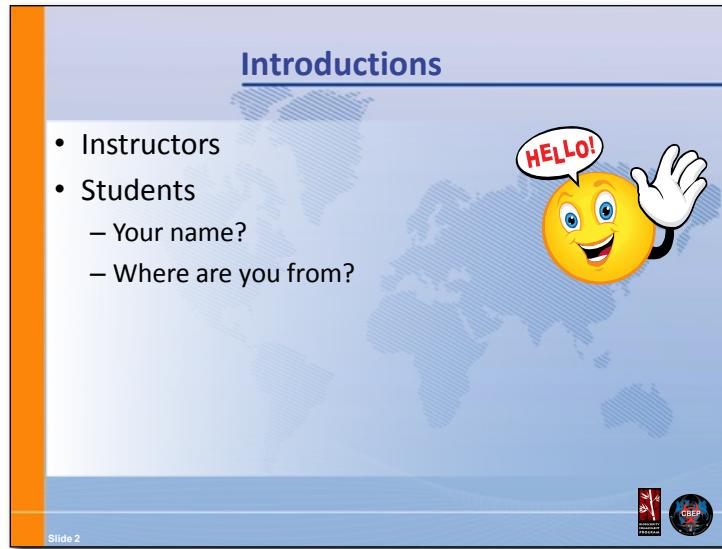


## *Biosafety Risk Assessment*

## *Welcome & Introductions*

Welcome to Biosafety Risk Assessment



A slide titled "Introductions" featuring a yellow smiley face with a speech bubble saying "HELLO!" and a hand waving. The background is a world map. The slide includes a bulleted list of "Instructors" and "Students" with questions, and logos for the University of Alberta and CIEP. A small "Slide 2" is visible in the bottom left corner.

**Introductions**

- Instructors
- Students
  - Your name?
  - Where are you from?

Slide 2



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?



### Course Objectives

- A risk assessment is defined as a procedure that analyzes a particular process or situation in order to determine the likelihood and consequences of a certain adverse event and will be unique to each laboratory.
- To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.
- A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk.
- Risk Evaluation is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk and is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution

Slide 4

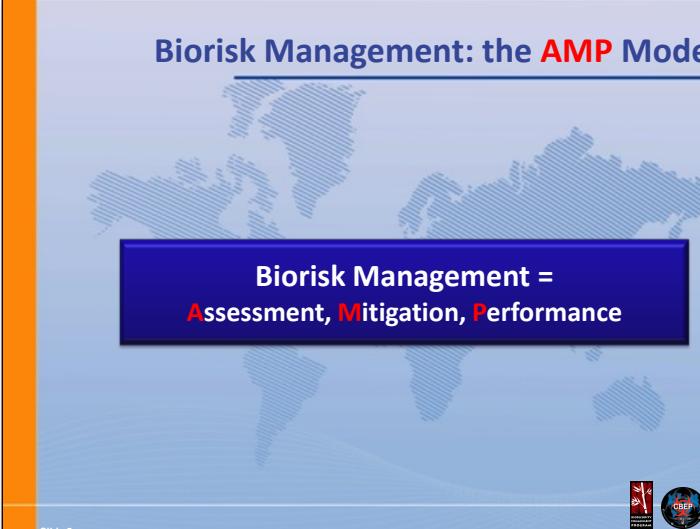
Two small circular logos: one with a stylized orange and red design, and another with a blue and white design.



## ***Biosafety Risk Assessment***

*Biorisk Management*

# Biorisk Management: the **AMP** Model



**Biorisk Management =  
Assessment, **Mitigation**, Performance**

CBEP

Record refresher notes on the AMP model and biorisk management.



## *Biosafety Risk Assessment*

## *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 6



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 7

Define Biorisk Mitigation:



### **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.



Slide 8

Define Performance:



## *Biosafety Risk Assessment*

## *Introduction to Biosafety Risk Assessment*

### **Introduction to Biosafety Risk Assessment**

A **biosafety risk assessment** is an analytical procedure designed to characterize and evaluate **safety** risks in a laboratory.



Slide 9

### **Introduction to Biosafety Risk Assessment**

To be comprehensive:

A **biosafety risk assessment** should consider **every activity and procedure** conducted in a laboratory that involves **infectious disease agents**.

Slide 10

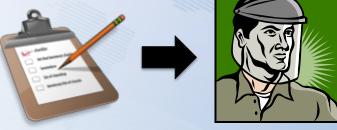


## Biosafety Risk Assessment

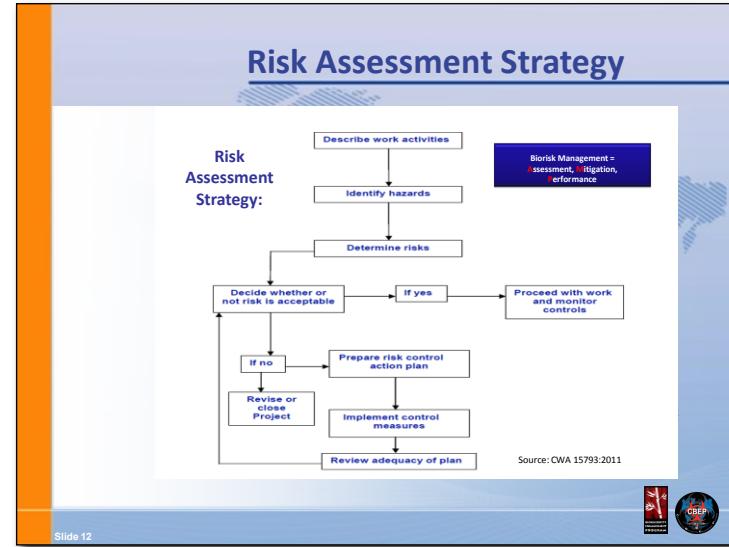
## Introduction to Biosafety Risk Assessment

### Introduction to Biosafety Risk Assessment

A **biosafety risk assessment** allows a laboratory to determine the relative level of risk its different activities pose, and helps guide **risk mitigation decisions** so these are targeted to the most important risk.



Slide 11





## *Biosafety Risk Assessment*

## *What is Risk?*

**Risk**

**Group Activity:**

**Question:** What is “**risk**”?

**In your groups**, please spend **5 minutes** to develop a **definition** for “**risk**”. Choose someone from your group to share the definition with the class.

What did your group come up with?

Slide 13

What is Risk?



## Biosafety Risk Assessment

## What is Risk?

**Risk**

**Question:** What is Risk?

**Risk is the likelihood of an undesirable event happening, that involves a specific hazard, and has consequences**

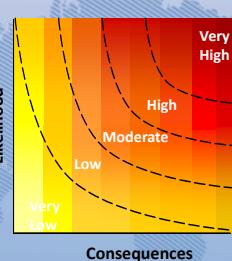
**Risk =  $f$  (likelihood, consequences)**  
or, more simply,

**Risk is a function of both the Likelihood of something happening and Consequences of that occurrence**

**Likelihood**

**Consequences**

**RISK**



Slide 14

How can Risk be expressed?

What is risk a function of ?



## Biosafety Risk Assessment

## What is Risk?

**Risk**

**Question:** What is the **risk** of being attacked by a tiger?

What would you need to know to answer this question?

To help with this task, in your group, spend **5 minutes** listing all **examples of useful information** on sticky-notes and place them on your flip chart.

Be prepared to report your **criteria** to the class.

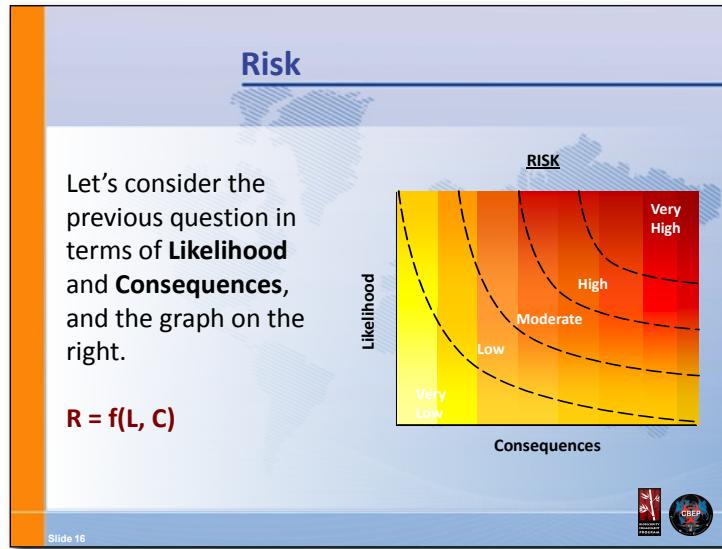
Slide 15

What is some information you would need to know the risk of being attacked by a tiger?



## Biosafety Risk Assessment

## What is Risk?



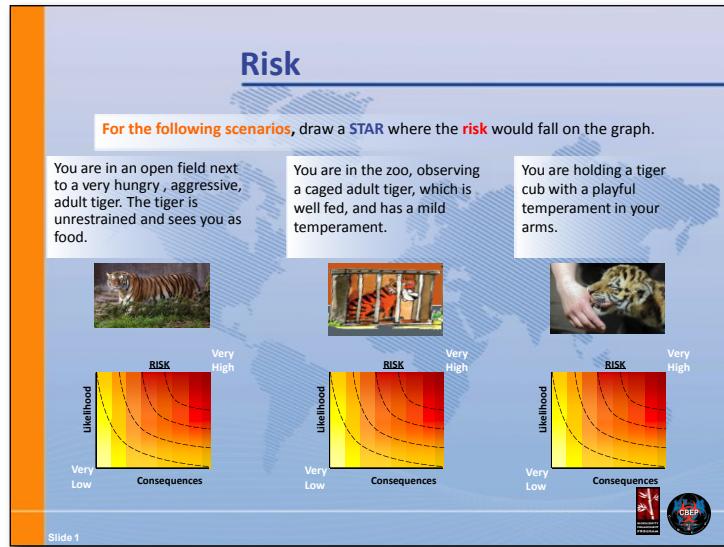
What is the likelihood of being attacked by a tiger?

What are the consequences of being attacked by a tiger?



## Biosafety Risk Assessment

## What is Risk?



What is the risk for each Scenario?

Scenario #1

Rationale:

Risk:

Scenario #2

Rationale:

Risk:

Scenario #3

Rationale:

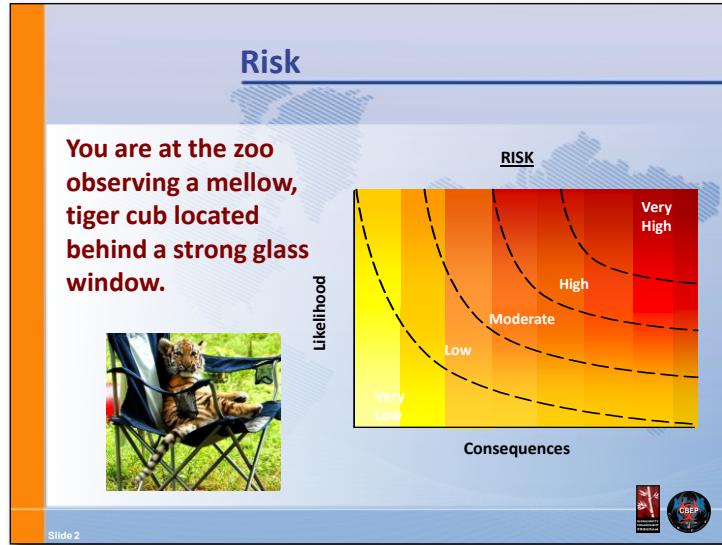
Risk:



## Biosafety Risk Assessment

## What is Risk?

What is the risk of being attacked in this scenario?





## *Biosafety Risk Assessment*

### **Biosafety Risk Assessment**

A **Risk Assessment** is a procedure that analyzes a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

In **Laboratory Biosafety**, we are concerned with preventing unintentional adverse events involving infectious disease agents.

To properly conduct a **laboratory biosafety risk assessment**, it is important first to gather certain information about the laboratory procedures involving biological agents and toxins, as well as information on the agents and toxins themselves.

Slide 19



## ***Biosafety Risk Assessment***

## ***Laboratory Biosafety Risk Assessment***

# Biosafety Risk Assessment

**Question:**

What factors should be considered in a **laboratory biosafety risk assessment**? (What are the factors that affect **Likelihood** and/or **Consequences**?)

In your group, please spend **10 minutes** to answer the above question.

To help with this task, list all the **factors** on sticky-notes and place them on your flip chart.

Be prepared to report your answers to the class.

What are some factors that should be considered in a laboratory biosafety risk assessment?

## Factors:



## Biosafety Risk Assessment

## Laboratory Biosafety Risk Assessment

### Risk Characterization

As you can see many of the factors regarding laboratory biosafety risk rely on the **agent characteristics** and the laboratory **procedures**.

The **risk of exposure** to an agent is dependent on these factors.

Slide 21



### Risk Characterization

**Activity:**

We will work together, through a series of examples to practice determining the **risk of exposure** associated with an experiment.

Slide 22





## Biosafety Risk Assessment

## Laboratory Biosafety Risk Assessment

### Risk Characterization

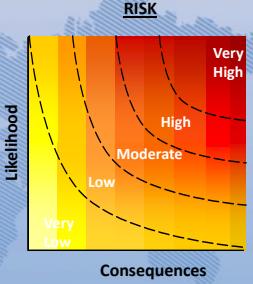
**Scenario:**  
Suppose you are working with a **seasonal influenza virus**, conducting **aerosol-challenge studies** on an animal host, with little respiratory protection.

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?

Slide 3



A risk matrix diagram titled 'RISK' in the top right corner. The vertical axis is labeled 'Likelihood' and the horizontal axis is labeled 'Consequences'. The matrix is divided into four quadrants: 'Very Low' (yellow), 'Low' (orange), 'Moderate' (red), and 'High' (dark red). The 'Very Low' and 'Low' quadrants are separated by a dashed line. The 'Moderate' and 'High' quadrants are separated by a solid line. The 'Very High' label is placed in the top right corner of the 'High' quadrant.

What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:



## Biosafety Risk Assessment

## Laboratory Biosafety Risk Assessment

### Risk Characterization

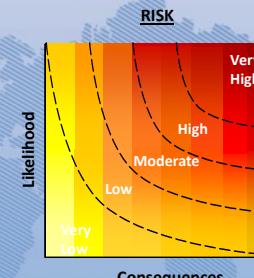
**Scenario:**  
You are working with wild-type **Ebola virus** in a high containment BSL 4-type laboratory, inoculating large numbers of mice with varying concentrations of virus to determine an LD50.

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?

Slide 4



A risk matrix diagram titled 'RISK' in the top right corner. The vertical axis is labeled 'Likelihood' and the horizontal axis is labeled 'Consequences'. The matrix is divided into four quadrants: 'Very Low' (top-left, yellow), 'Low' (middle-left, orange), 'Moderate' (middle-right, red), and 'High' (bottom-right, dark red). The 'Very Low' and 'Low' quadrants are separated by a dashed line. The 'Moderate' and 'High' quadrants are separated by a solid line. The word 'RISK' is written in a bold, sans-serif font at the top center of the matrix area.

What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:



## *Biosafety Risk Assessment*

## ***Laboratory Biosafety Risk Assessment***

## Biosafety Risk Assessment

## Notes:



## Biosafety Risk Assessment

## Laboratory Biosafety Risk Assessment

### BioRAM

One available tool to aid in the biosafety risk assessment process is the **Biosafety RAM** (**BioRAM**).

**BioRAM** is a computerized **risk assessment tool** developed by Sandia National Laboratories, in partnership with the international community, to facilitate laboratory **biosafety risk assessments** by simplifying **Risk Characterization**.

Slide 26



### BioRAM

**BioRAM** uses only one of several possible risk assessment methodologies.

It is based on the input of biosafety experts and validated around the world. The **BioRAM** tool helps determine *relative* risk levels in a **comparable** and **repeatable** way.

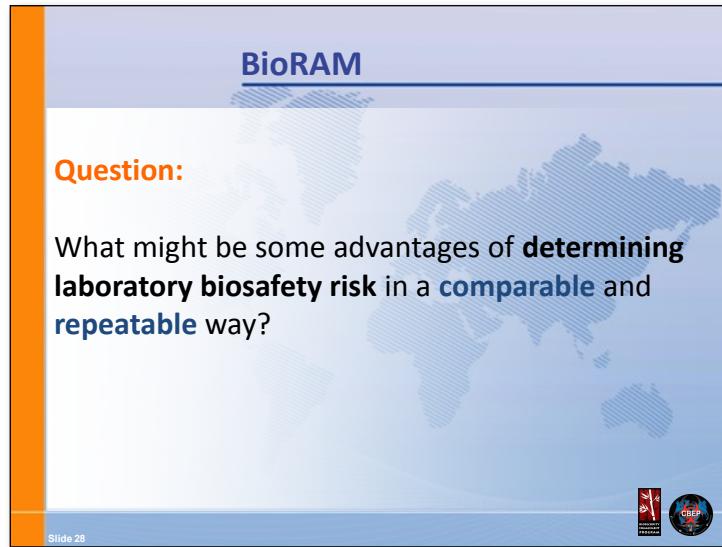
<http://biosecurity.sandia.gov/BioRAM/>

Slide 27





## *Biosafety Risk Assessment*

A slide titled "BioRAM" with a world map background. The title is in a blue box at the top. Below it, the word "Question:" is in orange. The main text is: "What might be some advantages of determining laboratory biosafety risk in a comparable and repeatable way?" At the bottom left is the text "Slide 28". At the bottom right are two small circular logos: one for the "Center for Biodefense" and another for "CBP".

## *Laboratory Biosafety Risk Assessment*

Laboratory Biosafety Risk Assessment:

Advantages:

Disadvantages:



### **Risk Evaluation**

**Risk Evaluation** is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk.

It is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

Slide 29



### **Risk Evaluation**

Unfortunately, there is no systematic way of **evaluating risk and determining risk acceptability**. This will depend on the perceptions of **individuals**, **institutions**, and the **community**.

Slide 30



**Risk Evaluation**

**Question:**

What factors might drive differences in risk acceptability between **individuals, institutions, and communities**?

**In your groups**, please spend **5 minutes** discussing this question and be prepared to share your thoughts with the class.

CBEP

### Individual Factors:

## Institution Factors:

## Community Factors:



### Risk Evaluation

Overall, two **institutions** with the **same computed risk “values”** for the risk characterization process may have **different risk evaluations (meanings of risk)**. E.g. Even moderate risk may be too much risk depending on the **individuals, institution** and **community** involved.

The **evaluation of risk** is reflected on the graph by the **arbitrary “isoquants”**.

Slide 32

### Risk Evaluation

**Risk Evaluation** drives investment decisions in an institution. If an institution is particularly **risk-averse**, it will spend more resources attempting to reduce the risks it faces. If a similar institution faces the same risks but is **less risk-averse**, it might proceed with procedures others may find too **“dangerous”**.

Slide 33



## Biosafety Risk Assessment

Review

### Review

**Review Question:**

What is **risk**?

Slide 34



### Review

**Review Question:**

What are some factors that would affect the **likelihood** of an exposure and the **consequences** of an exposure?

Slide 35





## Biosafety Risk Assessment

Review

### Review

#### Review Question:

How would you determine the **biosafety risk** of working with a new, unknown infectious disease agent?

Slide 36



### Review

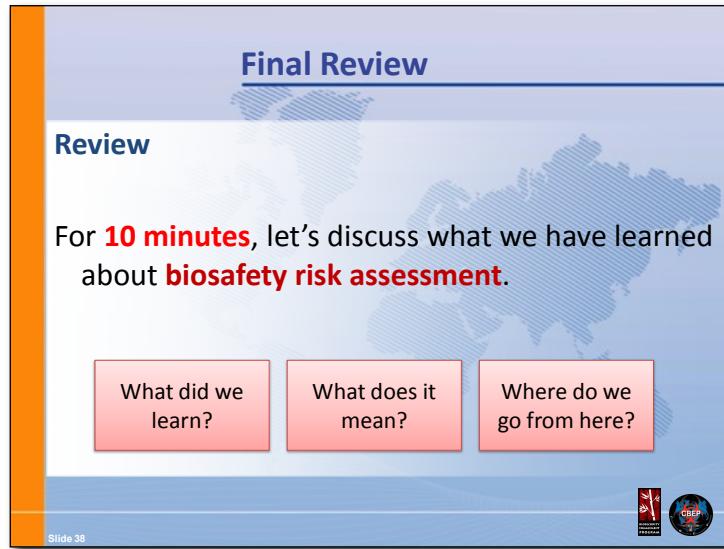
#### Review Questions:

How might the **community** where a facility is located in affect that facility's risk mitigation decisions?

Where does a facility's **biosafety risk assessment** tie in?

Slide 37





A slide titled "Final Review" with a world map background. The title is "Final Review" and the subtitle is "Review". The text on the slide reads: "For **10 minutes**, let's discuss what we have learned about **biosafety risk assessment**." Below this are three questions in pink boxes: "What did we learn?", "What does it mean?", and "Where do we go from here?". The slide is numbered "Slide 38" at the bottom left and features the CIEP logo at the bottom right.



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Slide 39



