



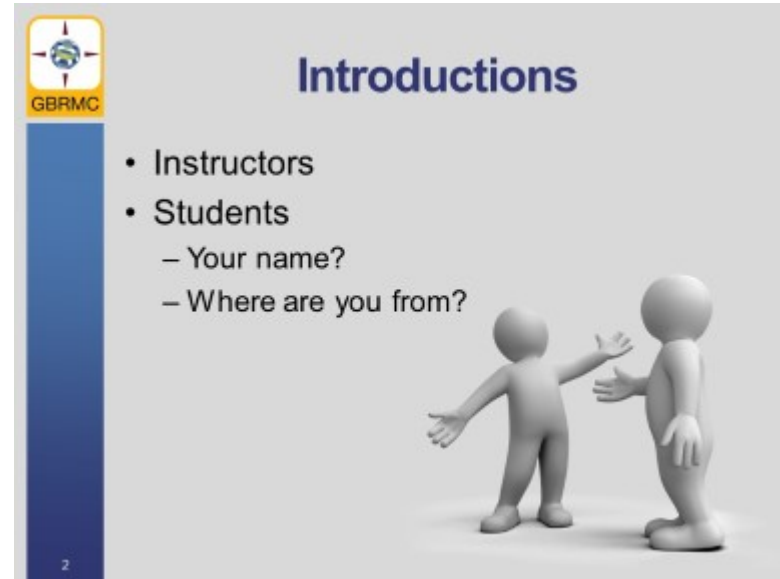
# Biosecurity Risk Assessment

## Student Guide

2012



GLOBAL BIORISK MANAGEMENT CURRICULUM



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# Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
<i>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.</i>					
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

- 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 risk.
- A biosecurity risk assessment is an analytical procedure designed to characterize security risks.
- The results of a biosecurity risk assessment will be unique to each institution and each laboratory or unity within that institution.
- To be comprehensive, a laboratory biosecurity risk assessment should consider every asset, as well as vulnerability in an institution and its component laboratories and units.
- A biosecurity risk assessment allows an institution and its component units to determine the relative level of security risk they face, and helps guide risk mitigation decisions so these are targeted to the most important risks.

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## Key Messages - continued

- To properly conduct a biosecurity risk assessment, it is important to first gather certain information about the biological agents and toxins that could be targeted by notional adversaries.
- Adversary Characterization is the process of determining specific attributes of potential adversaries that enable them to pose a threat to a biological agent or toxin.
- Each scenario should involve a specific biological agent or toxin, a specific adversary, and a particular way that adversary will attempt to steal and misuse the agent or toxin.
- After generating a series of scenarios, the vulnerabilities of a facility and/or its units to the threats posed in the scenario should be assessed.
- Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not

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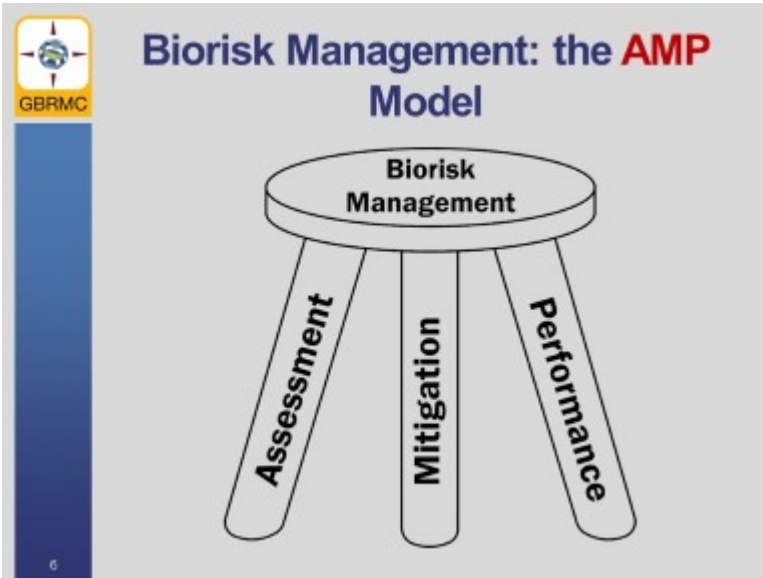
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- 
- Key Components of Biorisk Management**
- **Biorisk Assessment**
    - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding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



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## Key Components of Biorisk Management

- **Biorisk Performance**
  - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



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## Laboratory Biosecurity

For this course, **Laboratory Biosecurity** can be defined as:

*A set of preventive measures designed to reduce the risk of intentional removal (theft) or release of a valuable biological material in order to cause harm to others.*

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## Laboratory Biosecurity

**Group Exercise:**

**In your groups**, please spend **5 minutes** to identify as many **laboratory biosecurity** mitigation measures as you can.

Write each one on a **sticky note** and place them on your **flip-chart**.



11

What are some laboratory biosecurity mitigation measures?

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## Laboratory Biosecurity

**Questions:**

Do you need all of these **mitigation measures**?

How do you decide **which one** you need?



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How do you determine what biosecurity mitigation measures are needed?

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## Biosecurity Risk Assessment


 **Introduction to Biosecurity Risk Assessment**

A **biosecurity risk assessment** is an analytical procedure designed to characterize security risks in a laboratory.



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## Introduction to Biosecurity Risk Assessment

 **Introduction to Biosecurity Risk Assessment**

To be comprehensive:

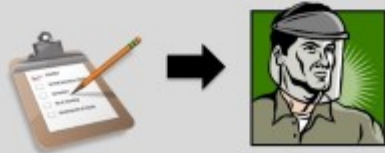
A laboratory **biosecurity risk assessment** should consider every **asset, adversary** and **vulnerability** in an institution and its component laboratories and units.

Slide 14



## Introduction to Biosecurity Risk Assessment

A **biosecurity risk assessment** allows an institution or laboratory to determine the relative risk of security threats and/or vulnerabilities to help **guide risk mitigation decisions** so these are targeted to the most important risk.



15

Notes:

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## Risk

### Group Exercise:

#### 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?

16

What is risk?

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 **Risk**

**Question:**  
**What is Risk?**  
*Risk is the likelihood of an undesirable event happening, that involves a specific hazard or threat 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**



The diagram is a 2D plot with 'Likelihood' on the vertical axis and 'Consequences' on the horizontal axis. The plot is divided into five regions by dashed lines, representing risk levels: 'Very Low' (bottom-left, yellow), 'Low' (bottom-center, light orange), 'Moderate' (center, orange), 'High' (top-center, dark orange), and 'Very High' (top-right, red).

How can Risk be expressed?

What is risk a function of?

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## 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.

18

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

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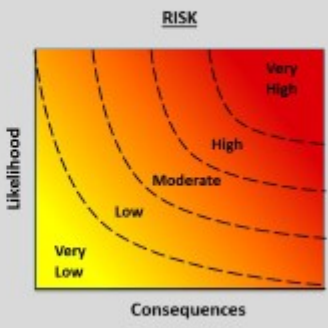
## Biosecurity Risk Assessment

## Introduction to Biosecurity Risk Assessment

 **Risk**

Let's consider the previous question in terms of **Likelihood** and **Consequences**, and the graph on the right.

**$R = f(L, C)$**



The graph is a risk matrix with 'Likelihood' on the vertical axis and 'Consequences' on the horizontal axis. The matrix is divided into five risk levels by dashed lines, with colors ranging from yellow (Very Low) to red (Very High). The levels are: Very Low (bottom-left), Low (middle-left), Moderate (middle), High (middle-right), and Very High (top-right).

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What is the likelihood of being attacked by a tiger?

What are the consequences of being attacked by a tiger?

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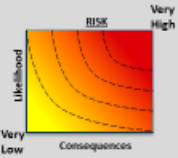
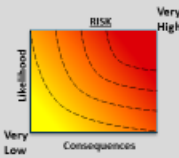
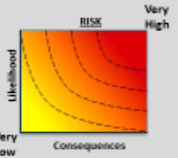
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# Biosecurity Risk Assessment

# Introduction to Biosecurity Risk Assessment

## Risk

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

<p>You are in an open field next to a very hungry, aggressive, adult tiger. The tiger is unrestrained and sees you as food.</p> 	<p>You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.</p> 	<p>You are holding a tiger cub with a playful temperament in your arms.</p> 
		

Slide 20

What is the risk for each Scenario?

Scenario #1

Rationale:

Risk:

Scenario #2

Rationale:

Risk:

Scenario #3

Rationale:

Risk:

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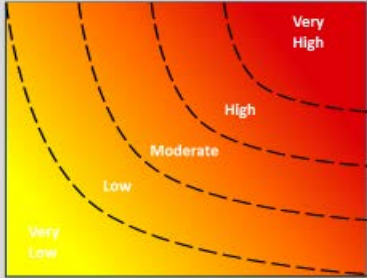
 GBRMC

You are at the zoo observing a mellow, tiger cub located behind a strong glass window.



**Risk**

**RISK**



Likelihood

Consequences

Very Low

Low

Moderate

High

Very High

Slide 21

What is the risk of being attacked in this scenario?

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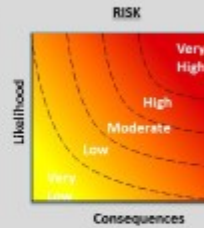
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## Biosecurity Risk Assessment

A **risk assessment** assigns values for **likelihood** and **consequences**, which allows us to represent the risk of a particular adverse event on a graph.



In **Biosecurity Risk Assessment**, we are concerned with **intentional adverse events** involving laboratory disease agents and/or their products.

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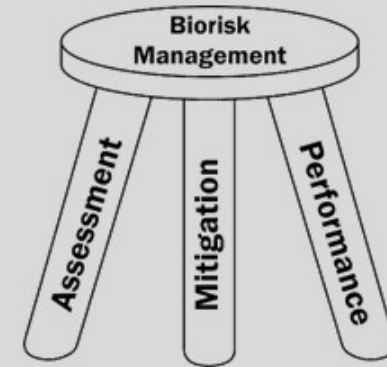
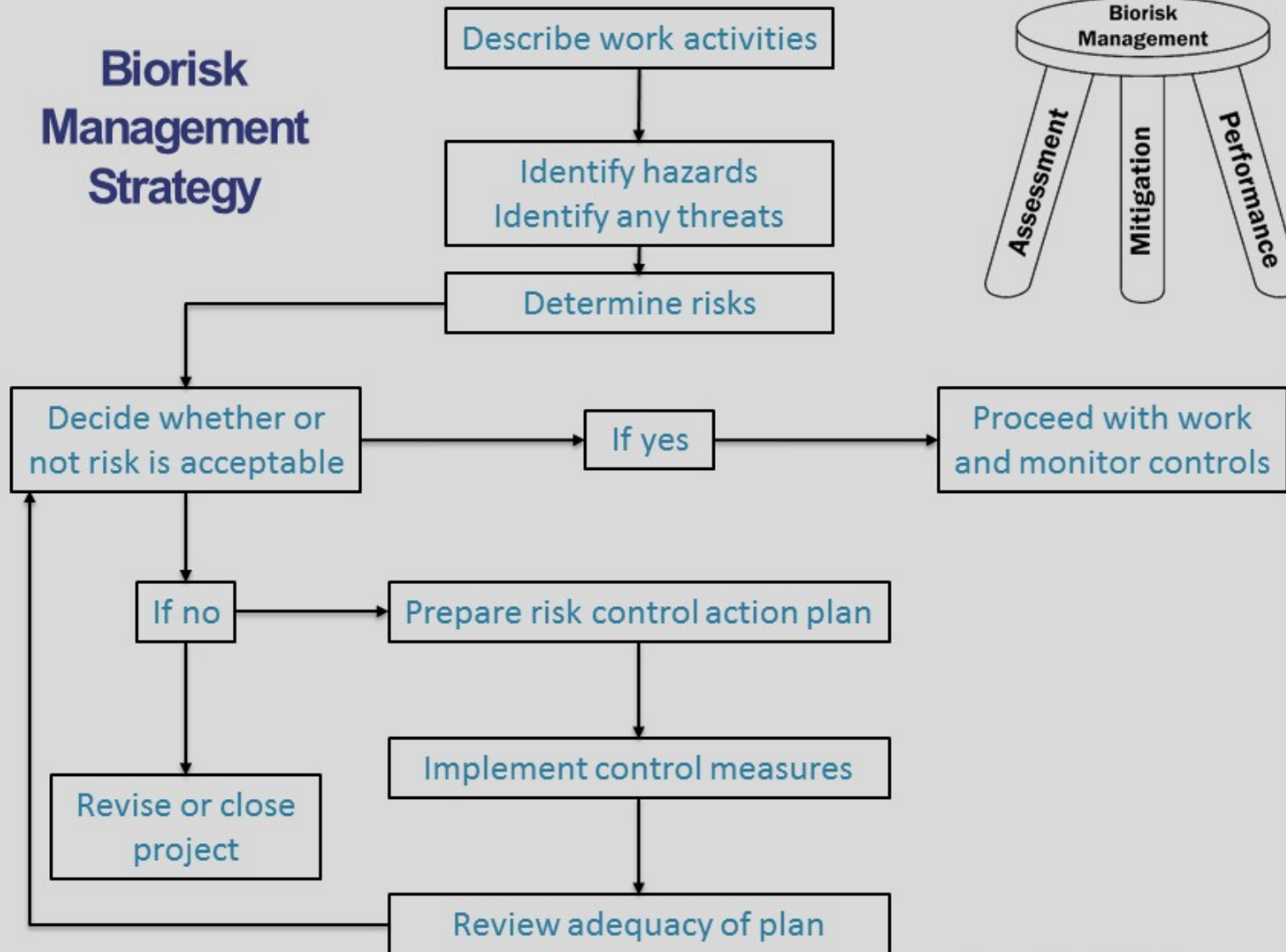
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# Biorisk Management Strategy



## Biosecurity Risk Assessment

## Introduction to Biosecurity Risk Assessment



### Biosecurity Risk Assessment

#### Group Exercise Step 1:

What factors should be considered in a **laboratory biosecurity 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.

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

Factors:

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## Biosecurity Risk Assessment

### Group Exercise Step 2:

Next, **categorize** the factors you identified in the previous activity as being important for a **laboratory biosecurity risk assessment**.

**In your group**, please spend **5 minutes** to categorize your **sticky notes**.

Be prepared to report your categories to the class.

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How did you categorize the factors you identified in the previous activity?

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## Biosecurity Risk Assessment

### Group Exercise Step 3:

Next, **organize the factors** you categorized in the previous activity into two groups:

Factors affecting **Likelihood**

Factors affecting **Consequences**

**In your group**, please spend **5 minutes** to organize your sticky notes.

Be prepared to report to the class.

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Which categories have factors that are most related to:  
Likelihood?

Consequences?

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## Risk Characterization

In the previous activities you have identified all the factors that should be considered in a **biosecurity risk assessment**. That is the first step in **Risk Characterization**.

**Risk Characterization** is the process of determining the **likelihood** and **consequences** of a particular risk.

Please recall that risk is associated with a **particular adverse event**. We can only determine the **likelihood** and **consequences** of a very clearly defined risk.

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## Risk Characterization

**Characterizing biosecurity risk** includes an in-depth analysis of laboratory **assets**, **potential adversaries**, and laboratory **vulnerabilities**.



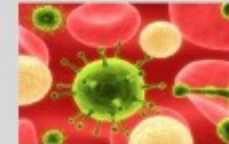
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## Asset Characterization

**Asset Characterization** is the process of gathering information about the biological agents and toxins that could potentially be targeted by notional adversaries.

These biological agents and toxins will be referred to as **“assets”**.



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## Asset Characterization

Determining the **ease or difficulty of malicious use (likelihood)** should involve assessing the following:

- The difficulty of **acquiring** the agent
- The difficulty of **processing** the agent into a suitable quantity in a suitable form
- The difficulty of **disseminating** the agent to cause harm

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## Asset Characterization

Determining the **potential consequences of the malicious use (consequences)** of a particular agent or toxin should involve assessing the following:

- The physical impact of an attack on a **population**
- The impact of an attack on the **economy**
- The impact of changes in **public perception**
- The impact on **facility operations**

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## Asset Characterization

### Questions:

How might the **environmental stability** of an infectious disease agent affect the **likelihood** of theft and misuse?

How might the **host range** of an infectious disease agent affect the **consequences** of theft and misuse?

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How might the environmental stability affect the likelihood of theft and misuse?

How might the host range of an infectious disease agent affect the consequences of theft and misuse?

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## Adversary Characterization

**Adversary Characterization** is the process of determining specific attributes of potential adversaries that enable them to pose a threat to a biological agent or toxin.

In the security community, **Adversary Characterization** is also known as **Threat Assessment**.

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## Adversary Characterization

Some characteristics of **potential adversaries** that could help determine the risk they pose, include:

- **Motive**
- **Means**
- **Opportunity**

Analyzing each of these characteristics in terms of **likelihood** and **consequences** is necessary for a biosecurity risk assessment.

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## Adversary Characterization

The question of **opportunity** raises the issue of **insider** versus **outsider** threat.

An **insider** is a person who has authorized access to a facility, its units (such as laboratories), and its assets.

An **outsider** is a person who does not have authorized access.



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## Adversary Characterization

**Insiders** tend to pose a **greater threat** than **outsiders** because they typically have both **greater means** and **opportunity** than an outsider.

**Insiders**, however, do not necessarily have different **motives** than **outsiders**.



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## Scenarios

Another useful tool for **Biosecurity Risk Assessment** is to work through possible **scenarios** to detect any vulnerabilities in the biosecurity management program.

Each evaluated **scenario** should involve a specific biological **agent**, a specific **adversary**, and a **particular way** that **adversary** will attempt to **steal and misuse** the **agent or toxin**.

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## Scenarios

Keep in mind that it is important to have a **screening process** to limit the number of **scenarios** generated, say by considering only those scenarios involving **biological agents capable of causing significant harm**.

The **criteria** used for screening should be documented in the assessment.

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## Scenarios

### Exercise:

We will work together, through a series of **scenarios** to practice **characterizing biosecurity risk**.



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## Scenarios

### Scenario:

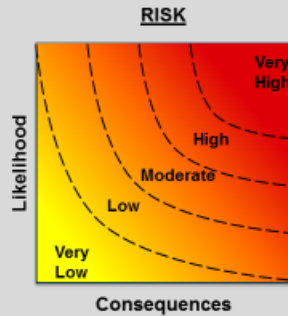
Your facility works with **wild-type Ebola virus** in a developing country with poor infrastructure and an active, wide-spread insurgency.

**In your groups, take 10 minutes**, to further expand on this scenario to include a specific **adversary** as well as a **particular way** that the **adversary** will attempt to **steal and misuse** the **asset**.

What is the **likelihood** of theft?

What are the **consequences** of theft?

What are some factors that should be considered?



Scenario:

Likelihood:

Consequences:

Factors:

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## Scenarios

### Scenario:

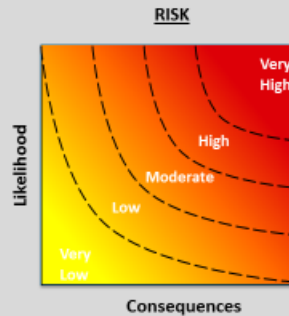
Suppose your facility stores large volumes of **Foot and Mouth Disease Virus** for use in animal research. Your facility's building is new and has excellent physical security.

In your groups, take **5 minutes**, to further expand on this scenario to include a specific **adversary** as well as a **particular way** that the **adversary** will attempt to **steal and misuse the asset**.

What is the **likelihood** of theft?

What are the **consequences** of theft?

What are some factors that should be considered?



Scenario:

Likelihood:

Consequences:

Factors:

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## Vulnerability Assessment

After generating a series of **scenarios**, the **vulnerabilities** of a facility and/or its units to the threats posed in the **scenario** should be assessed.

How well are the facility's existing **biosecurity risk mitigation** measures protecting against the threats in the scenarios?

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## Vulnerability Assessment

Biosecurity vulnerabilities can be assessed based on each of the **biosecurity system's individual components**

- **Physical Security**
- **Personnel Management**
- **Material Control and Accountability**
- **Transport Security**
- **Information Security**

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## Vulnerability Assessment

**For example**, is the **Physical Security** of a facility adequate to prevent an outsider from entering a particular laboratory and stealing several vials of an agent?

Are doors consistently locked? Are the locks reliable? If doors are locked, are there large windows in the laboratory that an outsider could enter from instead?

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## Biosecurity Risk Assessment

This exercise could be repeated for every **asset and adversary in a given scenario** in a laboratory or facility.

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

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## Risk Characterization

It is important that the **Risk Characterization** process be as **robust** as possible.

**Comparability** is the ability trust the accuracy of *differences* between assessments, due to similarities in their bases, assumptions, procedures and protocols.

**Repeatability** is the ability to conduct the same process in the same way for the same hazard or threat and situation over a period of time, or for different hazards, threats, and situations at the *same* time.

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## BioRAM

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

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

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## 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/>

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How would you determine laboratory biosafety and biosecurity risk at your facility?

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## Risk Evaluation

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



**Risk Evaluation** is the process of determining, subjectively, whether a risk is **high** or **low**, and whether it's **acceptable** or not.

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## Risk Evaluation

What is **“acceptable”** risk?



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## Risk Evaluation

The **evaluation of risk** is highly related to the concept of **Risk Acceptance**.



**Risk evaluation and acceptance** can vary with **culture, experience, resources, management, and even current events.**

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## 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.**



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## 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.

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Individual Factors:

Institution Factors:

Community Factors:

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## Risk Evaluation

If an **institution** finds a particular risk **unacceptable**, it will either **cease** the work resulting in that unacceptable risk, or it will **find ways to mitigate** that risk to a more acceptable level.



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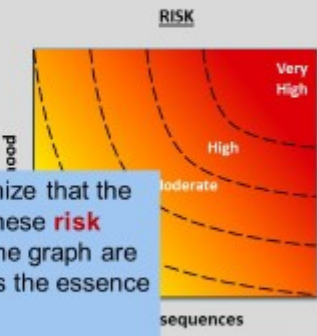
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## Risk Evaluation


The curves on this graph, called “**risk tolerance curves**”, show different levels of risk, from **Very Low** to **Very High**.

It is important to recognize that the **precise locations** of these **risk tolerance curves** on the graph are in fact **arbitrary**. This is the essence of **Risk Evaluation**.



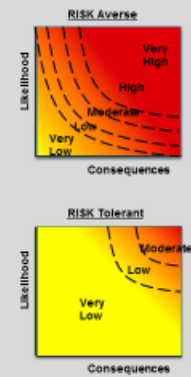
The graph shows a color gradient from yellow (Very Low) to red (Very High) with dashed curves representing risk tolerance levels. The y-axis is labeled 'likelihood' and the x-axis is labeled 'consequences'. Risk levels are labeled as Very Low, Moderate, High, and Very High.

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## Risk Evaluation

Overall, two **institutions** with the **same computed risk “values”** for the risk characterization process may have **different risk evaluations (meanings of risk)**. For example, what is a moderate risk for one institution could be a high risk for another, depending on what each entity decides is moderate or high.



The top graph, labeled 'RISK Averse', shows a risk tolerance curve that is shifted towards higher risk levels (red/orange) compared to the bottom graph, labeled 'RISK Tolerant', which shows a curve shifted towards lower risk levels (yellow/green). Both graphs use 'likelihood' for the y-axis and 'consequences' for the x-axis.

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## Risk Evaluation

An **institution** that considers a certain risk **high** might be motivated to spend a **large amount of resources** mitigating that risk.

Another **institution** that considers the **same** risk to be **moderate** might decide to spend a **small amount of resources** in mitigation instead.

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How does risk evaluation influence risk mitigation strategies?

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Review

**Question:**

What is **risk**?

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Review

**Question:**

How might the **ease of dissemination by aerosol** affect both the **likelihood** of exposure and the **consequences** of theft and misuse?

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## Review

**Question:**

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

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## Review

**Questions:**

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

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

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## Review

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

What did we learn?

What does it mean?

Where do we go from here?

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## Key Messages

- 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 risk.
- A biosecurity risk assessment is an analytical procedure designed to characterize security risks.
- The results of a biosecurity risk assessment will be unique to each institution and each laboratory or unity within that institution.
- To be comprehensive, a laboratory biosecurity risk assessment should consider every asset, as well as vulnerability in an institution and its component laboratories and units.
- A biosecurity risk assessment allows an institution and its component units to determine the relative level of security risk they face, and helps guide risk mitigation decisions so these are targeted to the most important risks.

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## Key Messages - continued

- To properly conduct a biosecurity risk assessment, it is important to first gather certain information about the biological agents and toxins that could be targeted by notional adversaries.
- Adversary Characterization is the process of determining specific attributes of potential adversaries that enable them to pose a threat to a biological agent or toxin.
- Each scenario should involve a specific biological agent or toxin, a specific adversary, and a particular way that adversary will attempt to steal and misuse the agent or toxin.
- After generating a series of scenarios, the vulnerabilities of a facility and/or its units to the threats posed in the scenario should be assessed.
- Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not

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# Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
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*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*