Biosafety Risk Assessment

Introductions

- Instructors
- Students
  - Your name?
  - Where are you from?

HELLO!

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

Course Objectives

- A risk assessment is defined as a procedure that analyzes a particular process or situation in order to determine the likelihood and consequences of a certain adverse event and will be unique to each laboratory.

- To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.

- A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk.

- Risk Evaluation is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk and is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution

Biorisk Management: the AMP Model

**Biorisk Management =
Assessment, Mitigation, Performance**

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

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

☣ **Performance**

– The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.
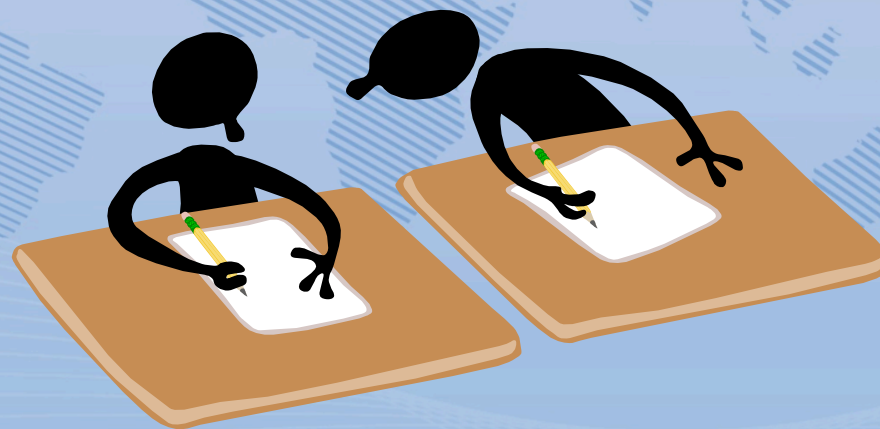
Introduction to Biosafety Risk Assessment

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

Introduction to Biosafety Risk Assessment

To be comprehensive:

A **biosafety risk assessment** should consider **every activity and procedure** conducted in a laboratory that involves **infectious disease agents**.
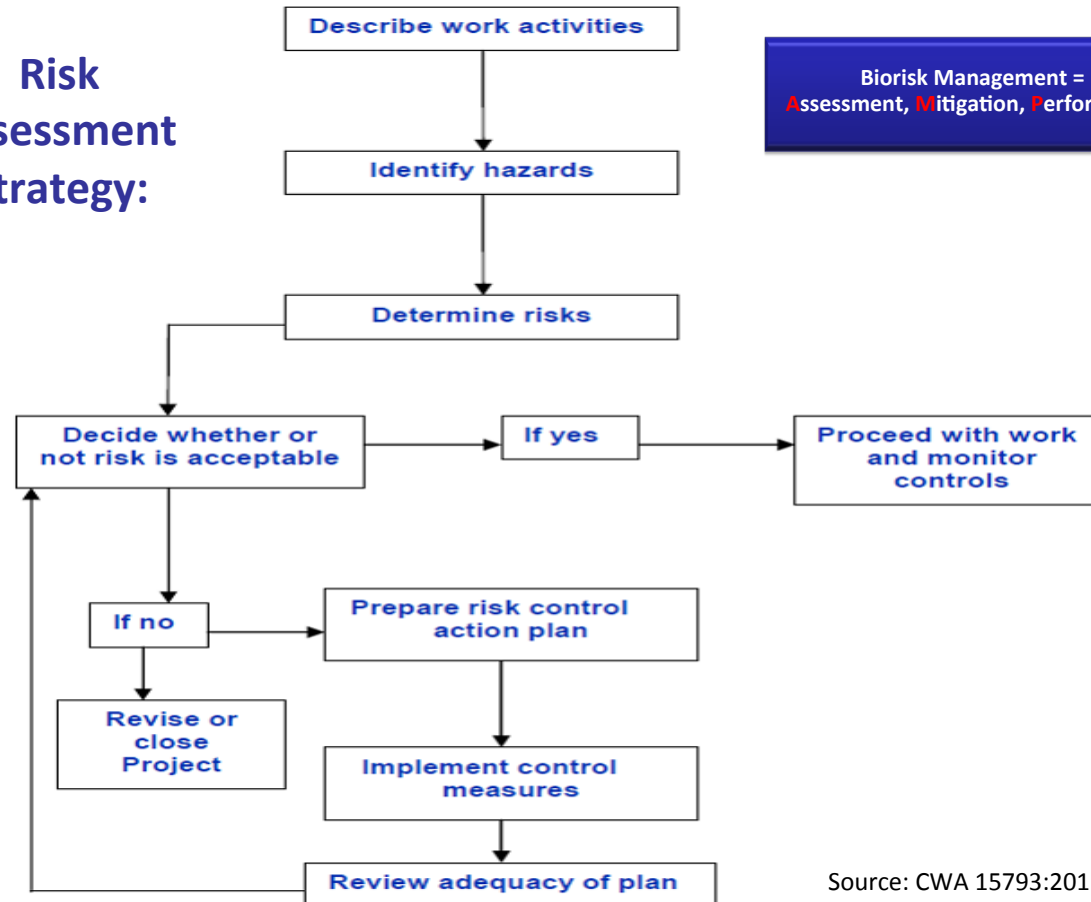
Introduction to
Biosafety Risk Assessment

A **biosafety risk assessment** allows a laboratory to determine the relative level of risk its different activities pose, and helps guide **risk mitigation decisions** so these are targeted to the most important risk.

Risk Assessment Strategy

Risk Assessment Strategy:

```
                    ┌──────────────────────┐
                    │ Describe work        │
                    │ activities           │
                    └──────────┬───────────┘
                               │
                    ┌──────────▼───────────┐
                    │ Identify hazards     │
                    └──────────┬───────────┘
                               │
                    ┌──────────▼───────────┐
                    │ Determine risks      │
                    └──────────────────────┘
```

┌──┐
│ **Biorisk Management =**   │
│ **Assessment, Mitigation, Performance**   │
└──┘

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

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, 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

<u>**RISK**</u>

Likelihood (y-axis)

Consequences (x-axis)

Very High

High

Moderate

Low

Very Low
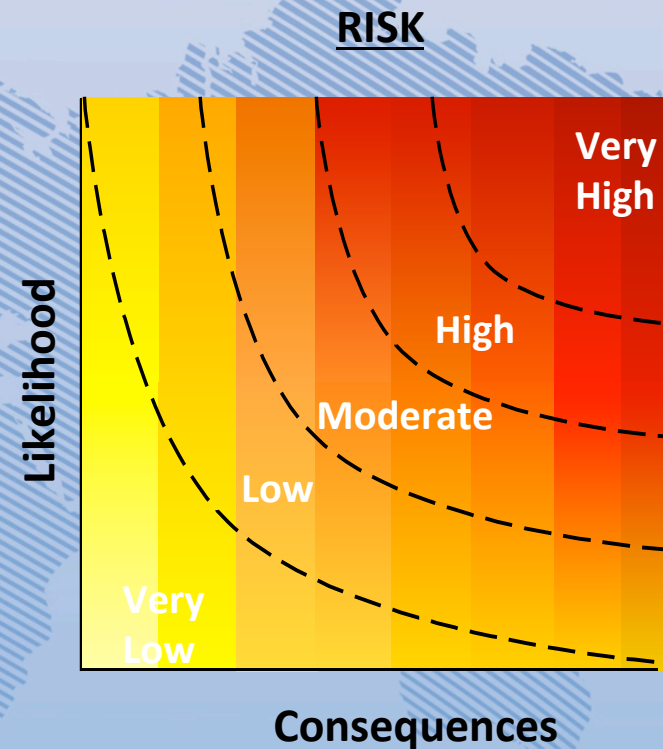
Risk

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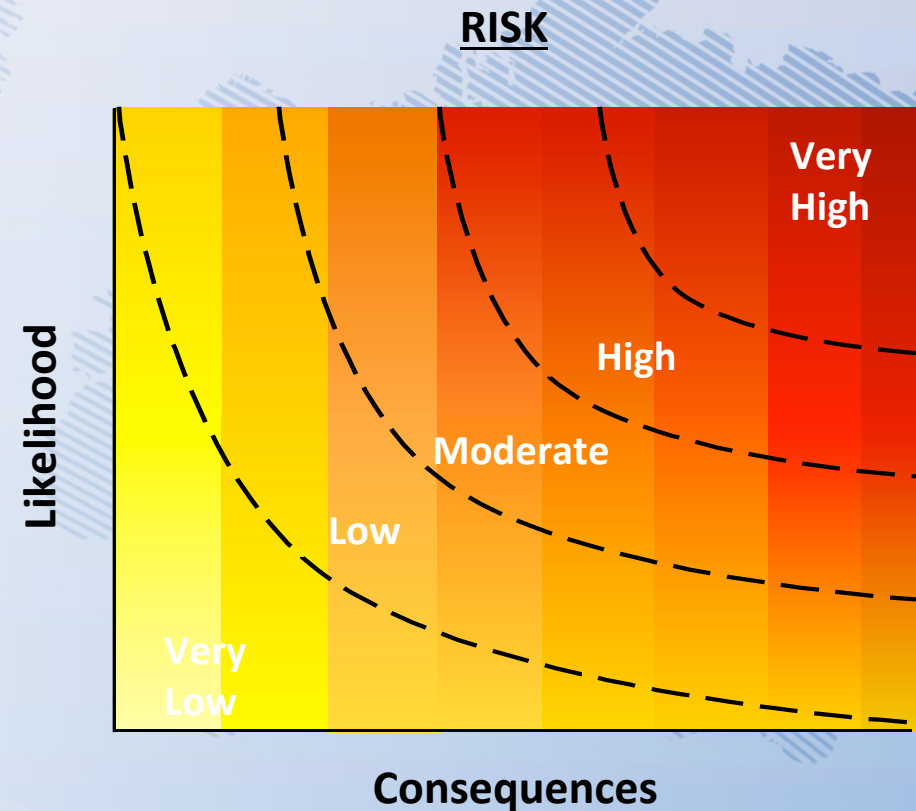
Be prepared to report your **criteria** to the class.

Risk

Let's consider the previous question in terms of **Likelihood** and **Consequences**, and the graph on the right.
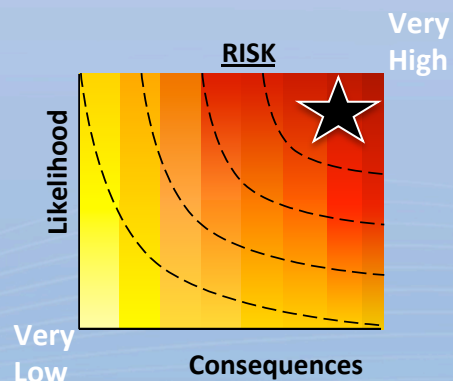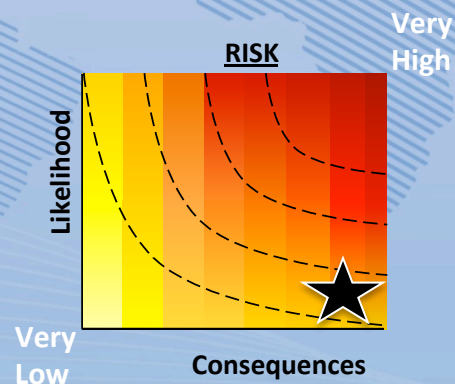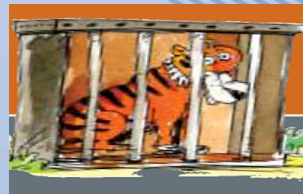
R = f(L, C)

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences

Risk

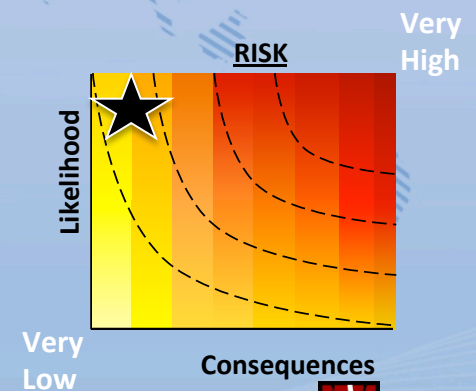**For the following scenarios**, draw a **STAR** where the **risk** would fall on the graph.

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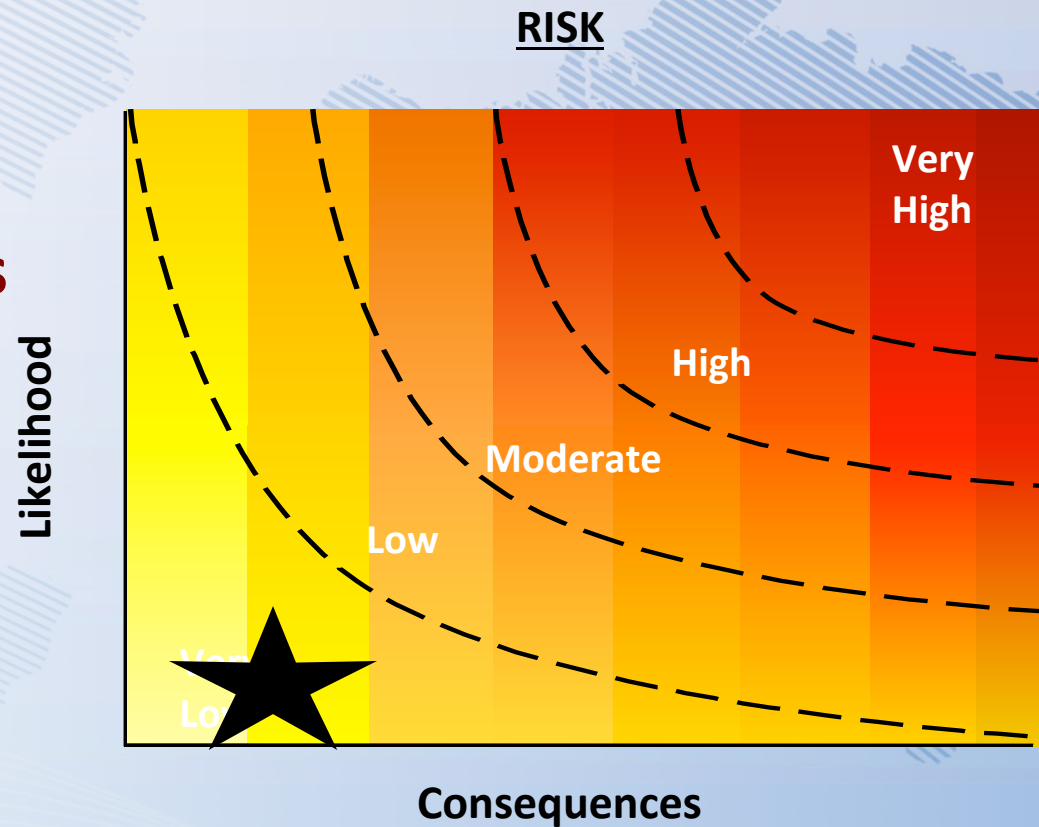
You are holding a tiger cub with a playful temperament in your arms.

RISK — Very High — Likelihood — Very Low — Consequences

RISK — Very High — Likelihood — Very Low — Consequences

RISK — Very High — Likelihood — Very Low — Consequences

Risk

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

RISK

Very High

High

Moderate

Low

Very Low

Likelihood

Consequences

Biosafety Risk Assessment

A **Risk Assessment** is a procedure that analyzes a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

In **Laboratory Biosafety**, we are concerned with preventing unintentional adverse events involving infectious disease agents.

To properly conduct a **laboratory biosafety risk assessment**, it is important first to gather certain information about the laboratory procedures involving biological agents and toxins, as well as information on the agents and toxins themselves.

Biosafety Risk Assessment

Question:

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

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

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

Be prepared to report your answers to the class.

Risk Characterization

As you can see many of the factors regarding laboratory biosafety risk rely on the **agent characteristics** and the laboratory **procedures**.

The **risk of exposure** to an agent is dependent on these factors.

Risk Characterization

Activity:

We will work together, through a series of examples to practice determining the **risk of exposure** associated with an experiment.
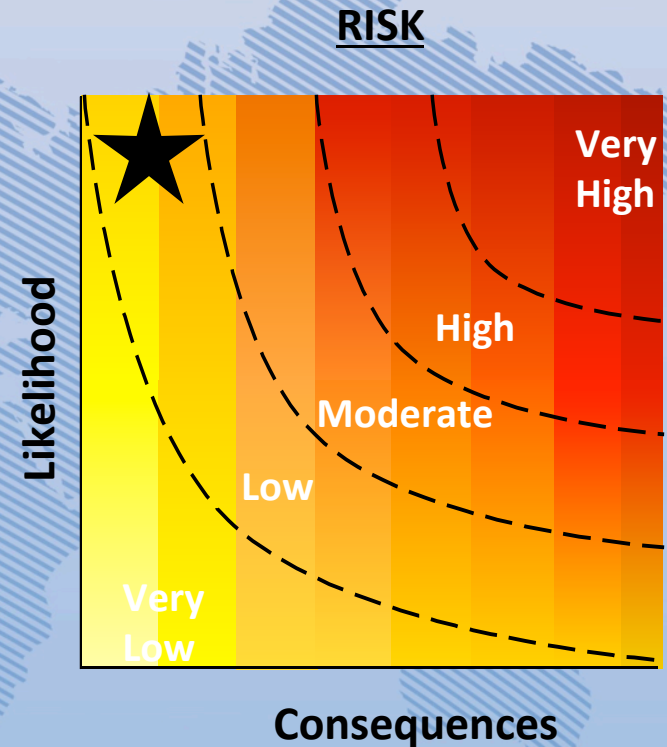
Risk Characterization

Scenario:

Suppose you are working with a **seasonal influenza virus**, conducting **aerosol-challenge studies** on an animal host, with little respiratory protection.

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?

RISK

Likelihood

Very High

High

Moderate

Low

Very Low

Consequences

Risk Characterization

Scenario:

You are working with wild-type **Ebola virus** in a high containment BSL 4-type laboratory, inoculating large numbers of mice with varying concentrations of virus to determine an LD50.

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?

RISK

Likelihood

Consequences

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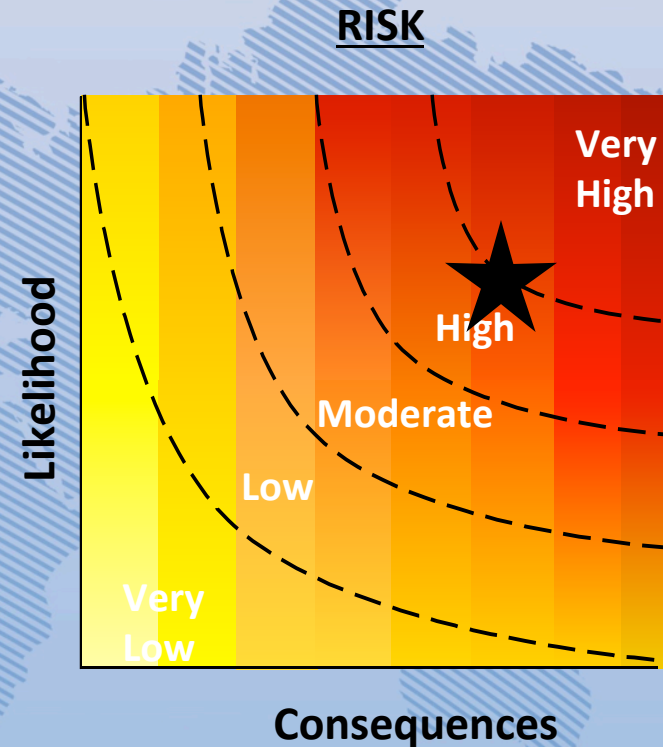
Biosafety Risk Assessment

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

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

BioRAM

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

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

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/

BioRAM

Question:

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

Risk Evaluation

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

It is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution.

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 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.

Risk Evaluation

Overall, two **institutions** with the **same computed risk "values"** for the risk characterization process may have **different risk evaluations** (*meanings of risk*). E.g. Even moderate risk may be too much risk depending on the **individuals**, **institution** and **community** involved.

The **evaluation of risk** is reflected on the graph by the **arbitrary** "**isoquants**".

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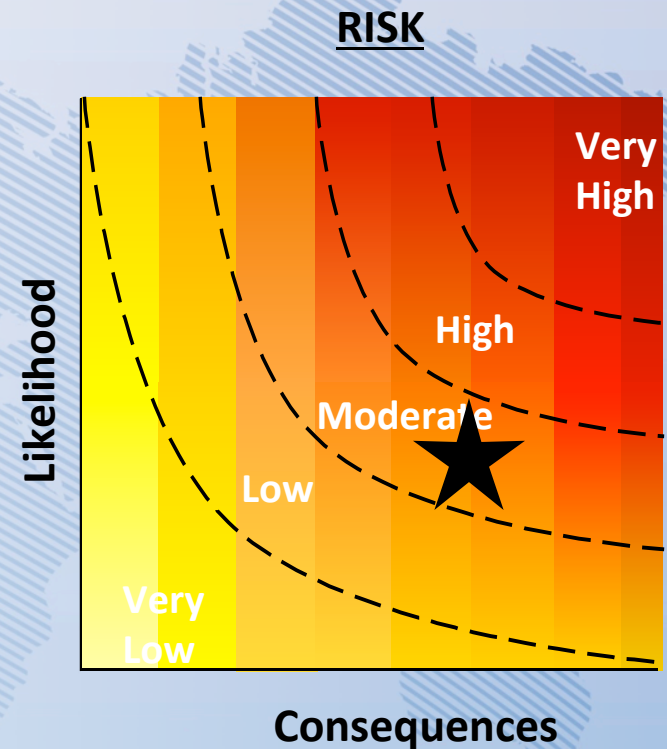
Risk Evaluation

Risk Evaluation drives investment decisions in an institution. If an institution is particularly **risk-averse**, it will spend more resources attempting to reduce the risks it faces. If a similar institution faces the same risks but is **less risk-averse**, it might proceed with procedures others may find too "**dangerous**".

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?

Final Review

Review

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

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

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Thank You!

Don't forget to complete your evaluation!

Break