Biorisk Assessment Characterization & Evaluation

Controlling Laboratory Biorisks 2012

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM
CTR

Course Overview

1. **Course Objectives and Introduction**

2. Basics of Risk Assessment

3. Risk Characterization

4. Risk Evaluation

5. Review

Course Objectives

- Be able to define risk.

- Be able to explain the dependence of likelihood and consequences on the risk assessment.

- Be able to describe the process of model development.

- Be able to describe the advantages of a robust structured risk assessment process.

Key Principles

- A biosafety and biosecurity 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 Characterization is the process of identifying the factors that contribute to risk and determining the likelihood and consequences that contribute to risk.

- Complete and thorough analysis of the different hazards, threats and situations that can affect risk will increase the robustness of the risk characterization process.

- 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.

Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

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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**.

Introduction

A **biological risk assessment** allows a facility, laboratory, or other operation 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 risks.

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.

Generally, we can classify biological risk assessments into two types:
- **Biosafety risk assessment**
- **Biosecurity risk assessment**

Introduction

A **biosafety risk assessment** is an analytical procedure designed to characterize *safety* risks associated with biological agents (pathogens/toxins) in a laboratory.

Introduction

A **biosecurity risk assessment** is an analytical procedure designed to characterize *security* risks associated with biological agents in a laboratory.
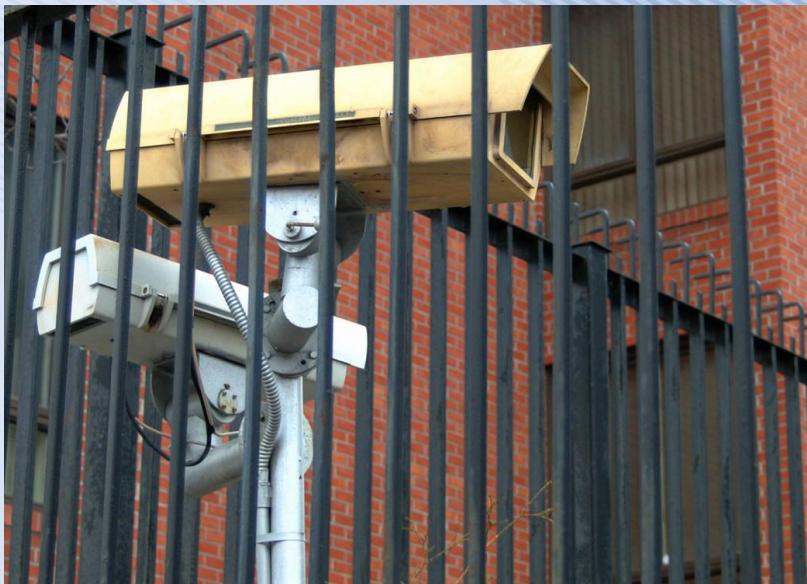
Introduction

To be comprehensive:

A **biosafety risk assessment** should consider every aspect of operations, including materials, equipment, and activities conducted that involves infectious disease agents or toxins.

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

Risk Assessment

Why is risk assessment so important?

Think about this question:

**Is conducting a risk assessment simple? Why or why not?**

Risk Assessment

Laboratory biosafety: containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]

Laboratory biosecurity: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. [2]
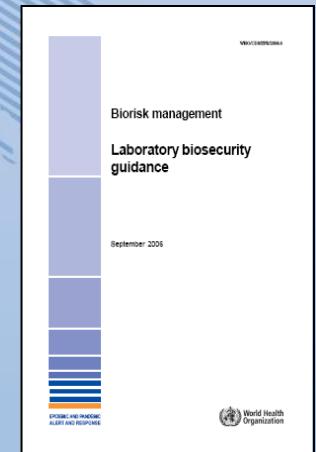
[1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)
[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

Introduction

Why perform a biological risk assessment?

The identification of preventive measures is determined by the **RISK ASSESSMENT**

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?

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 **BAD** happening and **Consequences** of that occurrence

Risk is a combination of the probability of occurrence of harm and the severity of that harm
(ISO/IEC Guide 51:1999)

RISK

Likelihood

Consequences

Very High

High

Moderate

Low

Very Low
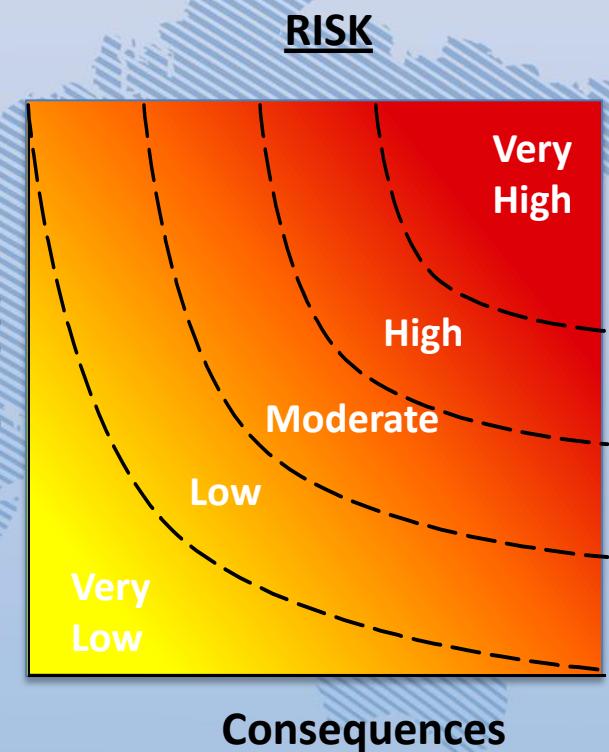
Risk

- A **hazard** is a source that has a potential for causing harm

- A **threat** is a person who has intent and/or ability to cause harm

- A risk can be based on either a hazard and/or a threat

- The term **hazard** is used in the **biosafety** context, and **threat** is used in the **biosecurity** context.

What is the risk of crossing the road?

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.

Risk

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

R = f(L, C)

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences
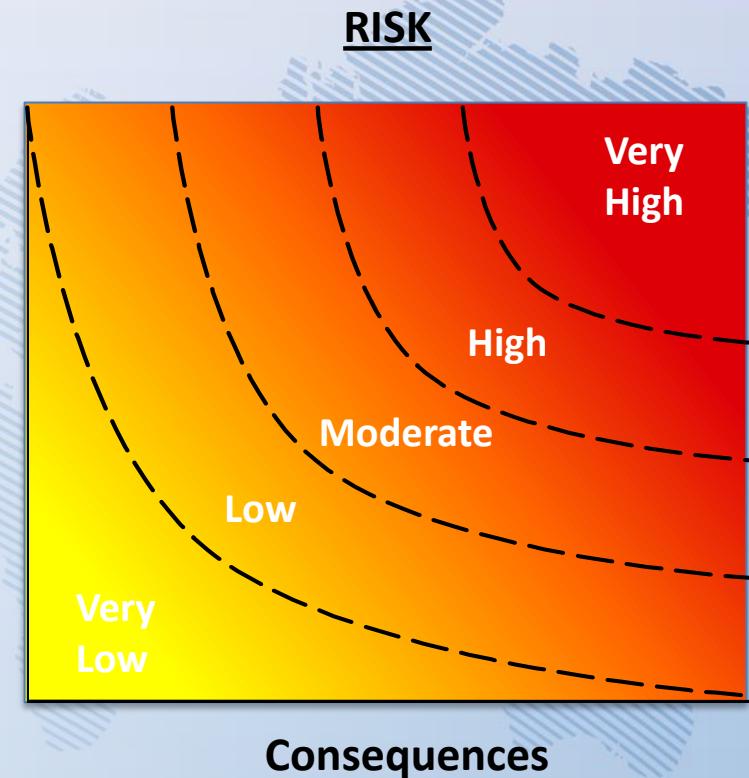
Risk

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.
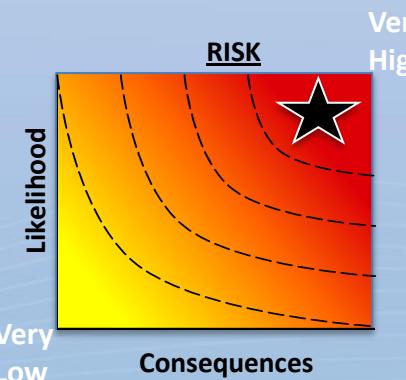
You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.
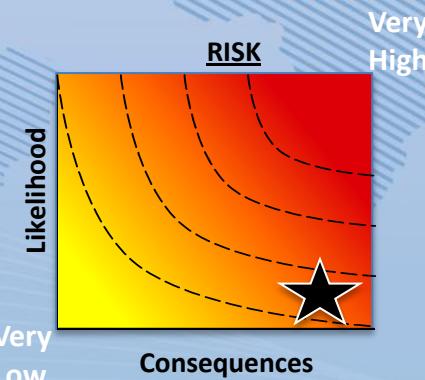
You are holding a tiger cub with a playful temperament in your arms.
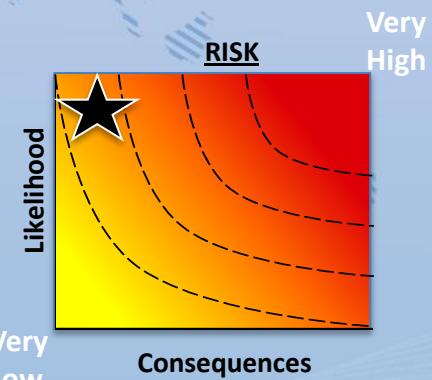
Risk

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

RISK

Likelihood

Very High

High

Moderate

Low

Very Low
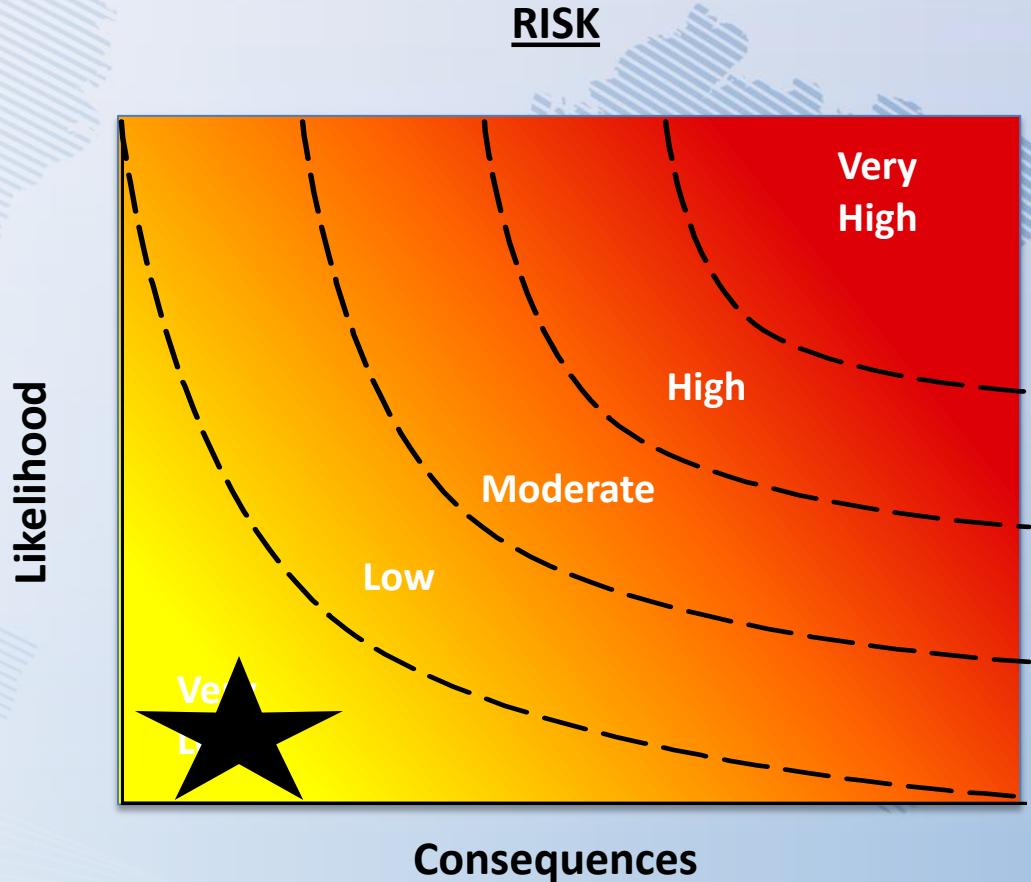
Consequences

Risk Assessment

A **risk assessment** could be defined as a procedure that analyses a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

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

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.

RISK

Very High

High

Moderate

Low

Very Low

Likelihood

Consequences

Risk Assessment Strategy

Risk Assessment Strategy:

Describe work activities → Identify hazards → Determine risks → Decide whether or not risk is acceptable

If yes → Proceed with work and monitor controls

If no → Prepare risk control action plan → Implement control measures → Review adequacy of plan

Revise or close Project

Biorisk Management = Assessment, Mitigation, Performance
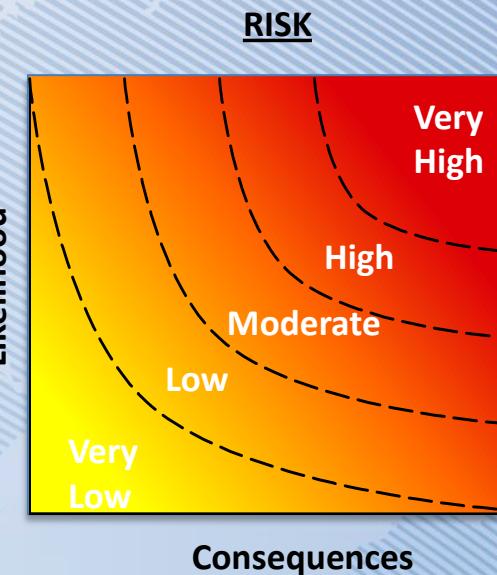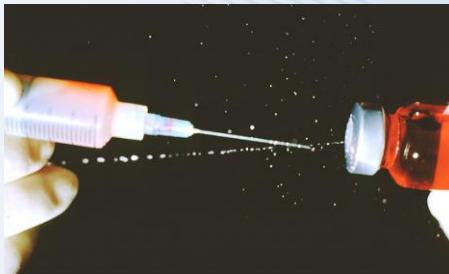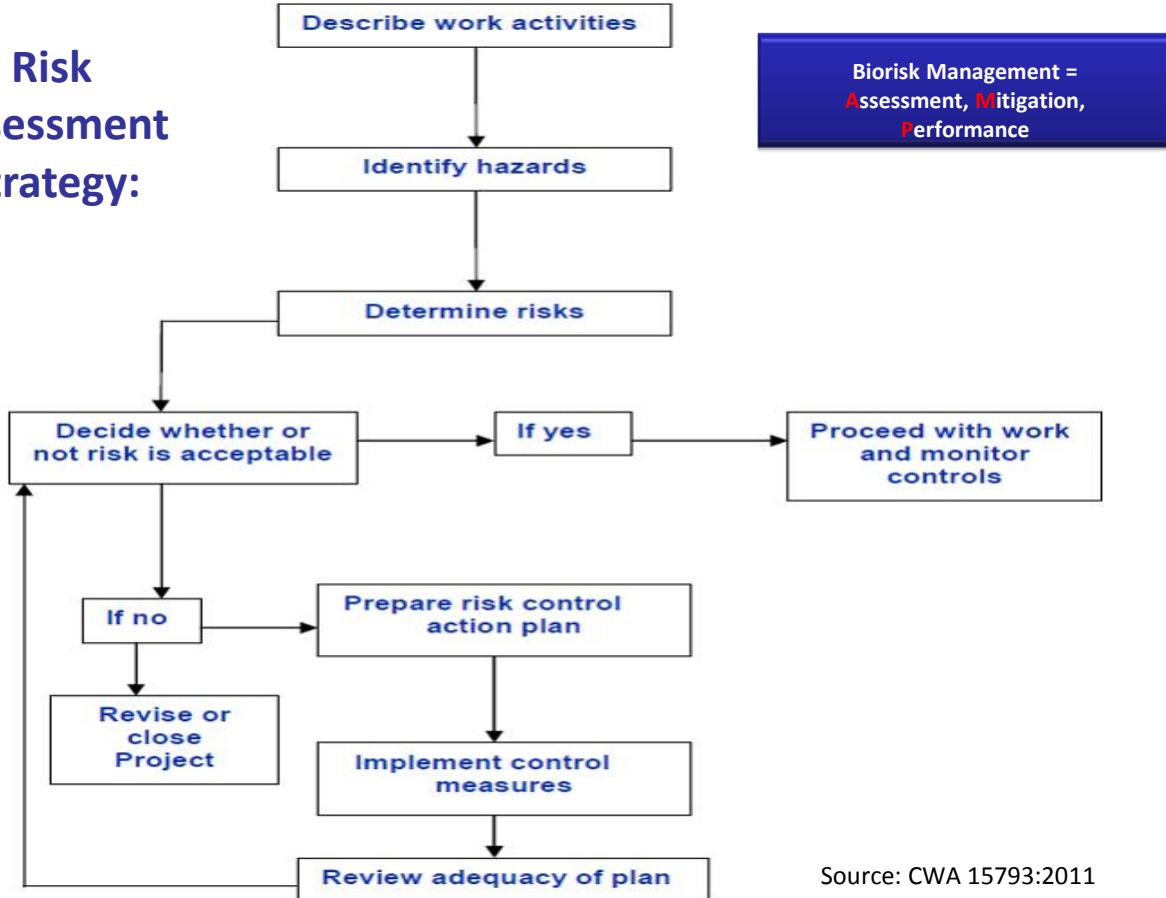
Source: CWA 15793:2011

What is the Objective?

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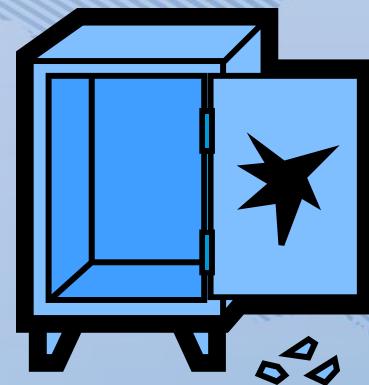
Biosafety Risk Assessment

Group Activity Step 1:

Think about the tiger scenario, and the broad categories that you came up with. What are some of the broad **categories** of factors that you need to look into to conduct a **biosafety risk assessment**? or a **biosecurity risk assessment**?

In your group, please spend **5 minutes** to answer the above question.

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

Be prepared to report your answers to the class.

Biosafety Risk Assessment

Group Activity Step 2:

Next, what are the key questions you need to answer to define the likelihood for one of the risks you defined?

What are the key questions you need to answer to define the consequences for one of the risks you defined?

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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3. **Risk Characterization**

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Risk Characterization

In the previous activities you have identified all the factors that should be considered in a **laboratory biosafety or biosecurity risk assessment**.

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

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.

Risk Characterization

Part of this process is the identification of the appropriate **hazard** or **threat**.

The **hazard** or **threat** is the **source** or **causative agent** of a particular **risk**.

The term **hazard** is used in the **biosafety** context, and **threat** is used in the **biosecurity** context.

Risk Characterization

For **Biosafety Risk**, the **hazard** is the biological material worked with in the lab.

Characterizing the material allows one to determine important parameters for **likelihood** and **consequences**, such as **route of exposure**, **infectious dose**, **incubation time**, **morbidity**, **mortality**, **communicability**, and others.
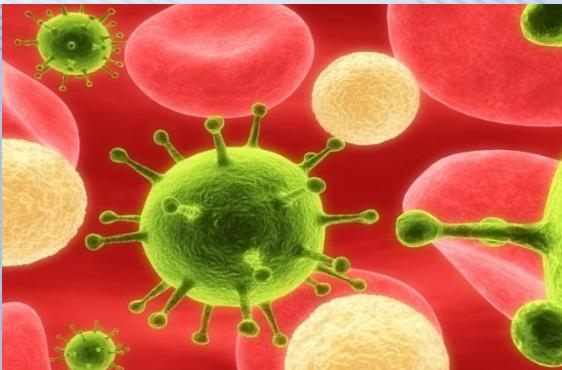
Risk Characterization

For **Biosecurity Risk**, the **threat** is the potential adversary who is interested in the biological materials.

Characterizing potential adversaries allows one to determine important parameters for **likelihood** and **consequences**, such **means**, **motives**, and **opportunity**.

Risk Characterization

Activity:

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

Risk Characterization

Scenario:

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.

What is the **hazard** in this scenario?

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?

RISK

Very High

High

Moderate

Low

Very Low

Likelihood

Consequences
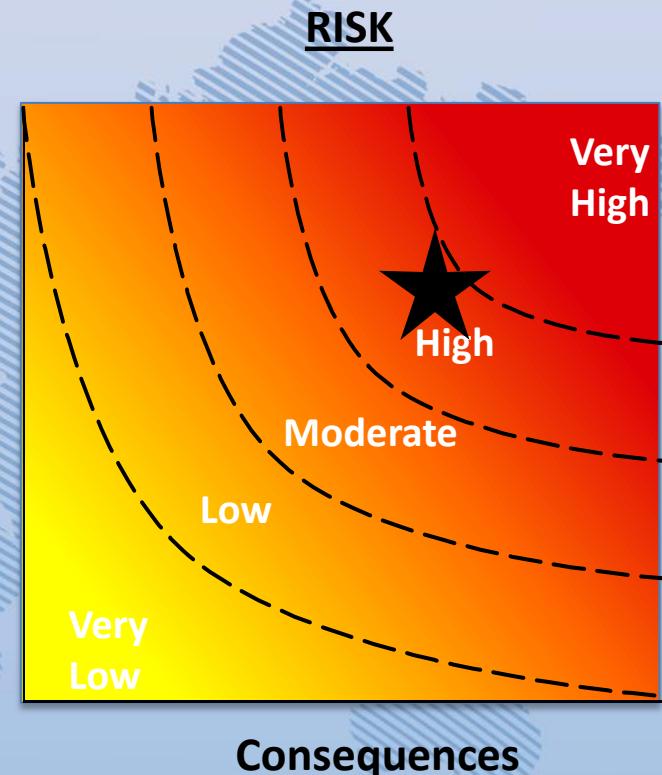
Risk Characterization

Scenario:

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.

What is the **threat** in this scenario?

What is the **likelihood** of a theft?

What are the **consequences** of a theft?

What are some factors that should be considered?

RISK

Likelihood

Consequences

Very High

High

Moderate

Low

Very Low
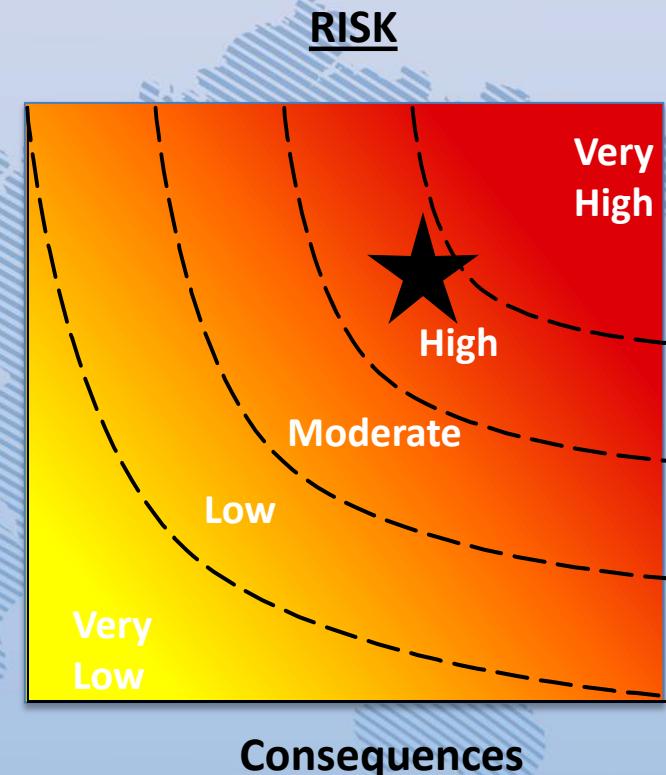
Risk Characterization

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**.

Risk Characterization
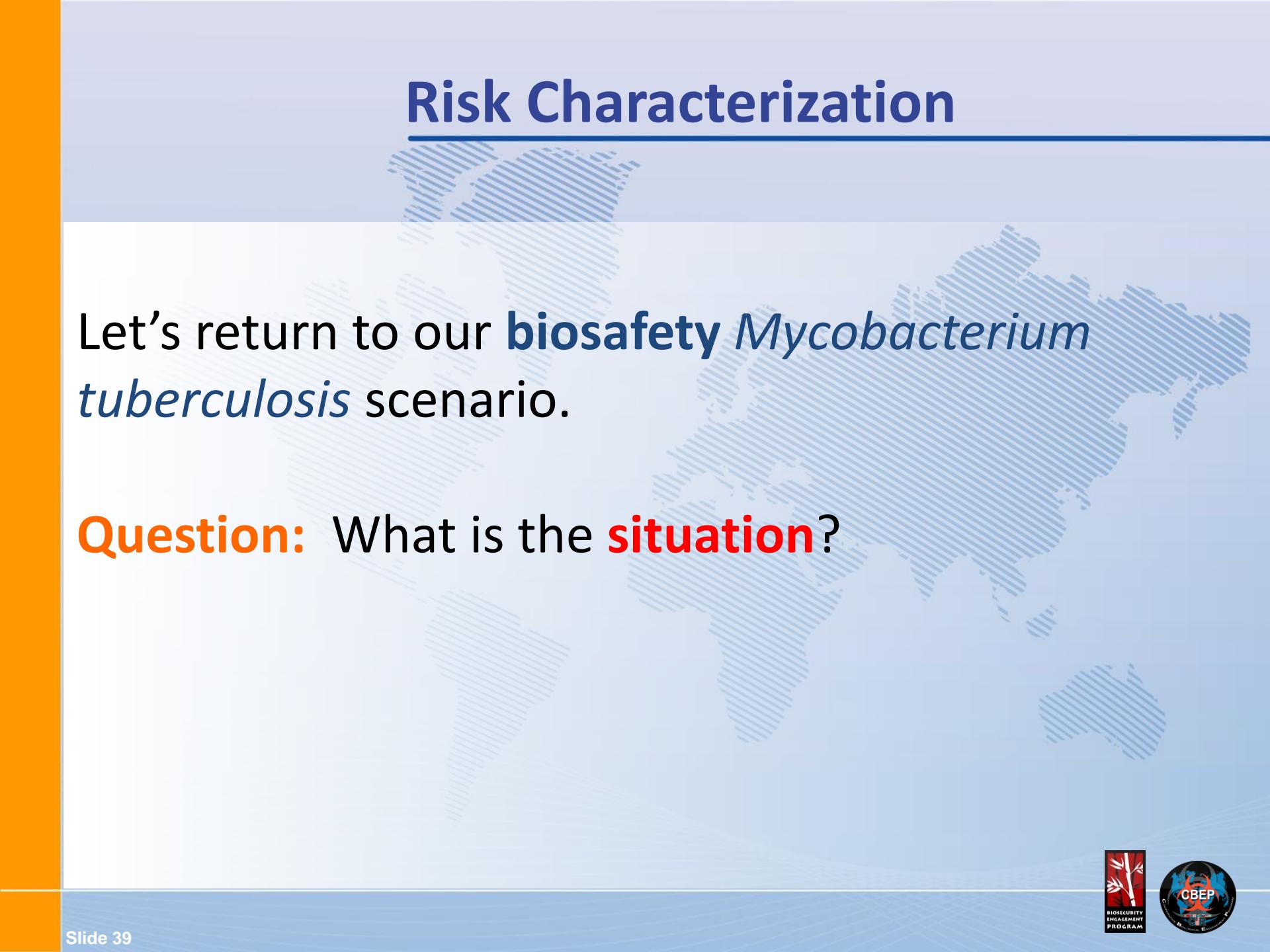
Let's return to our **biosafety** *Mycobacterium tuberculosis* scenario.

Question: What is the **situation**?

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?

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. It helps give meaning to risk.

For example:

Dependent on certain situation, or the PPE used, the risk of aerosol exposure may be higher than the risk of percutaneous exposure.

Risk is relative because it will change depending on the situation and the factors that go into determining the risk, themselves, are not absolute.

# Risk Characterization

To demonstrate the concept of **relative risk**, lets consider different biosafety and biosecurity risk mitigation efforts and their effects on likelihood and consequences.

Risk Characterization

Biosafety

The use of **personal protective equipment** lowers the **likelihood** of exposure.
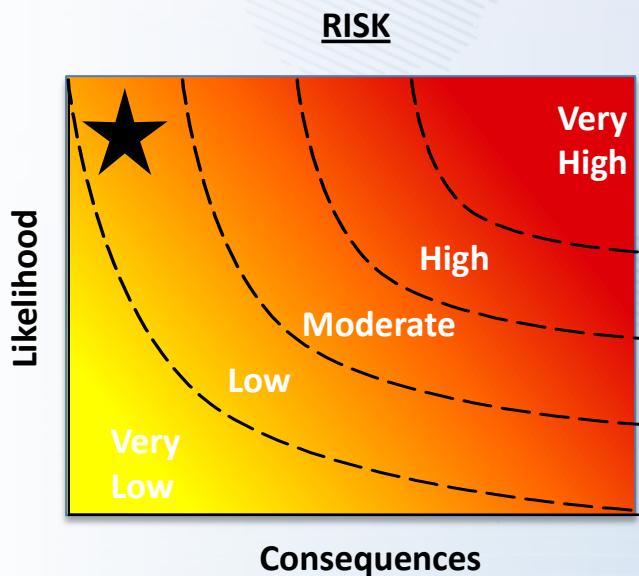
A **vaccine** lowers the **consequences** of exposure.
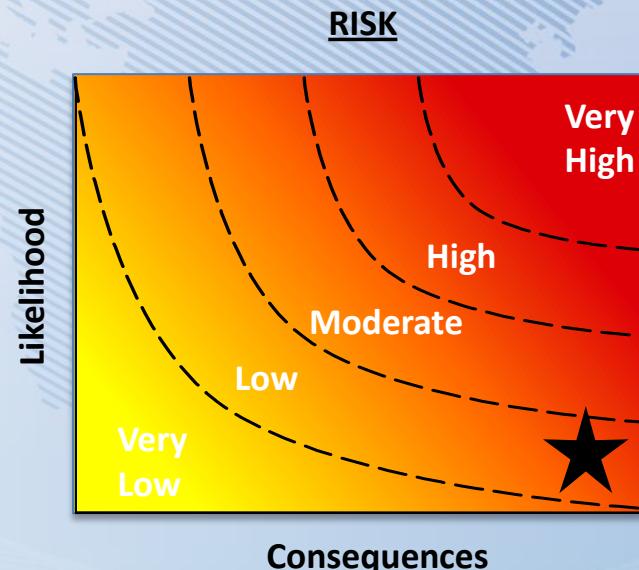
Risk Characterization

Biosecurity

The use of **physical barriers** lowers the **likelihood** **of theft**.
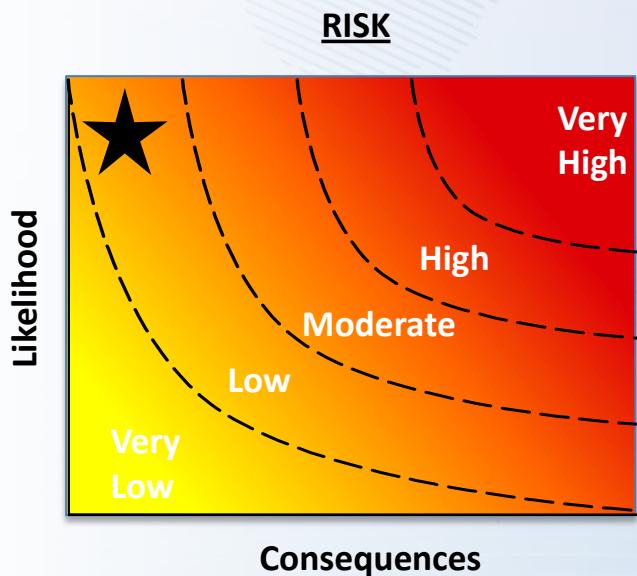
Availability of **therapeutics** lowers the **consequences** **of theft**.

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences
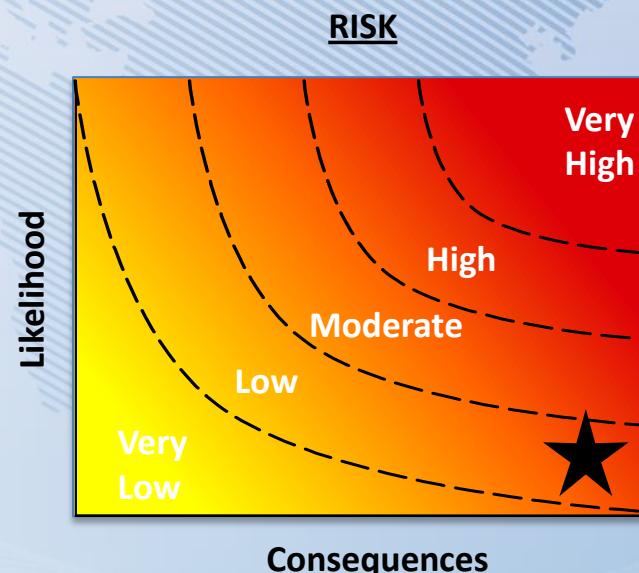
Risk Characterization

Understanding the **relative risk** associated with **different situations** or by implementing **different risk mitigation strategies** is important for the overall process of **characterizing risk**.

Risk Characterization

Naturally, each **facility**, **laboratory**, and **situation** will have its own unique set of **factors** that will be particularly relevant to fully **characterize risk**.

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.

Risk Characterization

A **robust risk characterization** process will generate similar results when assessing similar hazards or threats in similar situations, no matter who is following the methodology, where the characterization is being conducted, and when it's occurring.

A **robust risk characterization** makes a **risk assessment robust**.

BioRAM

One available tool to aid in the laboratory risk assessment process is the **Biosafety and 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**.

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/**

Question:

What might be some benefits of using a **robust**, structured risk assessment process?

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Risk Assessment Strategy

Risk Assessment Strategy:

Describe work activities

↓

Identify hazards

↓

Determine risks

↓

Decide whether or not risk is acceptable → If yes → Proceed with work and monitor controls

If no → Prepare risk control action plan

Revise or close Project

Implement control measures

Review adequacy of plan

Biorisk Management = Assessment, Mitigation, Performance
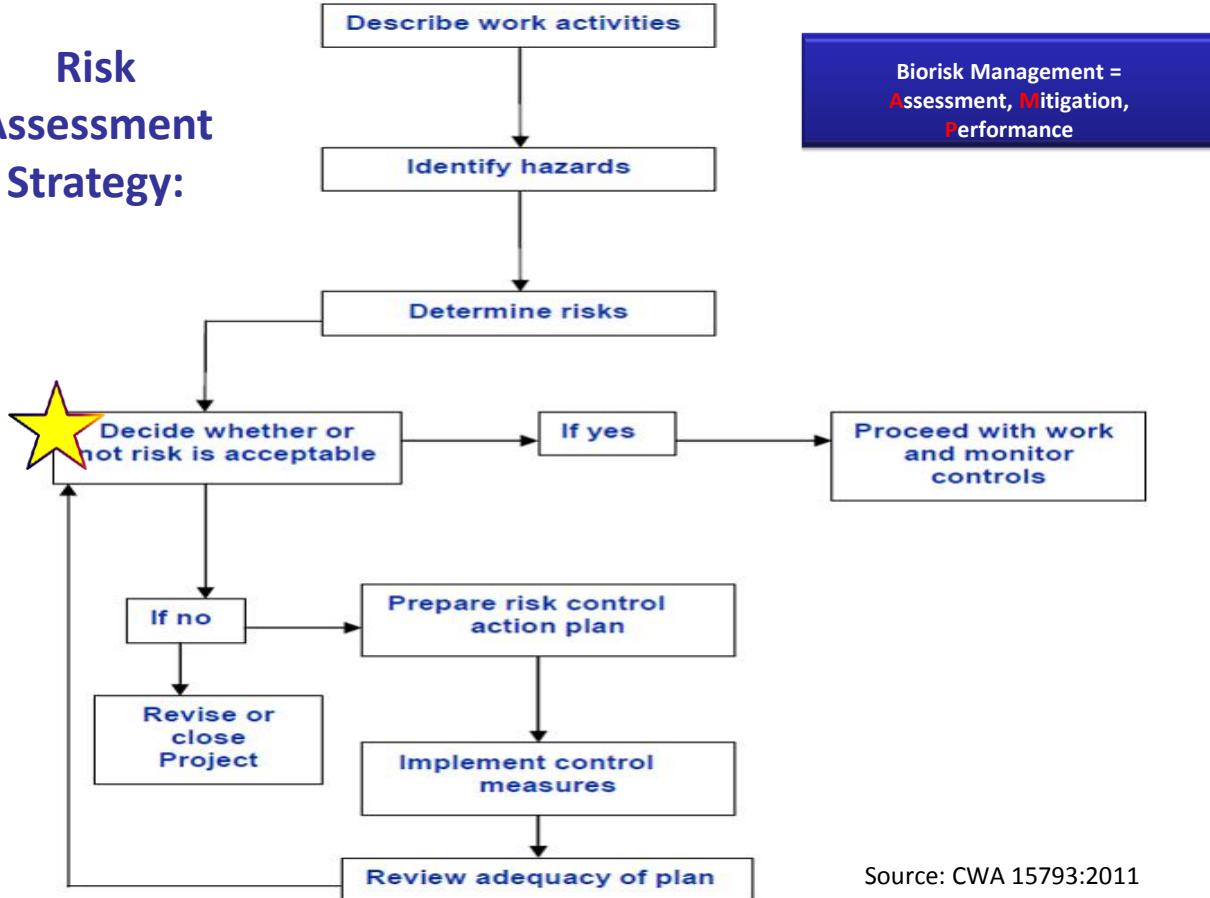
Source: CWA 15793:2011

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.

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**.

Risk Evaluation

Question:

What are some considerations when determining if a risk is acceptable?

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

Risk Evaluation

The curves on the graph, called "**isoquants**", show the different levels of risk, from **Very Low** to **Very High.**

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

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences
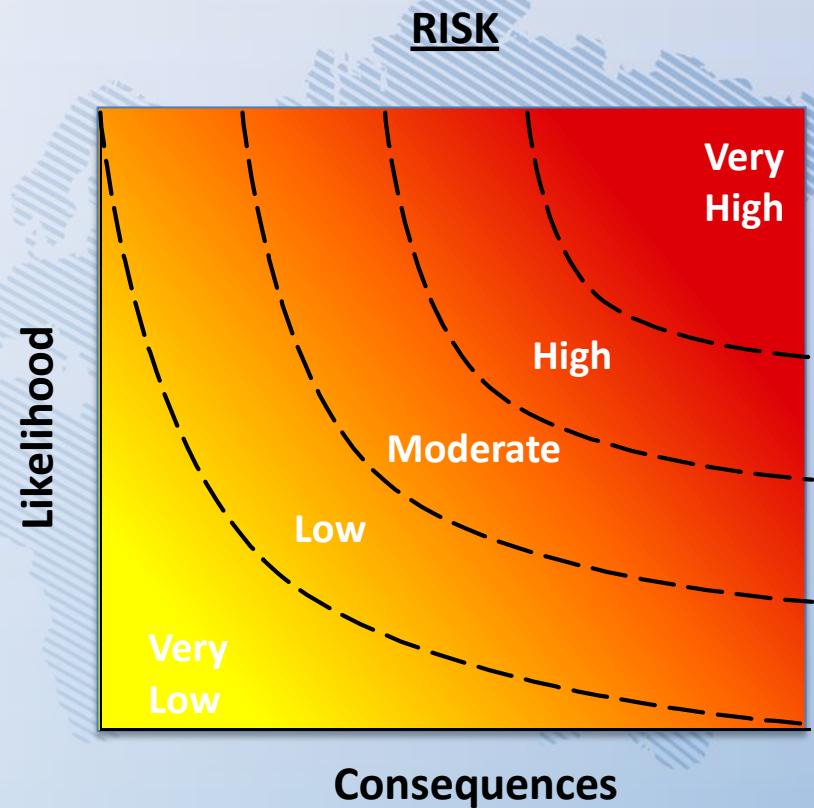
Risk Evaluation

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.

RISK Averse

Likelihood

Very High

High
Moderate
Low

Very Low

Consequences

RISK Tolerant

Likelihood

Moderate
Low

Very Low

Consequences
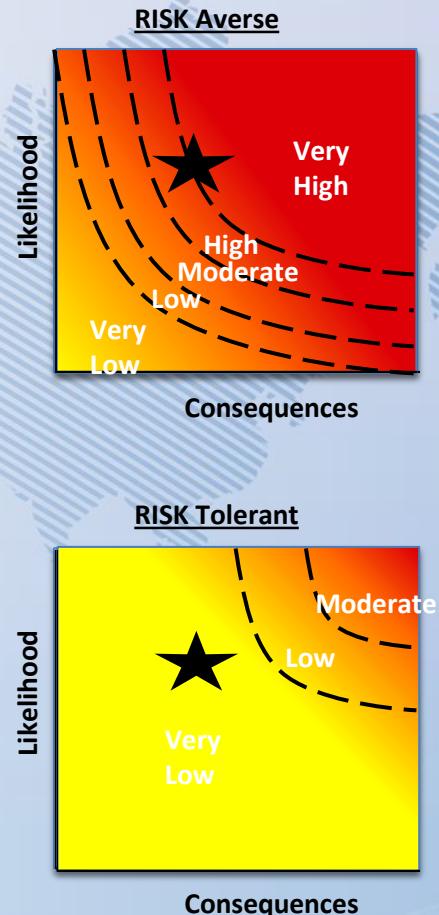
Risk Evaluation

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.

Risk Assessment Strategy

Risk Assessment Strategy:

Describe work activities

Identify hazards

Determine risks

Decide whether or not risk is acceptable → If yes → Proceed with work and monitor controls

If no → Prepare risk control action plan

Revise or close Project

Implement control measures

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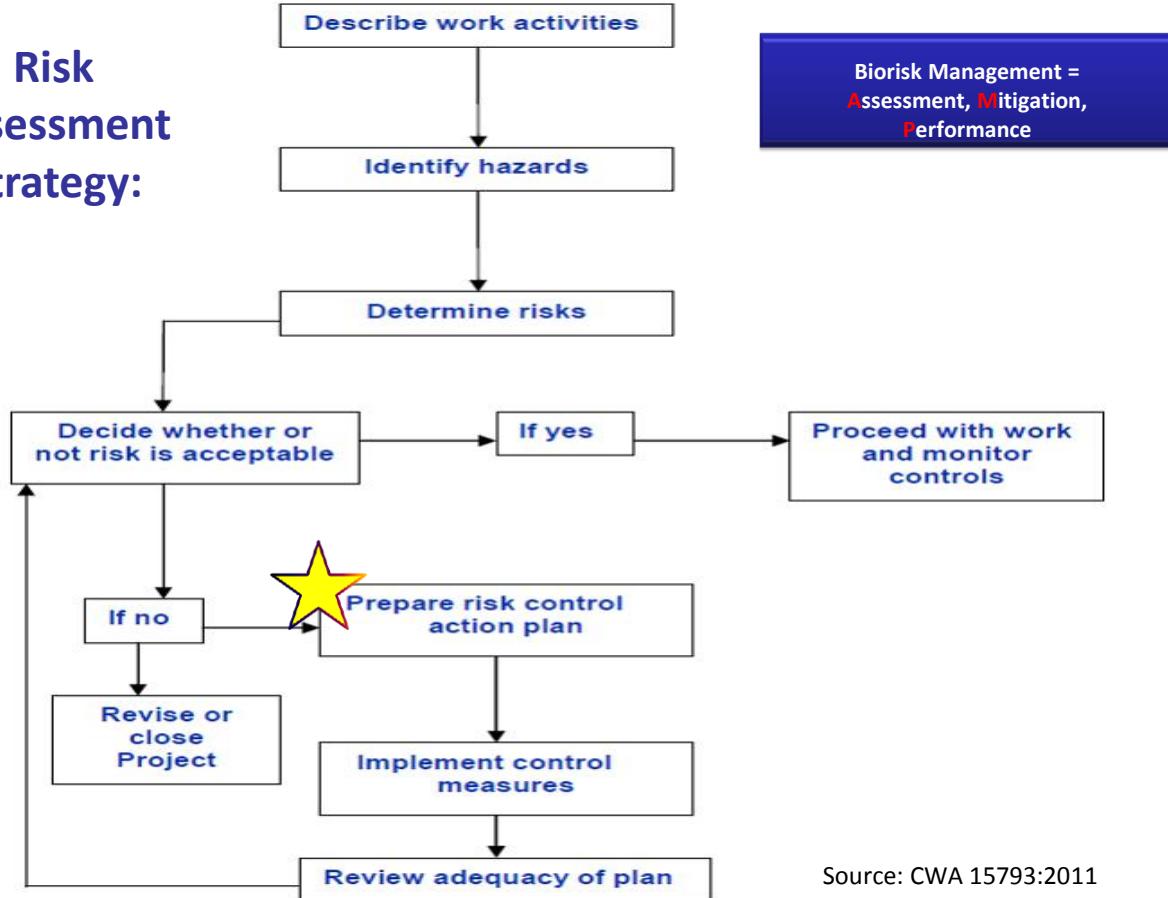
Source: CWA 15793:2011

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Review

Review Question:

What is **risk**?

Review

Review Question:

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

Review Question:

Neither a **hazard** or a **threat** are a **risk** without a _____?

Review

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?

Review

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**?

Review Question:

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

Final Review

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?