

# Biosafety Risk Assessment

## *Student Guide*



BIOSECURITY  
ENGAGEMENT  
PROGRAM




Welcome to Biosafety Risk Assessment





**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	
------	--	------	--	---------------	--

*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?

Slide 3

Use space on back, if needed



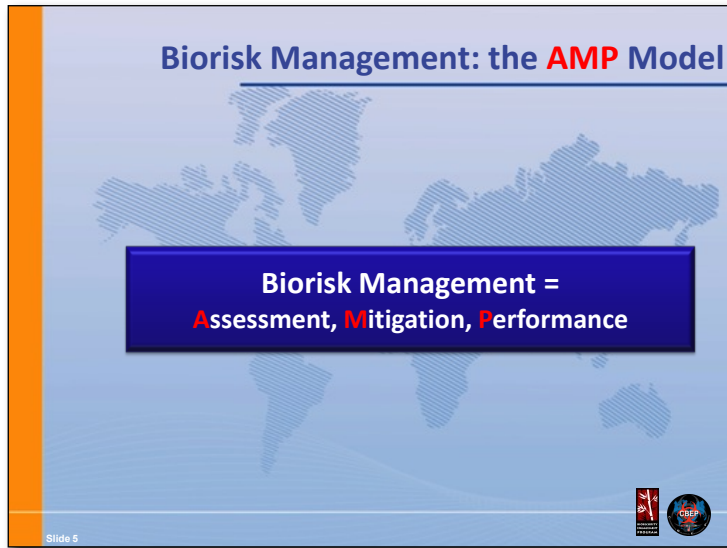


### Course Objectives

- 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



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 6



Define Biorisk Assessment:

<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>

**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:





**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

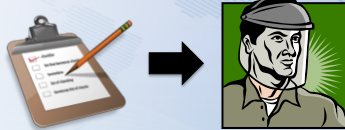


## Biosafety Risk Assessment

## Introduction to Biosafety Risk Assessment

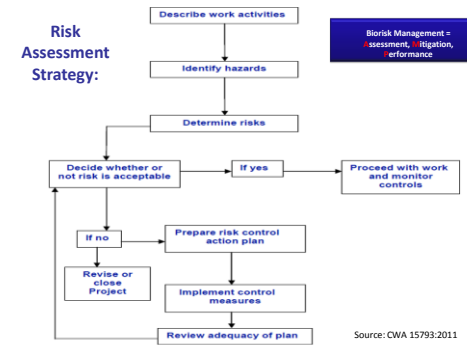
### Introduction to Biosafety Risk Assessment

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

### Risk Assessment Strategy



Slide 12

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



<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>

**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

Slide 14

How can Risk be expressed?

What is risk a function of ?

---

---

---

---

---

---

---

---

### Risk

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

What would you need to know to answer this question?

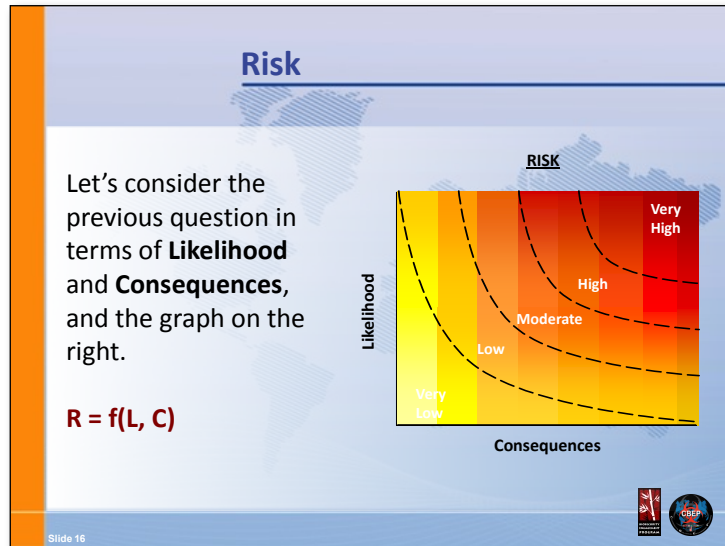
To help with this task, in your group, spend **5 minutes** listing all **examples of useful information** on sticky-notes and place them on your flip chart.

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?




What is the likelihood of being attacked by a tiger?

What are the consequences of being attacked by a tiger?


**Risk**

For the following scenarios, draw a STAR where the risk would fall on the graph.


You are in an open field next to a very hungry, aggressive, adult tiger. The tiger is unrestrained and sees you as food.

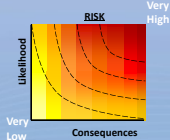
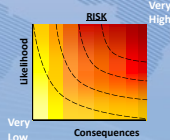
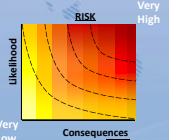


You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.



You are holding a tiger cub with a playful temperament in your arms.



Slide 1

What is the risk for each Scenario?

Scenario #1

Rationale:

Risk:

Scenario #2

Rationale:

Risk:

Scenario #3

Rationale:

Risk:

---

---

---

---

---

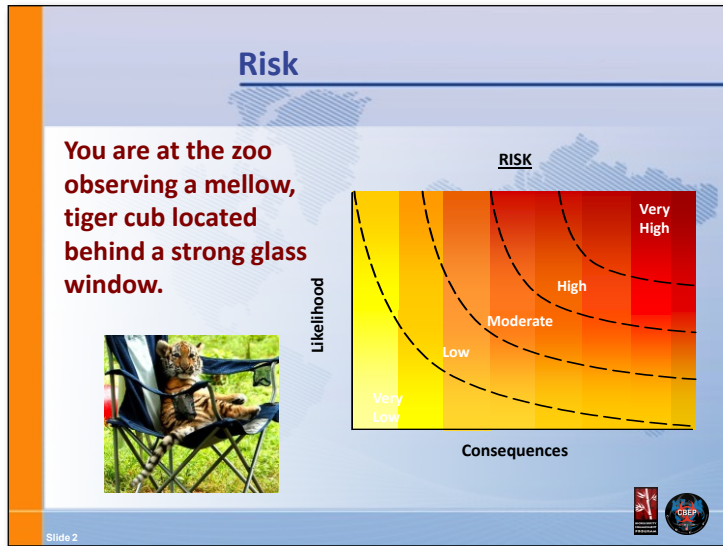
---

---

---

---

---



What is the risk of being attacked in this scenario?

---

---

---

---

---

---

## Biosafety Risk Assessment



## Laboratory 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

How does a risk assessment differ from a 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.

Slide 20

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

Factors:




### 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

**Risk Characterization**

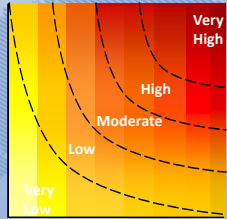
**Scenario:**

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?



The matrix plots Likelihood (Y-axis: Very Low, Low, Moderate, High, Very High) against Consequences (X-axis: Very Low, Low, Moderate, High, Very High). Risk levels are indicated by color: Very Low (yellow), Low (orange), Moderate (red-orange), High (red), and Very High (dark red). Dashed lines represent risk boundaries.

Slide 3

What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:

**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

What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:

---

---

---

---



---

---

### Biosafety Risk Assessment

This exercise could be repeated with every **organism** and every **procedure** conducted in a laboratory or facility.

Doing this in a comprehensive manner is one way to conduct a **facility-wide risk assessment**, which would then be, quite simply, the collection of the individual risk assessments for the individual procedures conducted in a laboratory or facility.



Slide 25

Notes:


### 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.

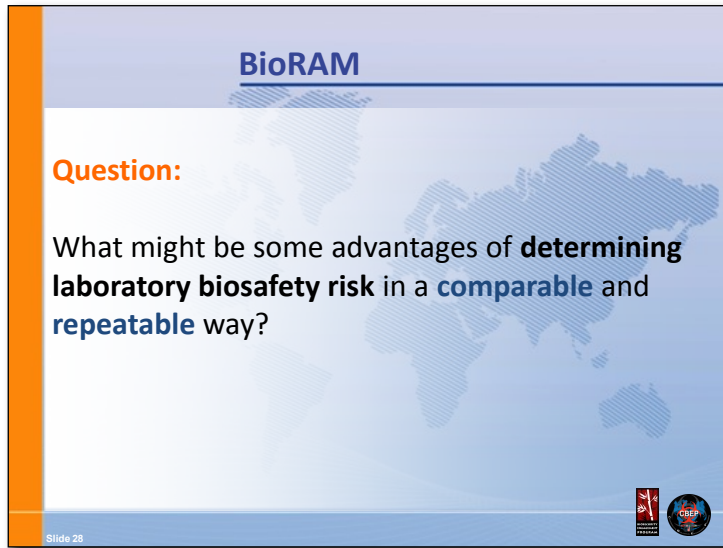
It is based on the input of biosafety experts and validated around the world. The **BioRAM** tool helps determine *relative* risk levels in a **comparable** and **repeatable** way.

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



Slide 27



A presentation slide titled "BioRAM" with a world map background. It contains a question about the advantages of determining laboratory biosafety risk in a comparable and repeatable way. The slide also includes a small logo in the bottom right corner and the text "Slide 28" in the bottom left corner.

**BioRAM**

**Question:**

What might be some advantages of **determining laboratory biosafety risk** in a **comparable** and **repeatable** way?

Slide 28

Laboratory Biosafety Risk Assessment:

Advantages:

Disadvantages:

<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>

### 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.



Slide 31

Individual Factors:

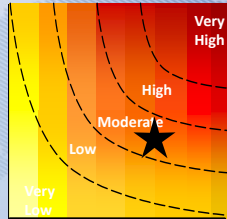
Institution Factors:

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

**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



---

---

---

---

---

---

---

---

---


---

**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



---

---

---

---

---

---

---

---

---

---



**Final Review**

**Review**

For **10 minutes**, let's discuss what we have learned about **biosafety risk assessment**.

What did we learn?

What does it mean?

Where do we go from here?

Slide 38

WHO OIE




### 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 39