SAND2013-6726P

Biorisk Characterization & Evaluation

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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:

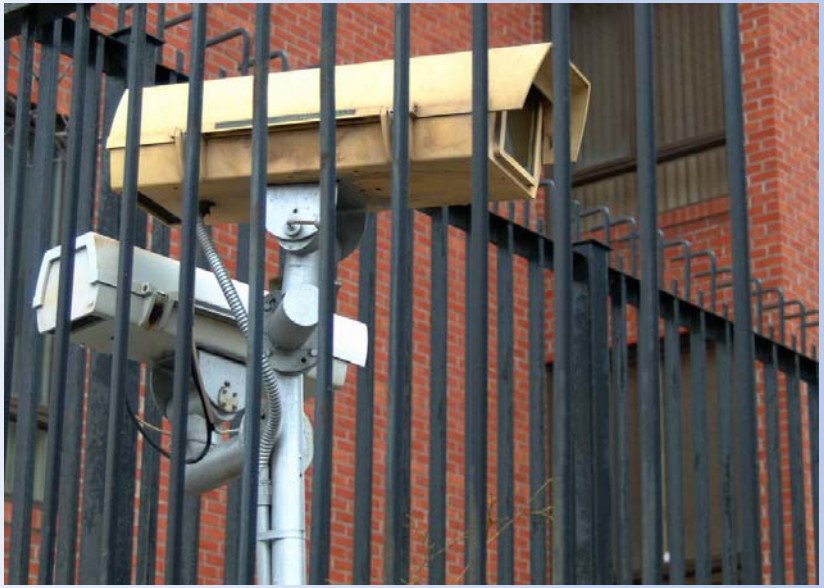
- **Biosafety risk assessment**
- **Biosecurity risk assessment**

Introduction

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

Introduction

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

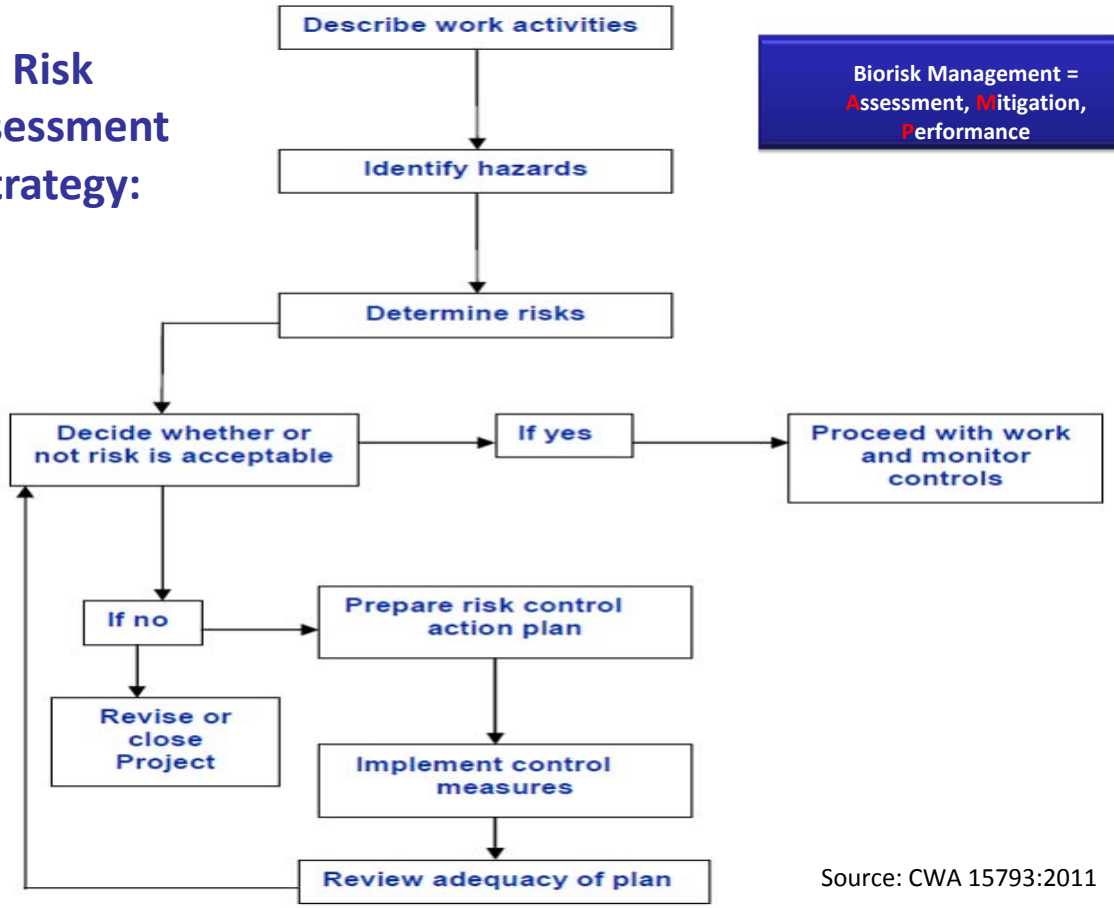
Introduction

Why perform a biological risk assessment?

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.

Risk Assessment Strategy

Risk Assessment Strategy:



Biorisk Management = Assessment, Mitigation, Performance

Source: CWA 15793:2011

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

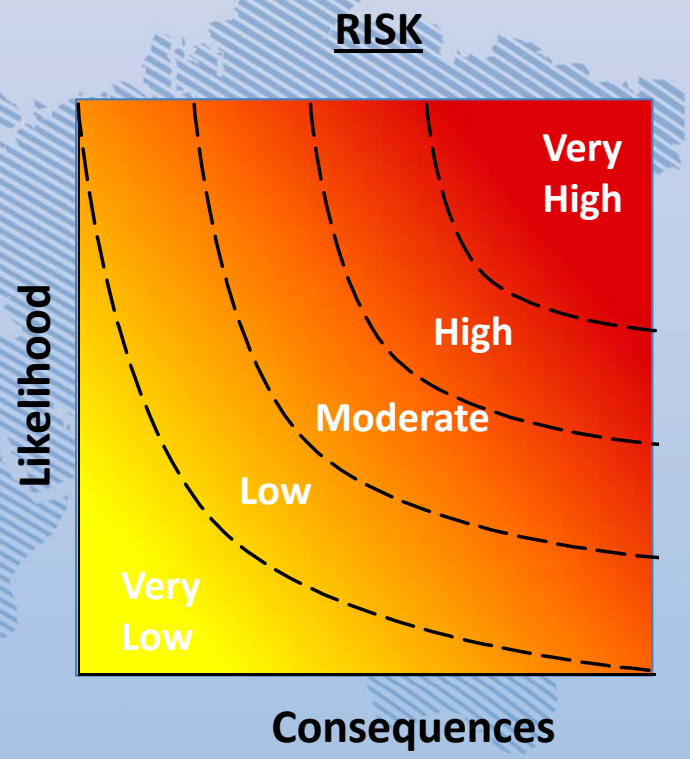
Question: What is Risk?

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 happening and **Consequences** of that occurrence



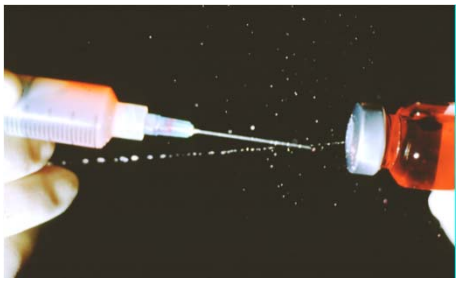
Risk Assessment

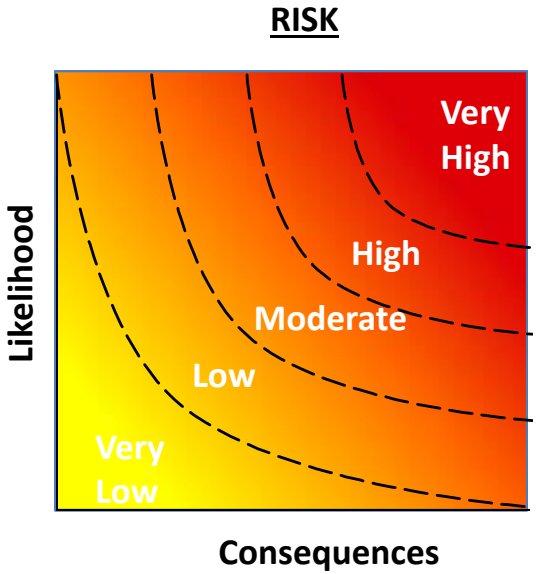
A **risk assessment** could be defined as a procedure that analyses a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

R = f(L, C)

Risk Assessment

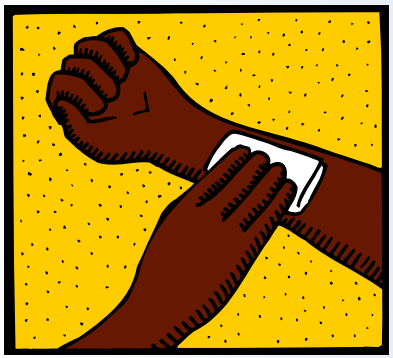
A **risk assessment** assigns values for **likelihood** and **consequences**, which allows us to represent the risk of a particular adverse event on a graph.

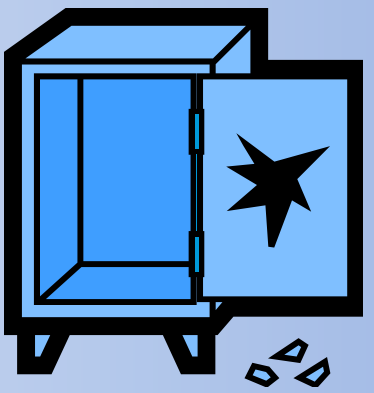




What is the Objective?

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





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**.

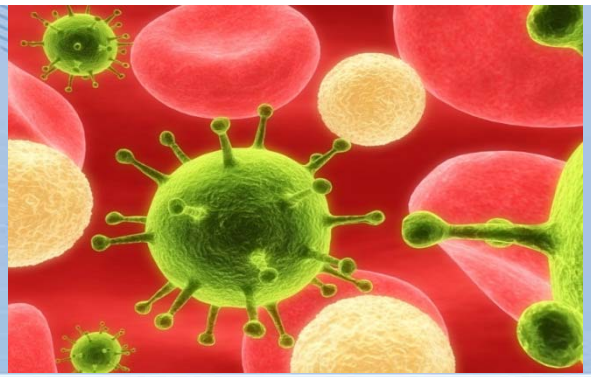
The **hazard** or **threat** is the **source** or **causative agent** of a particular **risk**.

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

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

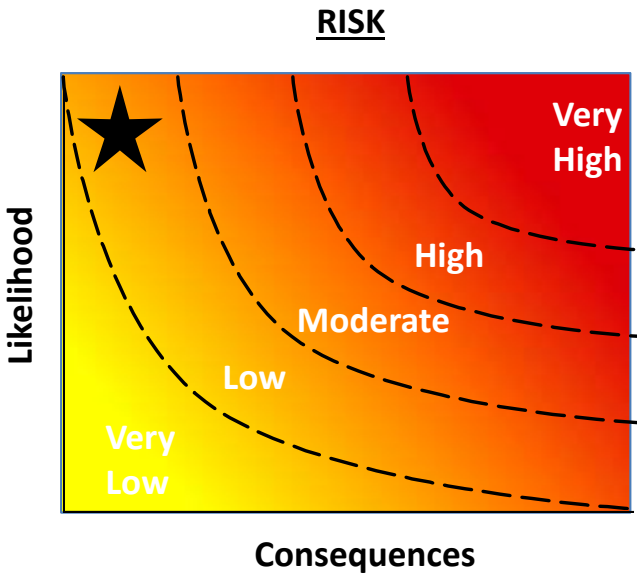
Activity:

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

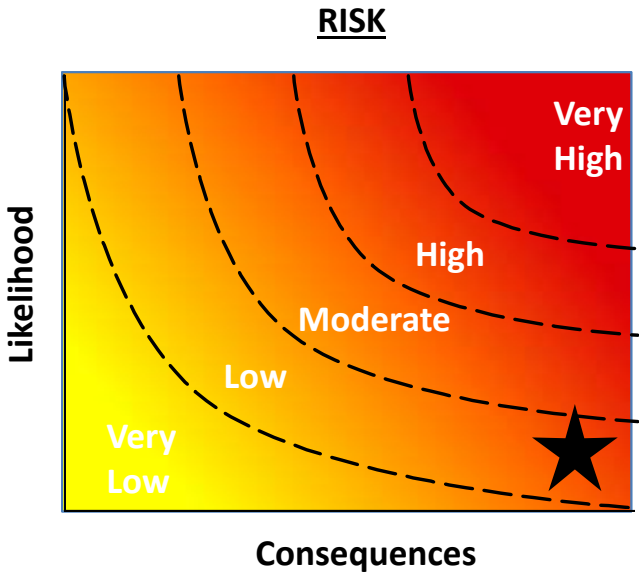
Risk Characterization

Biosafety

The use of **personal protective equipment** lowers the **likelihood of exposure**.



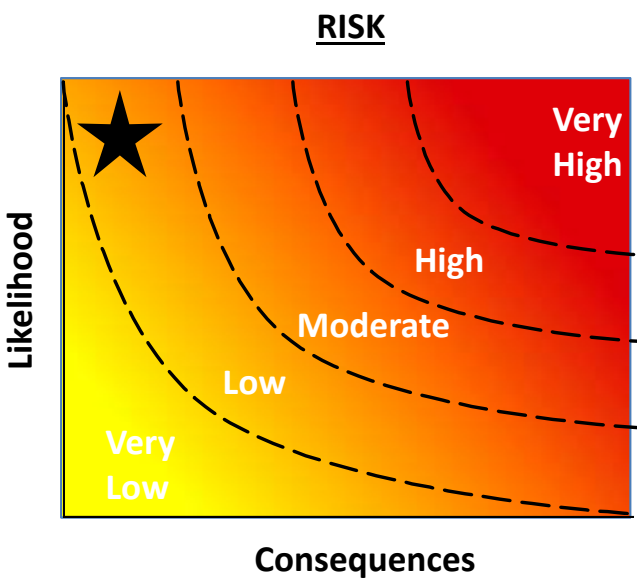
A **vaccine** lowers the **consequences of exposure**.



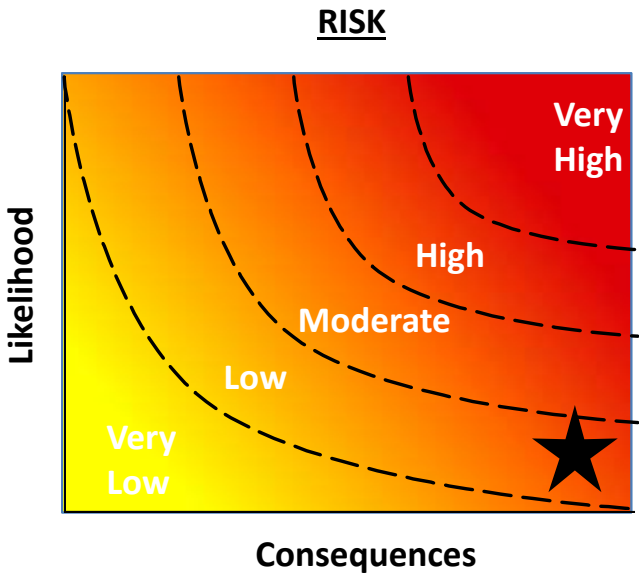
Risk Characterization

Biosecurity

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



Availability of **therapeutics** lowers the **consequences** **of threat**.



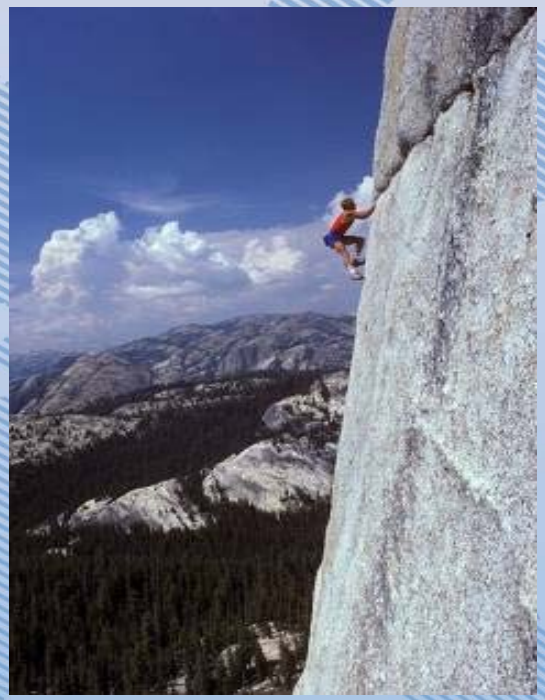
Risk Evaluation

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

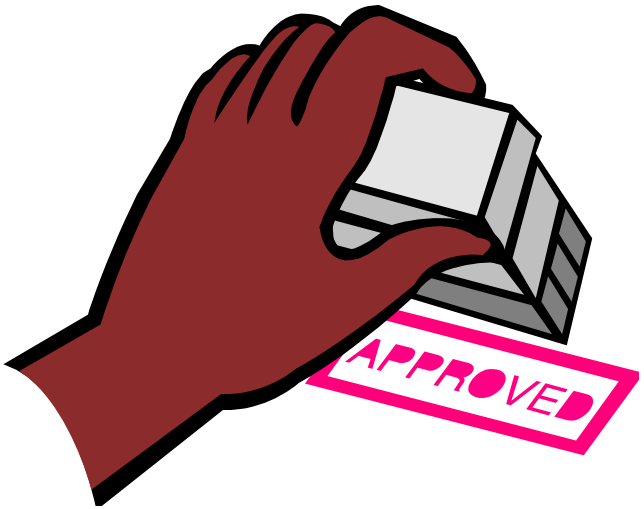
What is "**acceptable**" risk?



Risk Evaluation

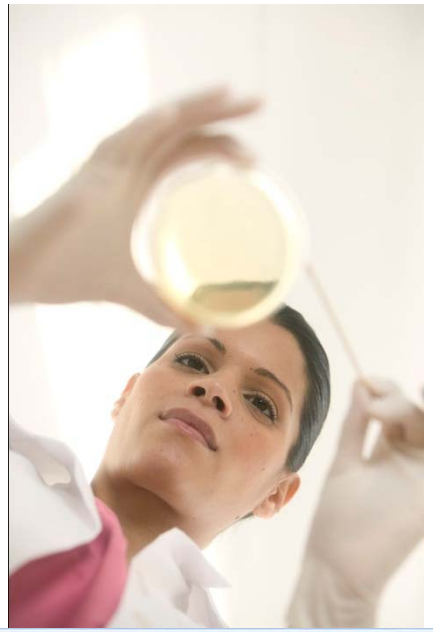
The **evaluation of risk** is highly related to the concept of **Risk Acceptance**.

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



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**.



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?

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?

Use space on back, if needed

Thank You!

Don't forget to complete your evaluation!

Review

Review Question:

What is **risk**?

Review

Review Question:

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

Review

Review Question:

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

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?

Review

Review Question:

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

Review

Review Question:

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

Review

Review Question:

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