



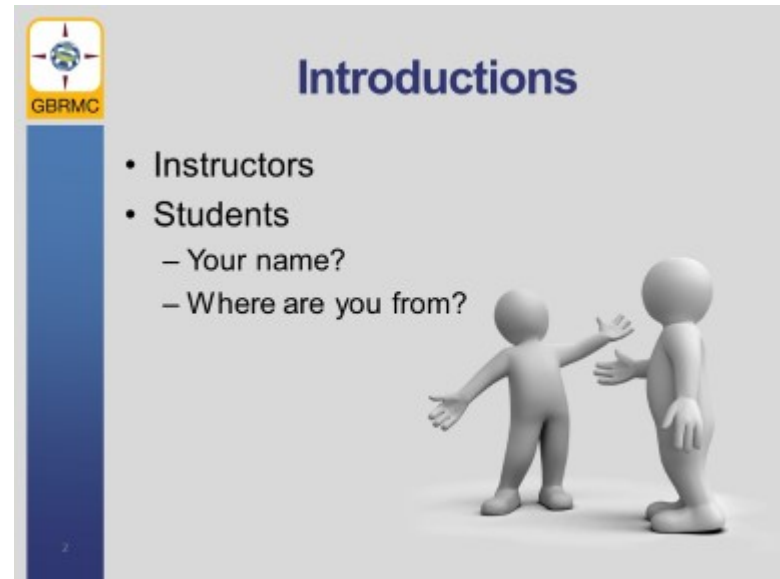
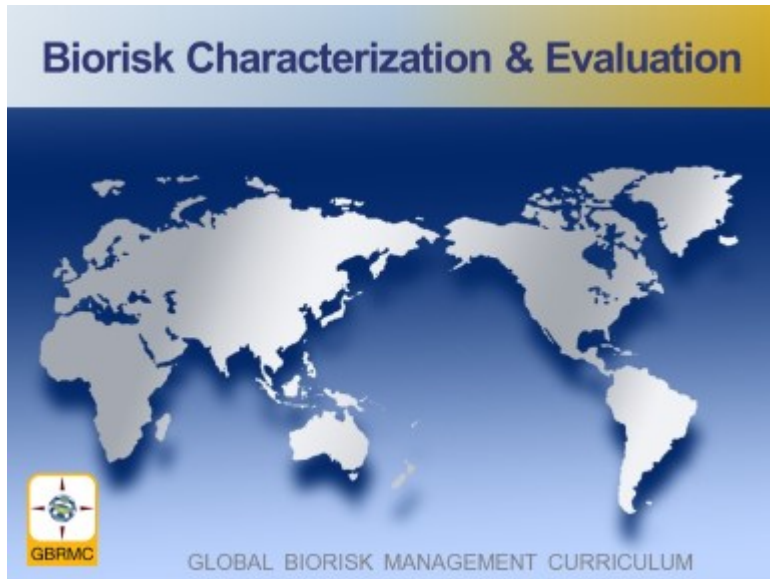
# Biorisk Characterization & Evaluation

## Student Guide

2017



GLOBAL BIORISK MANAGEMENT CURRICULUM



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## Course Overview

1. **Course Objectives and Introduction**
2. Basics of Risk Assessment
3. Risk Characterization
4. Risk Evaluation
5. Review

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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 supports understanding risks based upon activities and aids risk decision making
- Risk Characterization is the process of identifying the factors that contribute to risk and determining the likelihood and consequences that contribute to risk.
- Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

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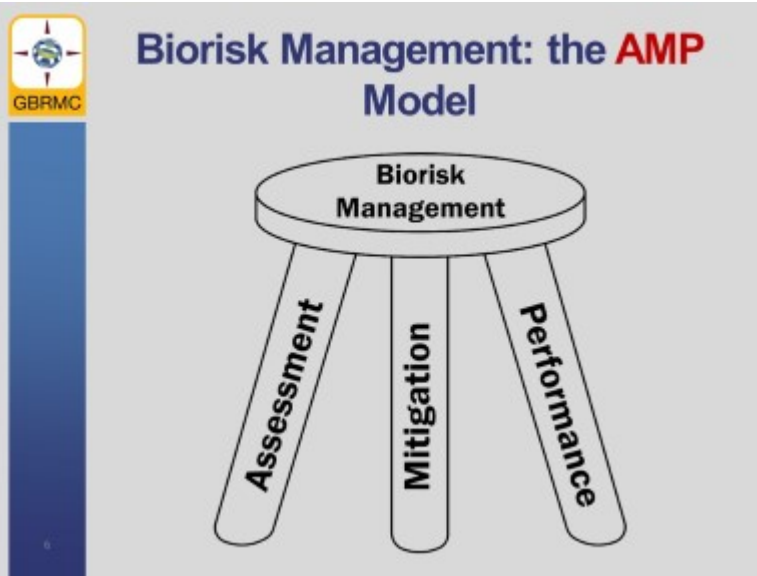
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**Key Components of Biorisk Management**

- **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



## 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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## Course Overview

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## Introduction

### Overview

This course is intended to offer a more complete understanding of the **Risk Characterization** and **Evaluation** processes within **Biological Risk Assessment**.

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## Introduction

A **biological risk assessment** is an analytical procedure designed to characterize biological risks in a facility, laboratory or unit within it, or other type of operation dealing with potential pathogens or toxins.

- **Biosafety risk assessment**
- **Biosecurity risk assessment**



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## Introduction

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



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## Introduction

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



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## Introduction

Why perform a biological risk assessment?



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## Risk

### Group Exercise:

**Question:** What is “**risk**”?

**In your group**, take **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?

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## Risk

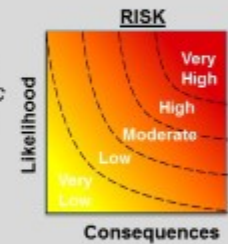
### Question:

**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



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## Risk

### Group Exercise:

In your group, spend **5 minutes** to discuss what you would need to know to answer the question:

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

List **examples of useful information** on **sticky-notes** and place them on your **flip chart**.

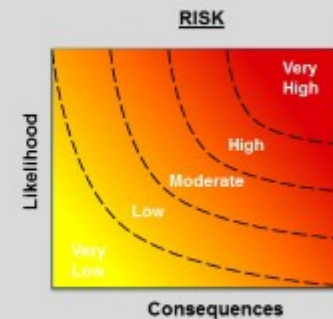
Be prepared to report your **criteria** to the class.

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## Risk

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



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

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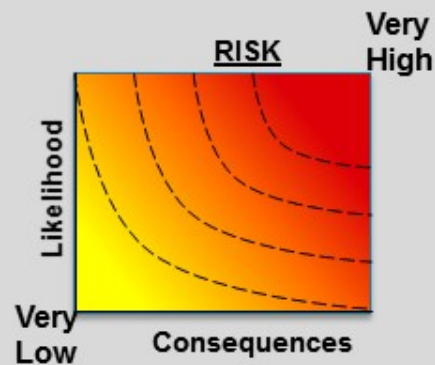
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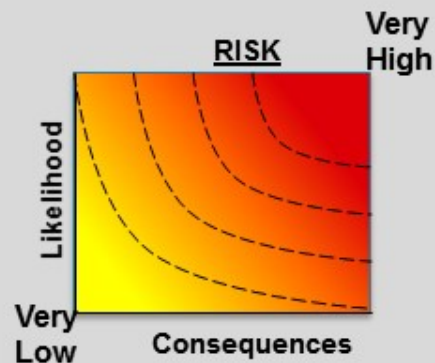
# Risk

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

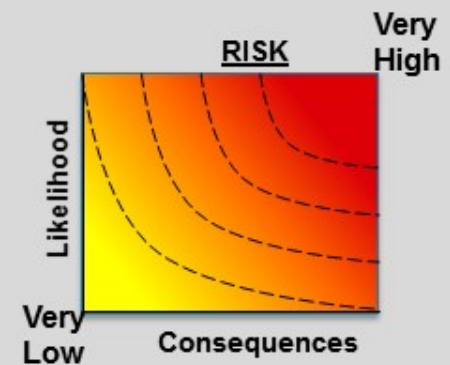
You are in an open field next to a very hungry, aggressive, adult tiger. The tiger is unrestrained and sees you as food.



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.

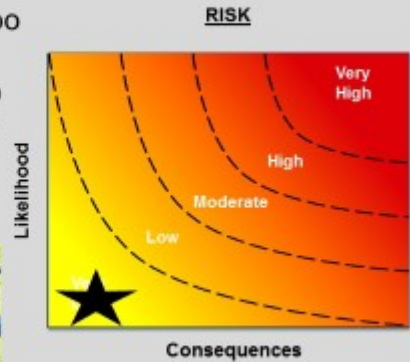




You are at the zoo observing a mellow, tiger cub located behind a strong glass window.



### Risk



### What is the Objective?

Risk assessment supports the selection of appropriate **laboratory biosafety** and **laboratory biosecurity** risk mitigation measures to reduce likelihood and consequences of:





## Risk Assessment

A **risk assessment** is process that characterizes a particular situation in order to determine the **likelihood** and **consequences** of a certain adverse event (Risk Characterization), and supports decision making regarding the acceptability of the risk (Risk Evaluation)

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## Biorisk Assessment

### Group Exercise Step 1:

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

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

List 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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## Biorisk Assessment

### Group Exercise Step 2:

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

Categorize the factors you identified in the previous activity as being important for a **laboratory biosafety** or **biosecurity risk assessment**.

Be prepared to report your categories to the class.

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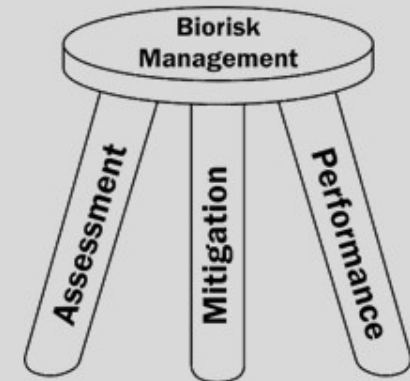
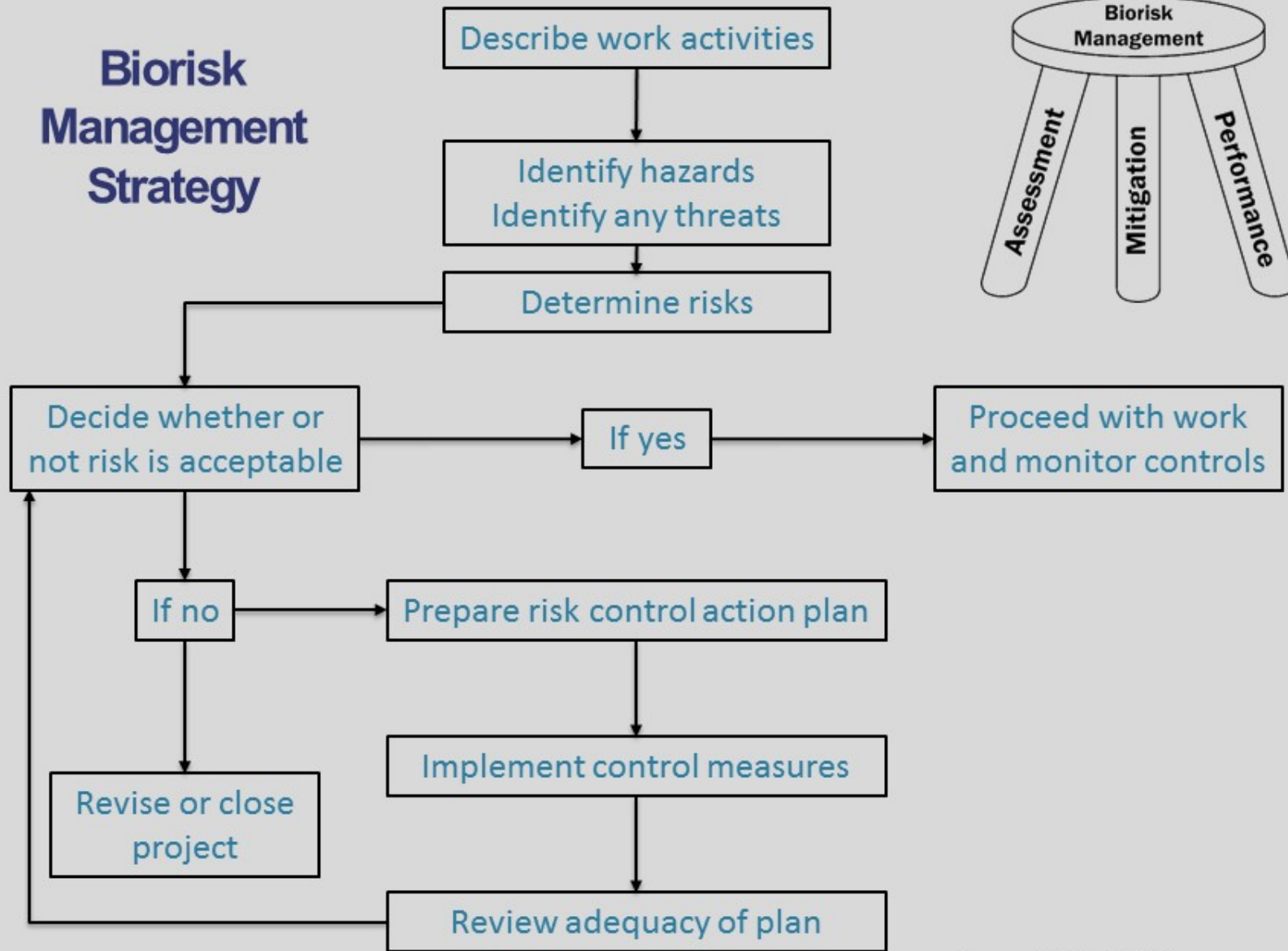
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# Biorisk Management Strategy



Source: CWA 15793:2011



## Course Overview

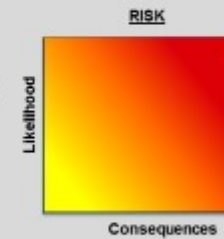
1. Course Objectives and Introduction
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## Risk Characterization

**Risk characterization** assigns values for **likelihood** and **consequences**, which allow us to determine the level of risk



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## Risk Characterization

A **hazard** or **threat** cannot in itself pose a **risk** without a specific **situation**.

Conversely, a **situation** also does not represent a **risk** without a **hazard** or **threat**.

Both a changing **hazard** or **threat**, and a changing **situation** will independently alter the scenario being assessed, and thus change the **risk**.

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## Risk Characterization

The first step in a risk assessment is the identification of **hazards** and **threats** based upon the situation.

- A **Hazard** is something with the potential to cause harm
- A **Threat** is someone with intent to cause harm

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## Risk Characterization

The next step in a risk assessment is the characterization of the **hazards** and **threats** based upon the likelihood and consequences.

- For a **Hazard** consider the likelihood of the hazard to cause harm and the extent of the harm
- For a **Threat** consider the likelihood of the threat to successfully achieve their goal and the consequences of that goal

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## Risk Characterization

### Exercise:

We will work together, through a series of examples to practice **characterizing biological risk.**



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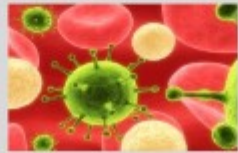
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## Biosafety Risk Characterization

For **Biosafety Risks** the **hazard** is the biological material

*(Other safety risks may exist in the context of the situation, but for this activity we will focus on the biological material)*



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## Hazard Characterization

### Group Exercise:

If **characterizing** the **hazard** is intended to identify the likelihood and consequences of a bad event (i.e. exposure), what do you need to know about the **hazard**?

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## Hazard Characterization

### Group Exercise Situation:

A lab worker has just prepared a culture of *Mycobacterium tuberculosis* in order to conduct a drug sensitivity test. He is wearing gloves, a surgical mask, and lab coat, and is using a Biosafety Cabinet which has not been certified in three years.

In your group, take **10 minutes** to discuss the situation, and:

- Identify the biological **hazard**.
- List all the questions you would need to ask to comprehensively characterize the hazard on sticky notes.

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## Hazard Characterization

### Group Exercise Situation:

A lab worker has just prepared a culture of *Mycobacterium tuberculosis* in order to conduct a drug sensitivity test. He is wearing gloves, a surgical mask, and lab coat, and is using a Biosafety Cabinet which has not been certified in three years.

In your group, take **10 minutes** to discuss the **hazard** in this situation. Using the factors you considered previously:

- What is the **likelihood** of exposure?
- What are the **consequences** of exposure?

What are some of the biggest factors in your decision?

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 **Hazard Characterization**

**Group Exercise Situation:**

A lab worker has just prepared a culture of *Mycobacterium tuberculosis* in order to conduct a drug sensitivity test. He is wearing gloves, a surgical mask, and lab coat, and is using a Biosafety Cabinet which has not been certified in three years.


**RISK**

Likelihood




Consequences

37

 **Biosecurity Risk Characterization**

For **Biosecurity Risks** the **threat** is an adversary aiming to acquire the biological material (**hazard**) and use it to cause harm

*(Other security risks may exist in the context of the situation, but for this activity we will focus on the theft and release of the biological material)*



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## Threat Characterization

### Group Exercise:

If **characterizing** the **threat** is intended to identify the likelihood and consequences of a bad event (i.e. theft and subsequent release), what do you need to know about the **threat** and about the **hazard**?

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## Threat Characterization

### Group Exercise Situation:

The lab worker discovers his culture of *Mycobacterium tuberculosis* is Extremely Drug Resistant (XDR). Meanwhile, a local animal rights group has threatened to disrupt laboratory operations and generate publicity by breaking in and stealing agents. They believe taking samples of XDR will generate the most publicity.

**In your group**, take **10 minutes** to discuss the situation, and:

- Identify the **threats** and **hazards** (targets for theft and release).
- List all the questions you would need to ask to comprehensively characterize the **threat** on sticky notes.

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## Threat Characterization

### Group Exercise Situation:

The lab worker discovers his culture of *Mycobacterium tuberculosis* is Extremely Drug Resistant (XDR). Meanwhile, a local animal rights group has threatened to disrupt laboratory operations and generate publicity by breaking in and stealing agents. They believe taking samples of XDR will generate the most publicity.

In your group, take **10 minutes** to discuss the **threat** in this situation? And what is their target (**hazard**)? Using the factors you considered previously:

- What is the **likelihood** of a theft to occur?
- What are the **consequences** of a theft?

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What are some of the biggest factors in your decisions?

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## Threat Characterization

### Group Exercise Situation:

The lab worker discovers his culture of *Mycobacterium tuberculosis* is Extremely Drug Resistant (XDR). Meanwhile, a local animal rights group has threatened to disrupt laboratory operations and generate publicity by breaking in and stealing agents. They believe taking samples of XDR will generate the most publicity.



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## Risk Characterization

### Discussion:

How would the risk change if the lab worker wore a **respirator** instead of a surgical mask, and was working in a **biosafety cabinet** that had been **certified** in the **last six months**?

OR

If there were **strict physical security** measures in place at the laboratory to keep unauthorized people out?

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## Risk Characterization

Another consideration in characterizing risk is the concept of **relative risk**.

**Relative risk** is the value of one particular risk (in terms of likelihood and consequences) in the context of another risk.

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## Risk Characterization

Understanding the **relative risk** is important for the overall process of **characterizing risk**.



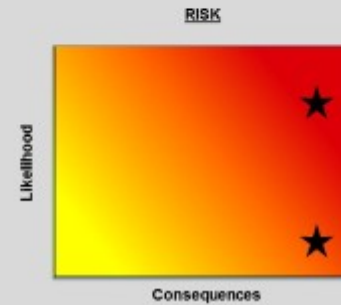
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## Relative Risk

The use of personal protective equipment can lower the **likelihood** of exposure.

A vaccine can lower the **consequences** of exposure.



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### Relative Risk

The use of physical barriers lowers the **likelihood** of theft.

Availability of therapeutics can lower the **consequences** of theft and malicious release.

**RISK**



Likelihood

Consequences

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## Course Overview

1. Course Objectives and Introduction
2. Basics of Risk Assessment
3. Risk Characterization
- 4. Risk Evaluation**
5. Review

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## Risk Evaluation

The **Risk Assessment** process does not end with **Risk Characterization**.

You must also **evaluate** the risk.

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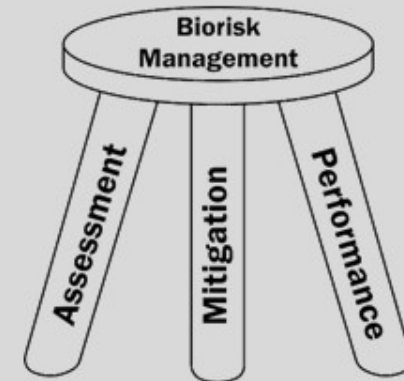
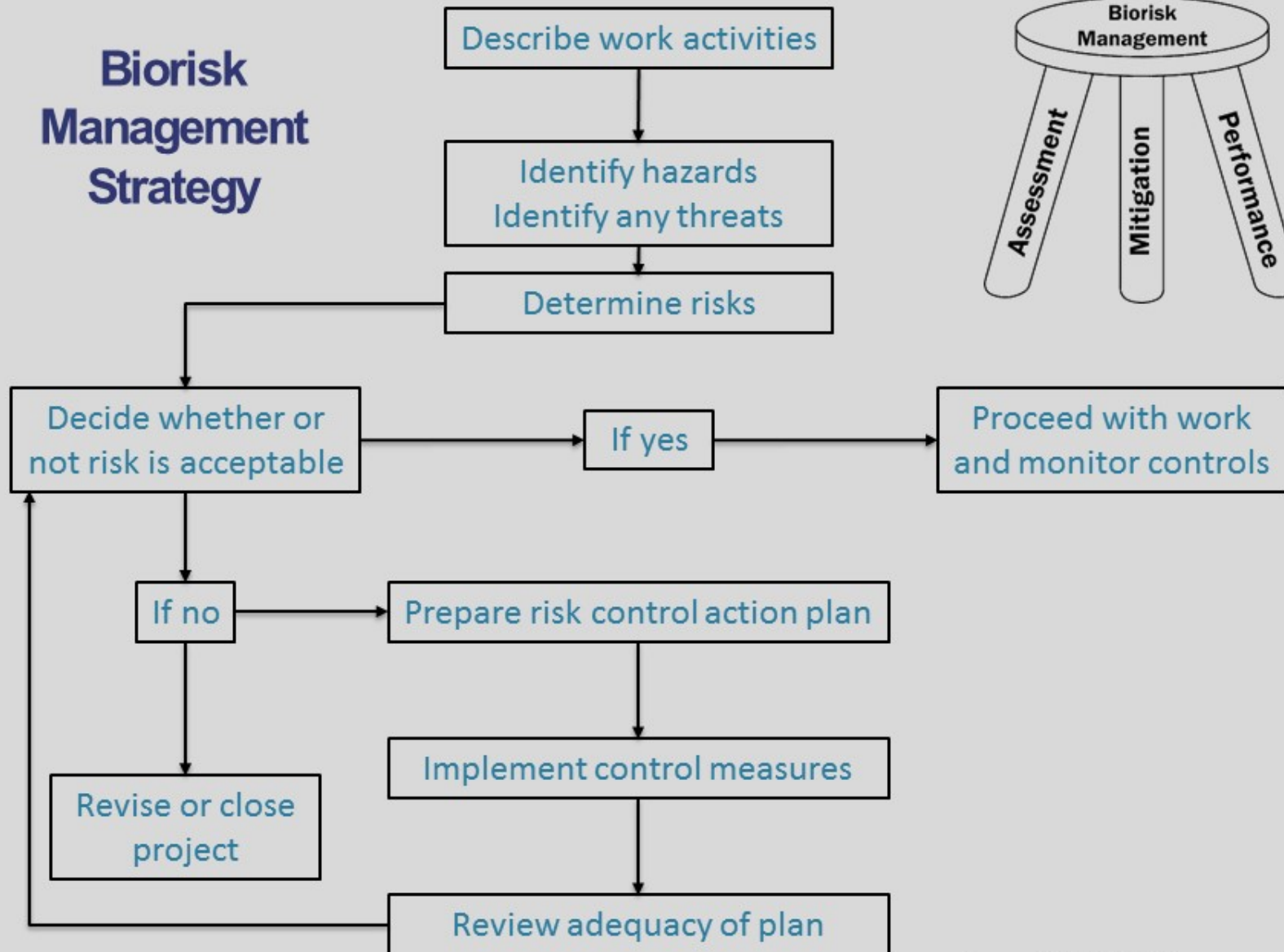
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# Biorisk Management Strategy



Source: CWA 15793:2011



## Risk Evaluation

**Risk Evaluation** is the process of determining, subjectively, whether a risk is **high** or **low**, and whether it's **acceptable** (proceed with work) or not (leading to the implementation of risk mitigation measures).

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## Risk Evaluation



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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**.



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## Risk Evaluation

**Question:**

**In your group**, please spend **5 minutes** discussing the question:

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

Be prepared to share your thoughts with the class.

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## Risk Evaluation

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

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## Risk Evaluation

There is **no systematic way** of evaluating risk or to determine risk acceptability.



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## Risk Evaluation

Consider a risk determined to be High, is this risk unacceptable? If so, what do we do...

- Should we stop the work? What is the impact to stopping the work?
- Do we implement risk mitigation measures to lower the risk? What are the impacts to implementation of risk mitigation measures?

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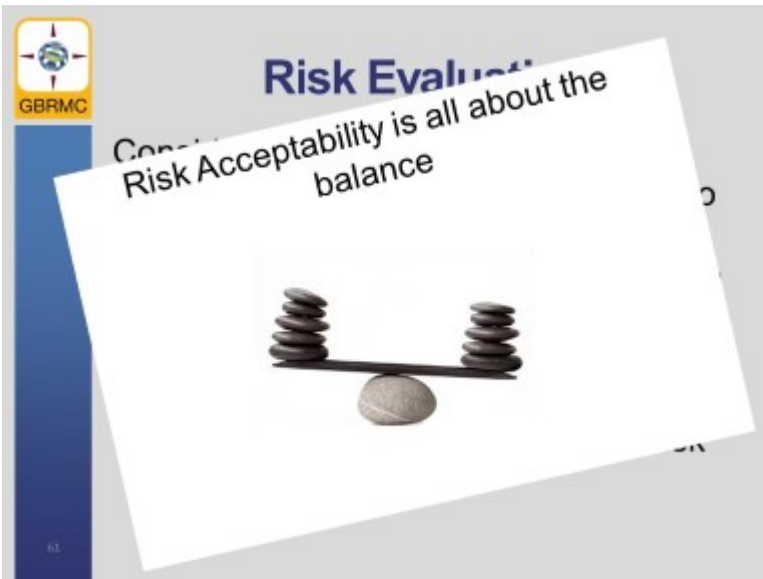
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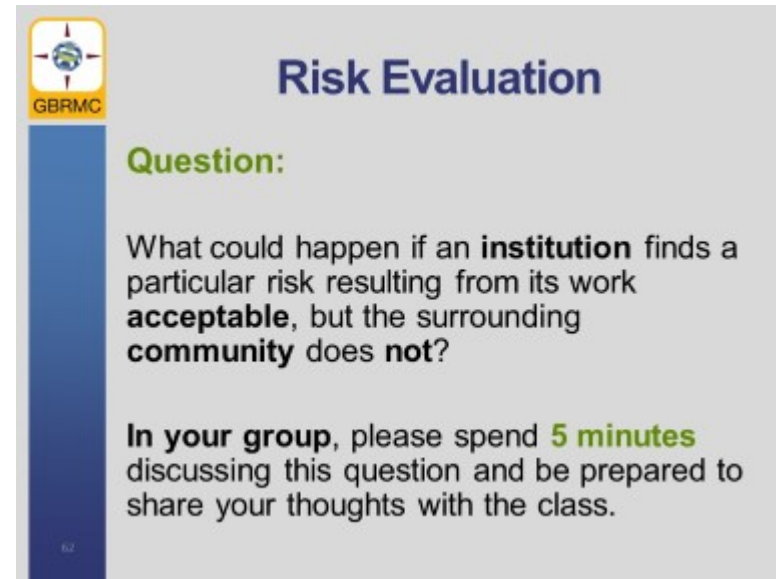
GBRMC

## Risk Evaluation

Concept: Risk Acceptability is all about the balance



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GBRMC

## Risk Evaluation

**Question:**

What could happen if an **institution** finds a particular risk resulting from its work **acceptable**, but the surrounding **community** does **not**?

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

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## Risk Evaluation

The **community's risk acceptability level** is still important for the **institution** because an **institution in conflict** with the **community** may not be able to operate normally.



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## Risk Evaluation

Only an institution can determine whether a particular risk is **Very High, High, Moderate, Low, or Very Low.**



**Question:**

So how can your **risk evaluation** be communicated? Consider how you would depict it on the likelihood consequences graph of risk?

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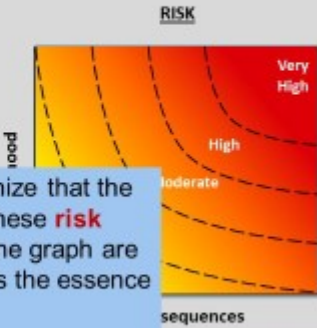
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 **Risk Evaluation**


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**.

 **Risk Evaluation**

Different **institutions** will have different definitions for what is **high** or **low**, or even what the **shapes** of the curves are.



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## Risk Evaluation

### Group Exercise:

What is the difference between **Risk Averse** and **Risk Tolerant**?

**In your group**, please spend **10 minutes** to write in the **risk tolerance curves** on the following two graphs depicting a **Risk Averse** and a **Risk Tolerant** evaluation.

Be prepared to present to the class.

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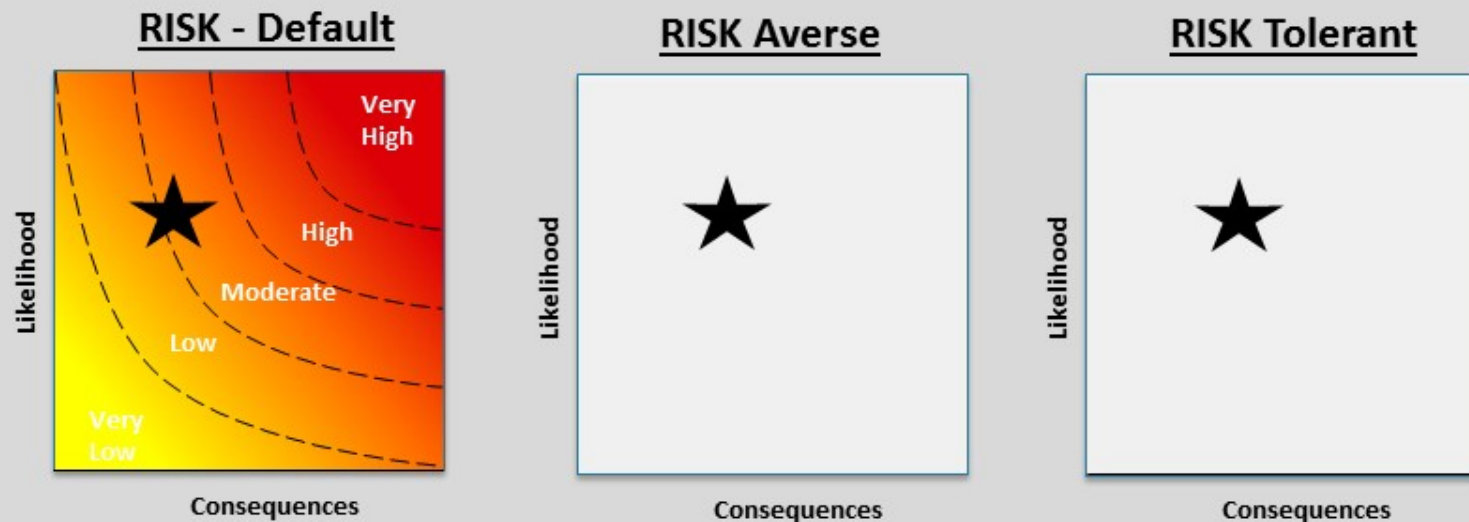
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# Risk Evaluation

What is the difference between **Risk Averse** and **Risk Tolerant**?

How might these two characteristics be depicted using the **risk tolerance curves** on the graph?





## 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 **risk-tolerant**, it might proceed with procedures others may find too **“dangerous”**.

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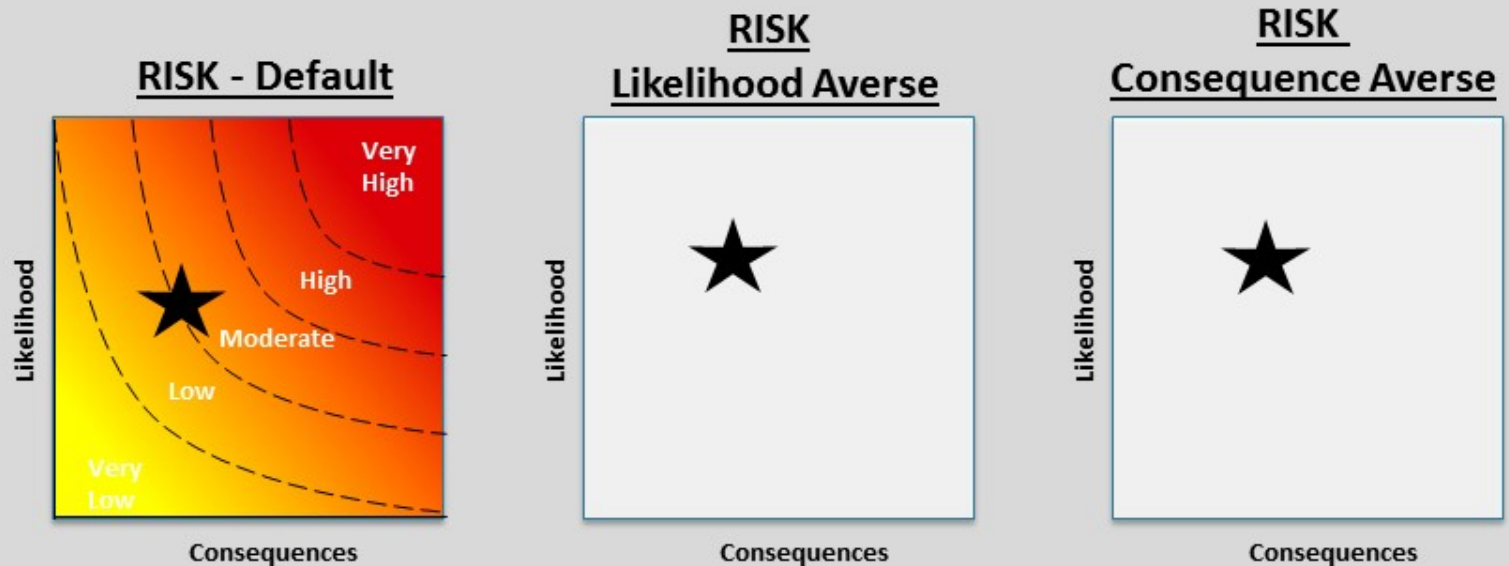
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# Risk Evaluation

What might the **risk tolerance curves** of an institution that is **Likelihood Averse** or **Consequence Averse** look like?





## Risk Evaluation

- When might an institute become **risk-tolerant**?
- When might an institute become more **consequence adverse**?
- When might an institute become more **likelihood adverse**?

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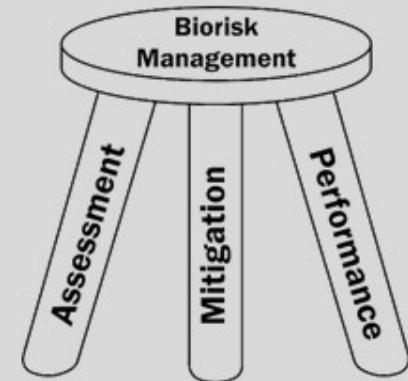
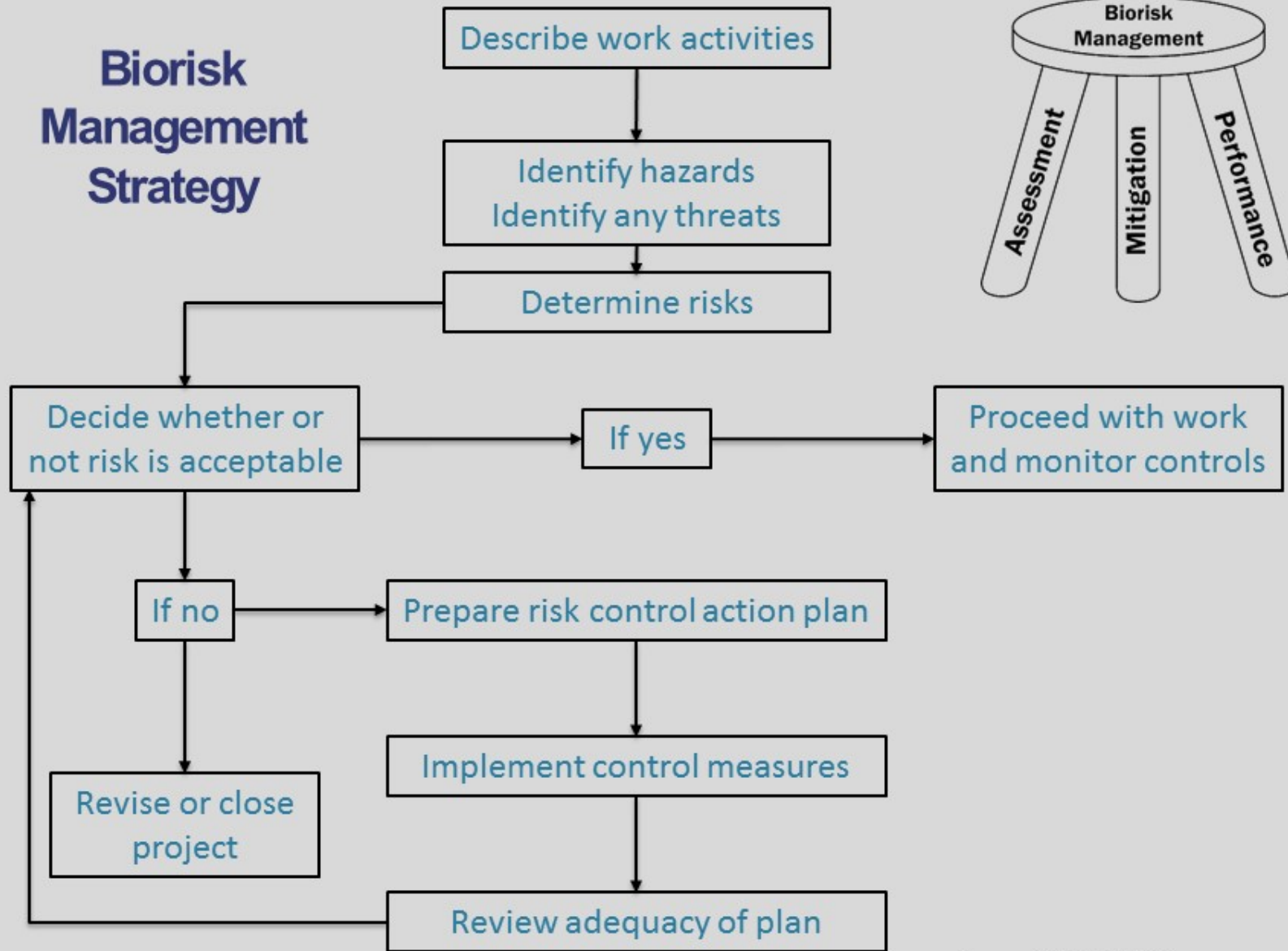
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# Biorisk Management Strategy



Source: CWA 15793:2011



## Course Overview

1. Course Objectives and Introduction
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5. **Review**



## Review

**Question:**

What is **risk**?

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**Review**

**Question:**

What is the difference between a **hazard** and a **threat**?

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**Review**

**Question:**

Neither a **hazard** or a **threat** are a **risk** without a \_\_\_\_\_?

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## Review

### Question:

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

Where does **likelihood** and **consequences** fit in?

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## Review

### Question:

If your **risk evaluation** profile shows you are **likelihood-averse**, will you be more likely to focus mitigation efforts on **vaccines** and **therapeutics**, or **personal protective equipment**?

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## Review

**Question:**

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

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## Final Review

For **10 minutes**, let's discuss what we have learned about **risk characterization and evaluation**.

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

- A risk assessment supports understanding risks based upon activities and aids risk decision making
- Risk Characterization is the process of identifying the factors that contribute to risk and determining the likelihood and consequences that contribute to risk.
- Risk Evaluation is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

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## References and Tools

**BioRAM is available from:**

- <http://www.biosecurity.sandia.gov/BioRAM/>
- **And on your flash drives!**

**Guidance on risk assessment by IFBA**

- [http://www.internationalbiosafety.org/images/IFBA\\_docs/Laboratory%20Biosafety%20and%20Biosecurity%20Risk%20Assessment.pdf](http://www.internationalbiosafety.org/images/IFBA_docs/Laboratory%20Biosafety%20and%20Biosecurity%20Risk%20Assessment.pdf)

**Laboratory Biorisk Management**

- <https://www.crcpress.com/Laboratory-Biorisk-Management-Biosafety-and-Biosecurity/Salerno-Gaudioso/p/book/9781466593640>



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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?