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Biosafety Risk Assessment

Student Guide

2012

GLOBAL BIORISK MANAGEMENT CURRICULUM


Biosafety Risk Assessment
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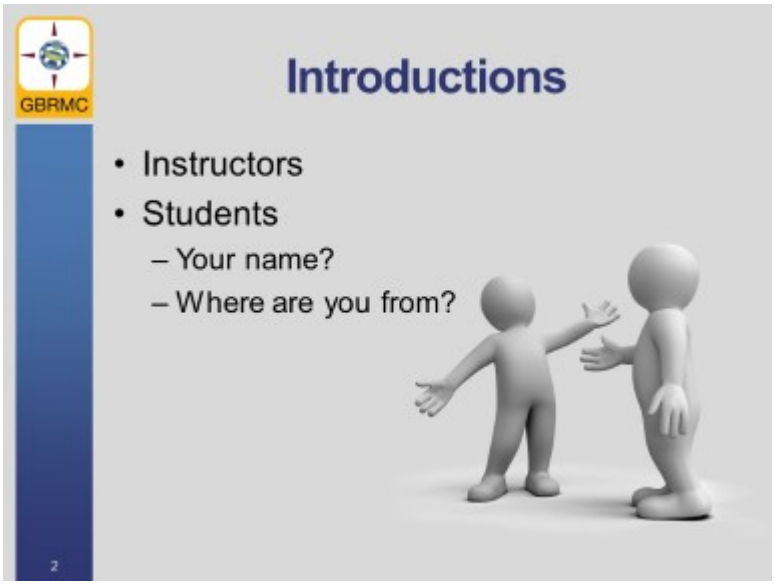
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Introductions
• Instructors
• Students
– Your name?
– Where are you from?
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Action Plan

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?

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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 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

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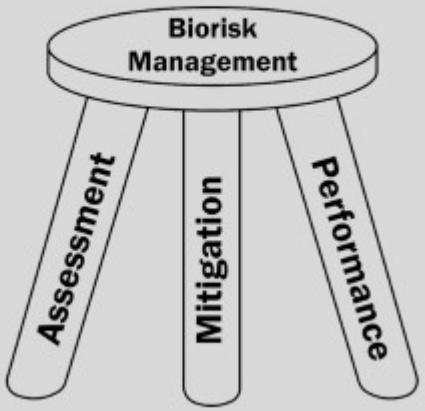
Biorisk Management: the AMP Model



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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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Introduction to Biosafety Risk Assessment

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

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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**.

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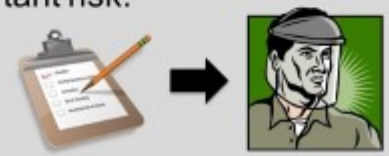
Introduction to Biosafety Risk Assessment

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.



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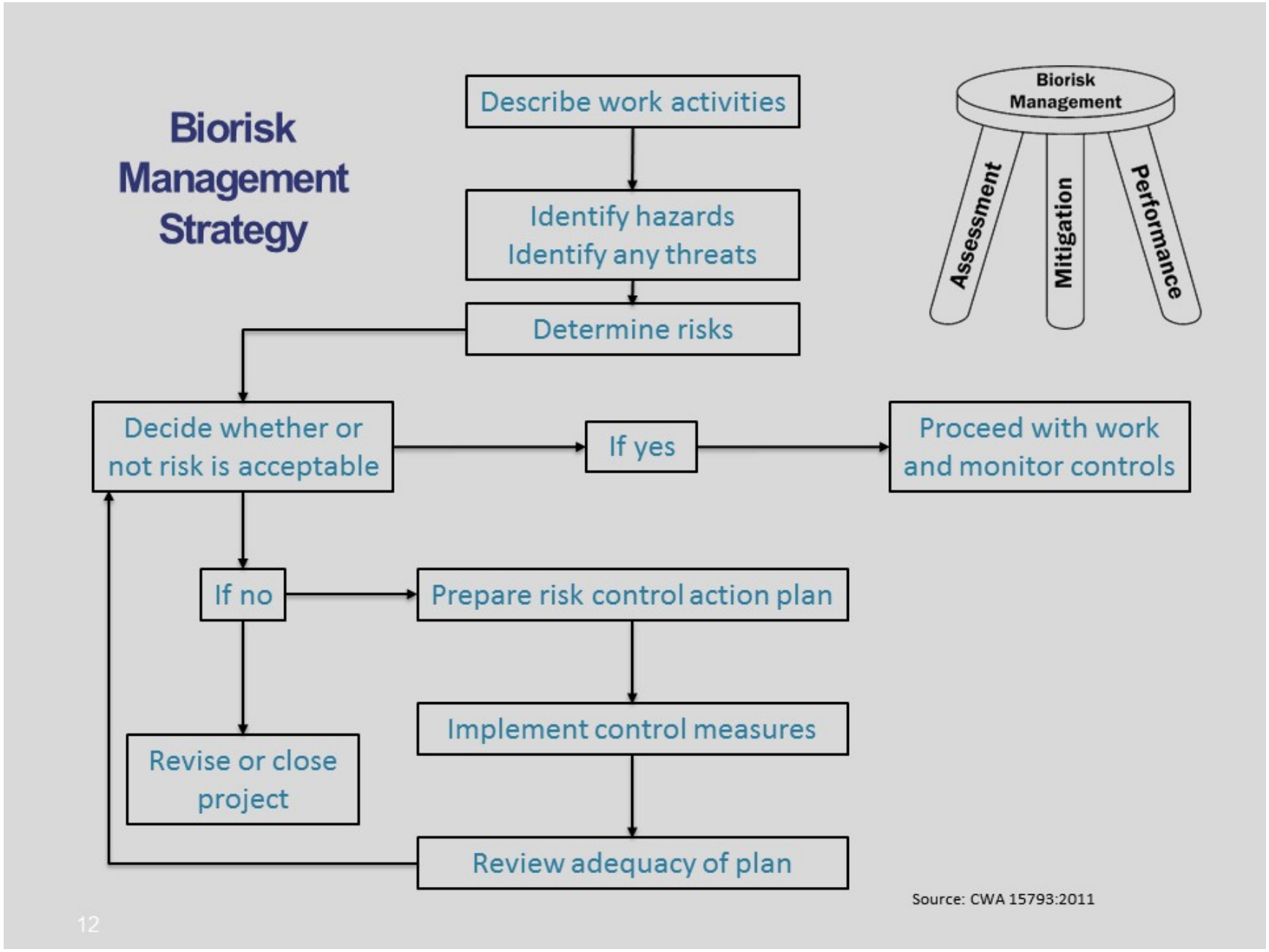
Biorisk Management Strategy
Describe work activities
Identify hazards
Identify any threats
Determine risks
Decide whether or not risk is acceptable
If yes
Proceed with work and monitor controls
If no
Prepare risk control action plan
Implement control measures
Review adequacy of plan
Revise or close project
Biorisk Management
Assessment
Mitigation
Performance
Source: CWA 15793:2011
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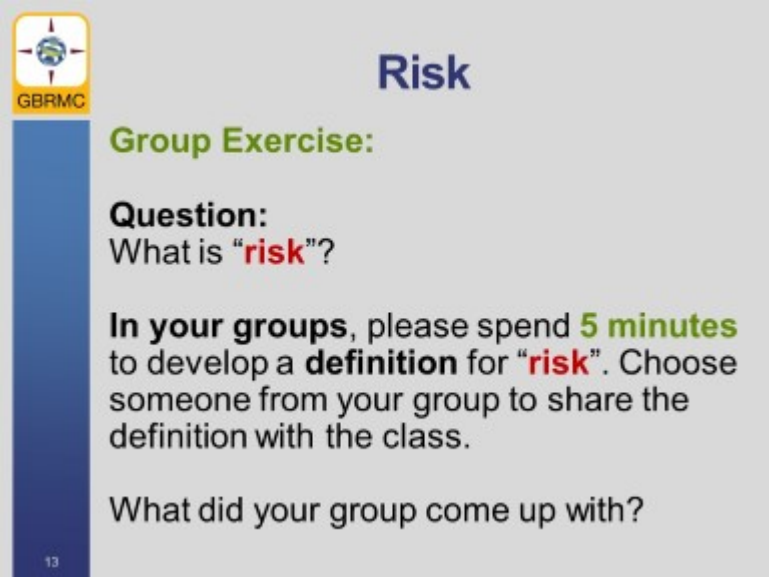
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Risk
Group Exercise:
Question:
What is "risk"?
In your groups, please spend 5 minutes to develop a definition for "risk". Choose someone from your group to share the definition with the class.
What did your group come up with?
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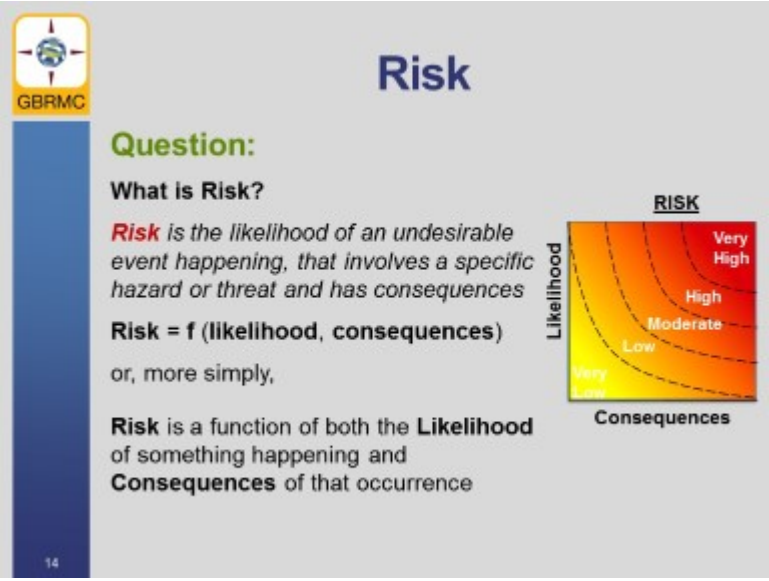
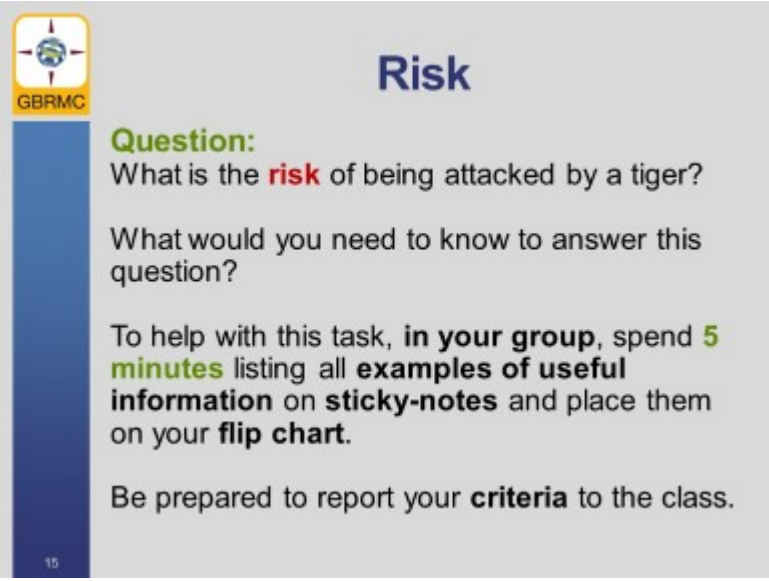
What is Risk?

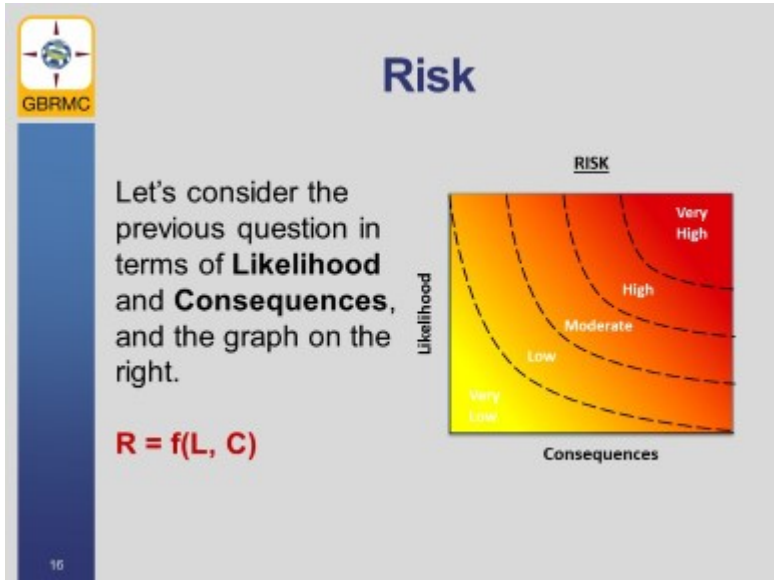


How can Risk be expressed?

What is risk a function of ?

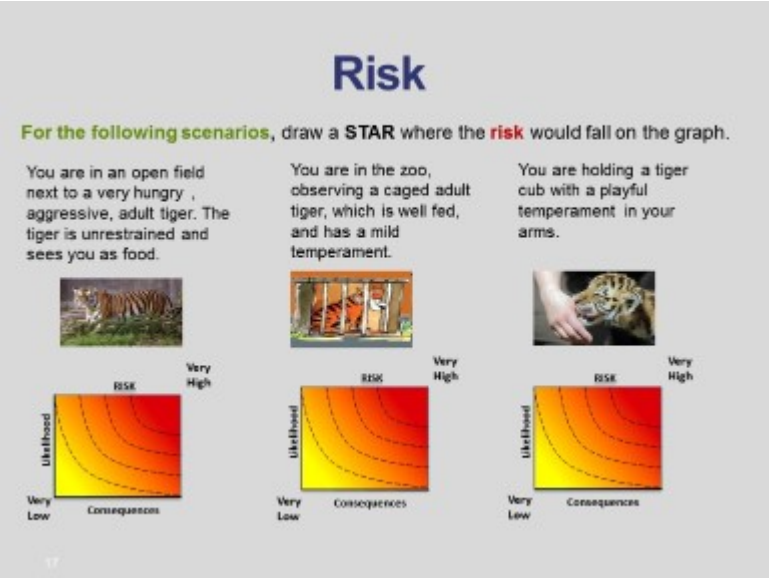


What is some information you would need to know the risk of being attacked by a tiger?



What is the likelihood of being attacked by a tiger?

What are the consequences of being attacked by a tiger?



What is the risk for each Scenario?

Scenario #1

Rationale:

Risk:

Scenario #2

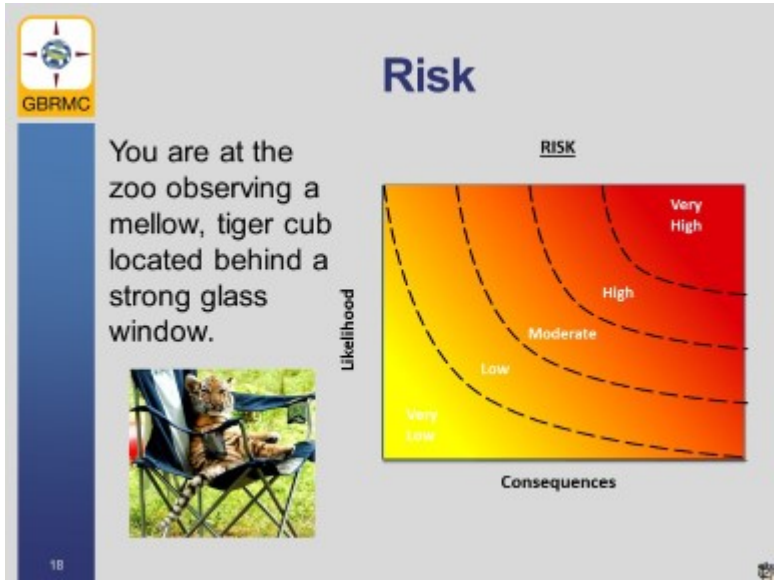
Rationale:

Risk:

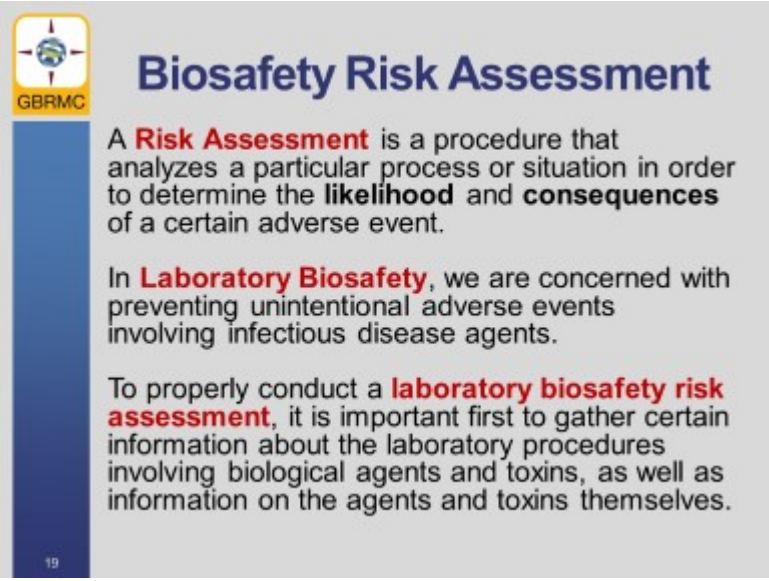
Scenario #3

Rationale:

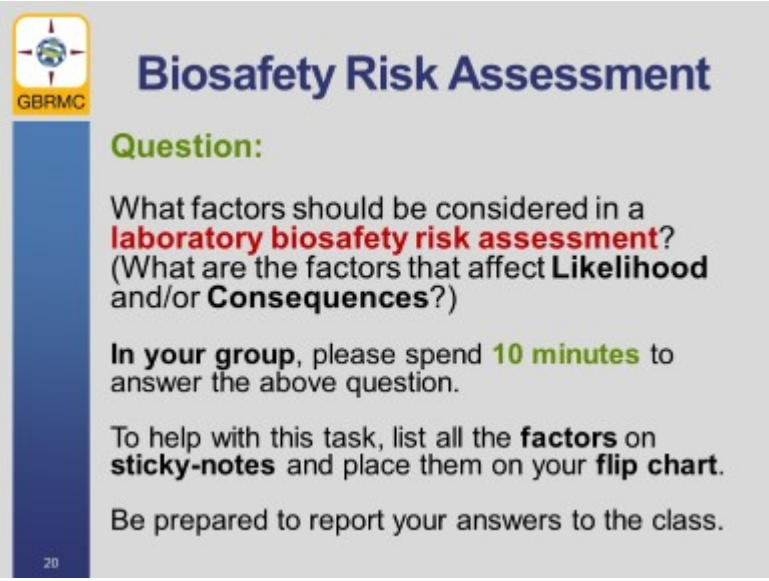
Risk:



What is the risk of being attacked in this scenario?



How does a risk assessment differ from a laboratory biosafety risk assessment?



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

Factors:

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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.

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Risk Characterization

Exercise:

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

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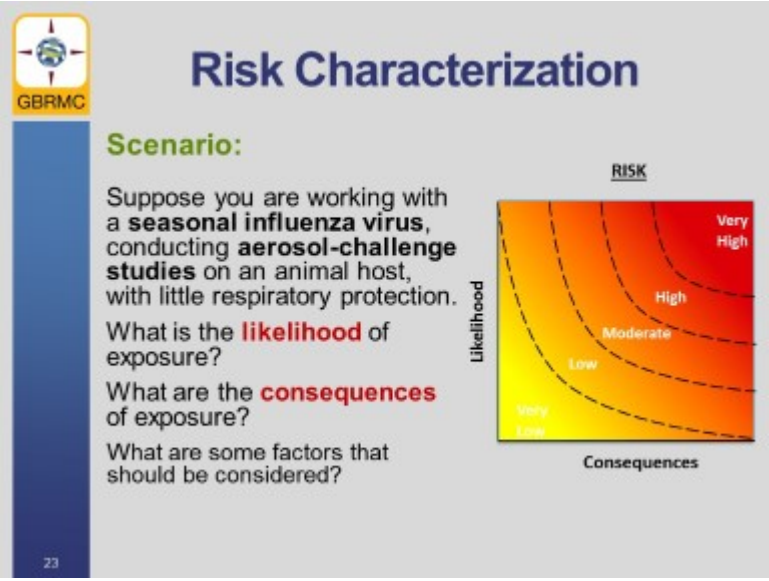
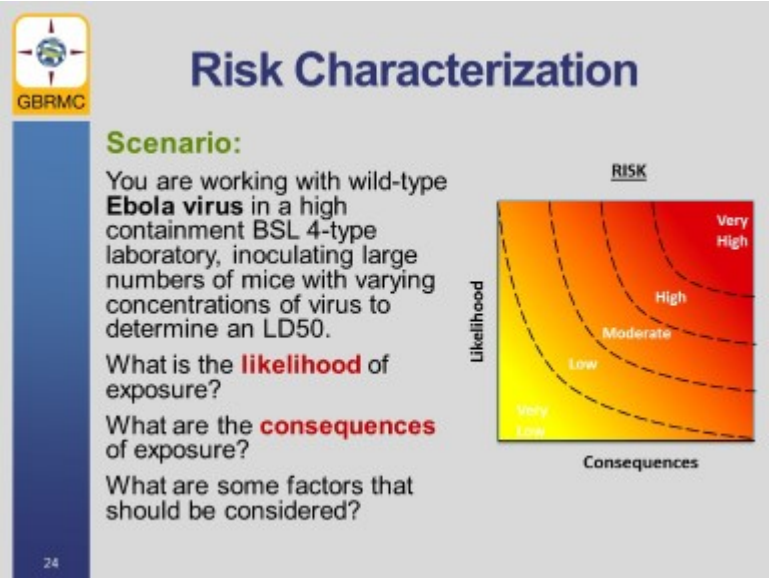


What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:

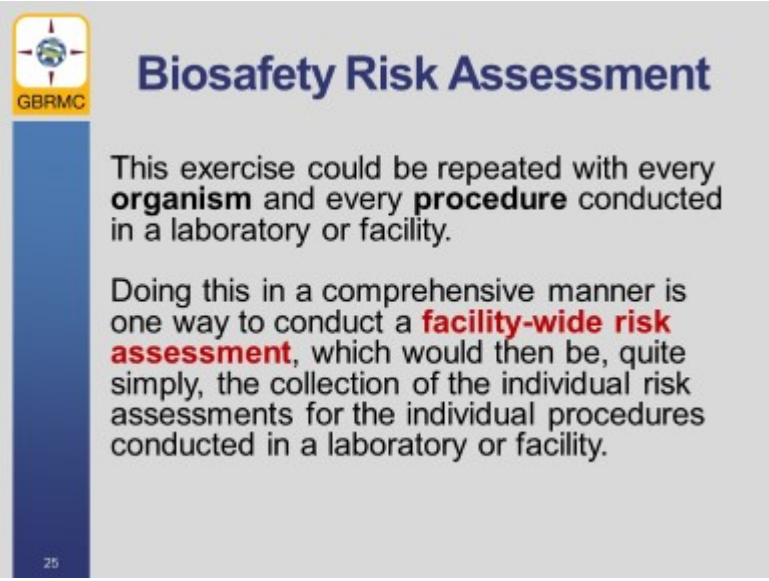


What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale: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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.
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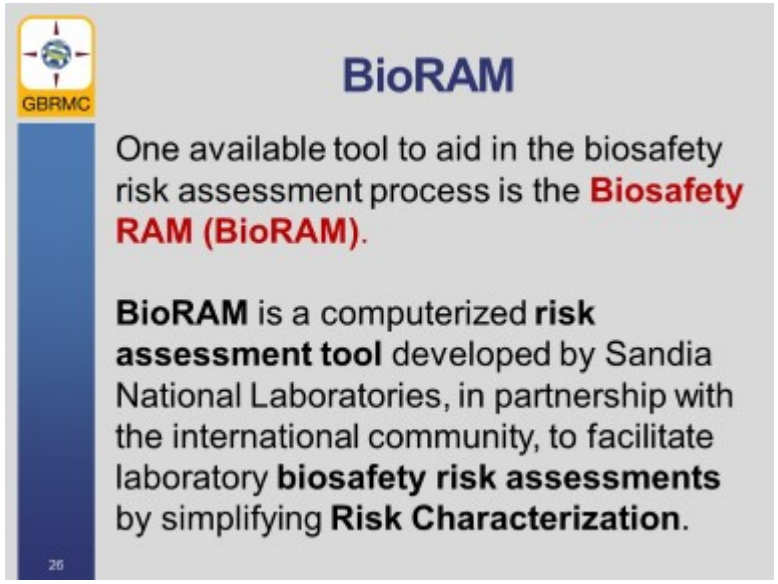
Notes: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BioRAM
One available tool to aid in the biosafety risk assessment process is the Biosafety RAM (BioRAM).
BioRAM is a computerized risk assessment tool developed by Sandia National Laboratories, in partnership with the international community, to facilitate laboratory biosafety risk assessments by simplifying Risk Characterization.
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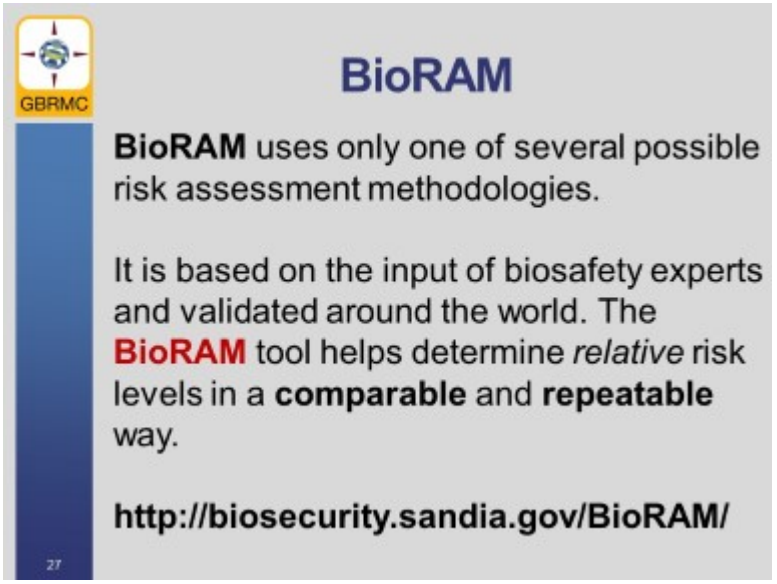
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BioRAM
BioRAM uses only one of several possible risk assessment methodologies.
It is based on the input of biosafety experts and validated around the world. The BioRAM tool helps determine relative risk levels in a comparable and repeatable way.
http://biosecurity.sandia.gov/BioRAM/
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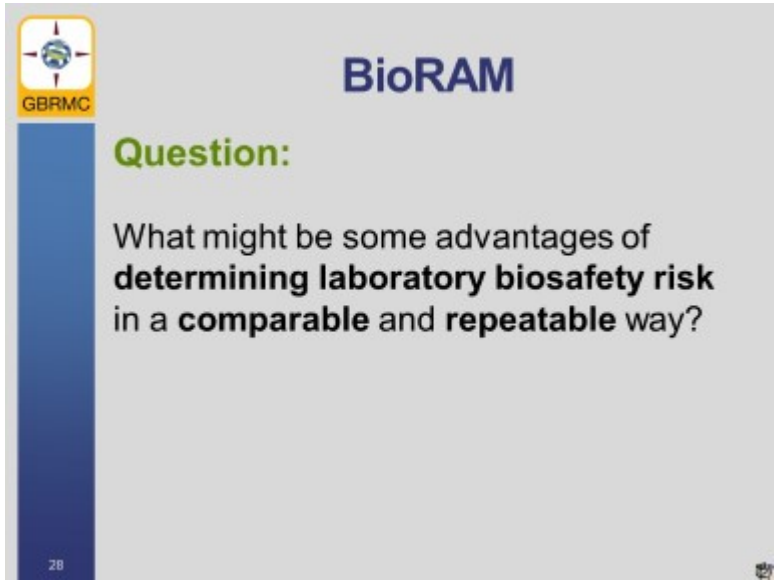

Laboratory Biosafety Risk Assessment:

Advantages:

Disadvantages:

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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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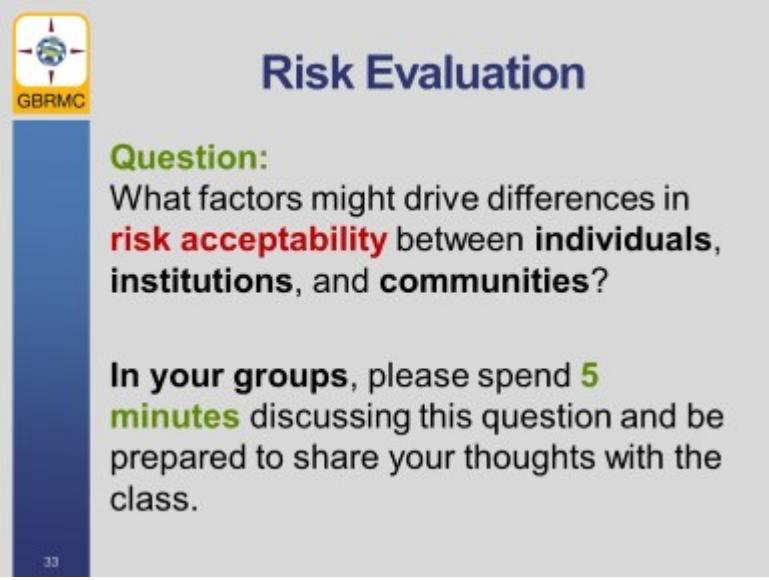
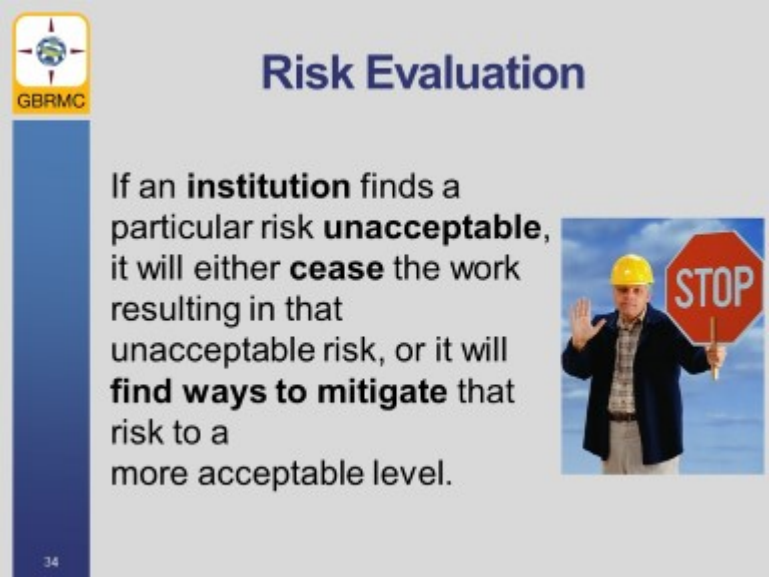


Individual Factors:

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.
STOP
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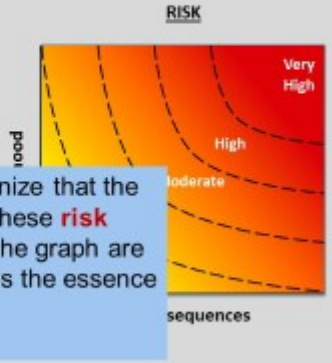
Risk Evaluation

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**.

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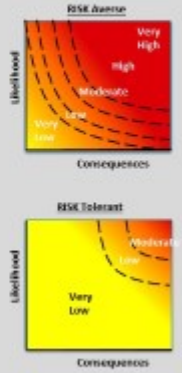
Risk Evaluation

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.



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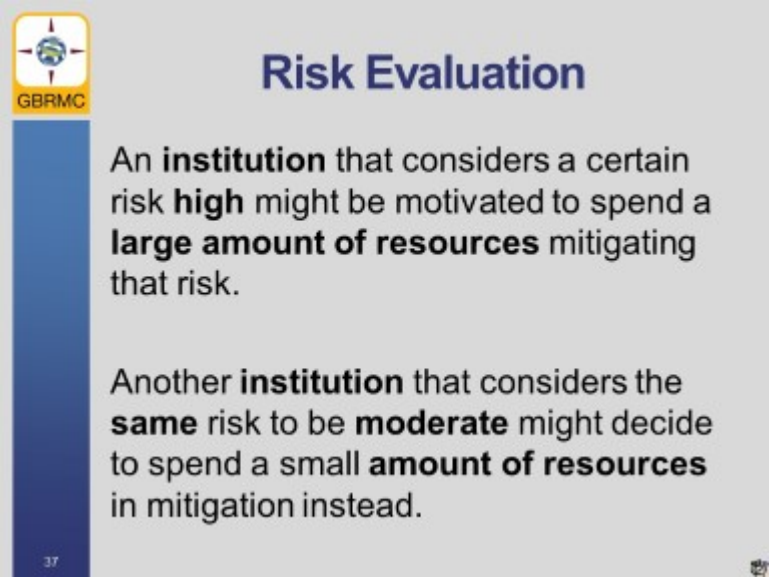

How does risk evaluation influence risk mitigation strategies?


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Review
Question:
What is risk?
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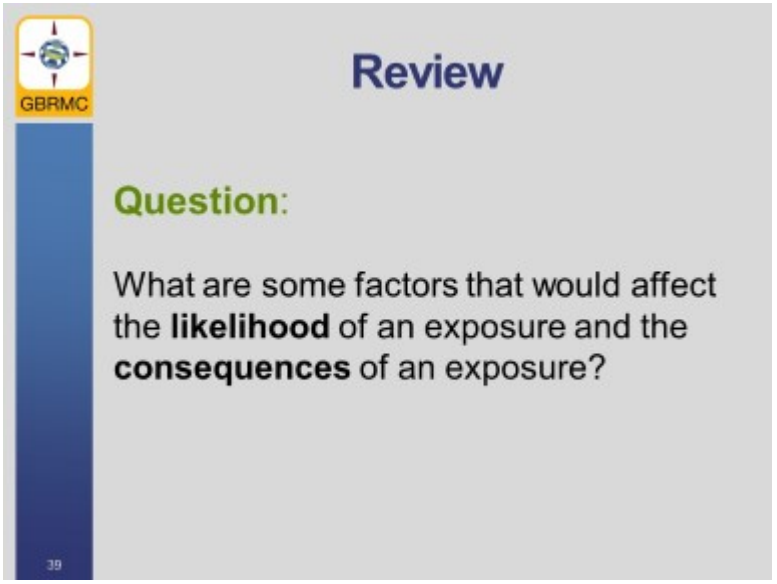
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Review
Question:
What are some factors that would affect the likelihood of an exposure and the consequences of an exposure?
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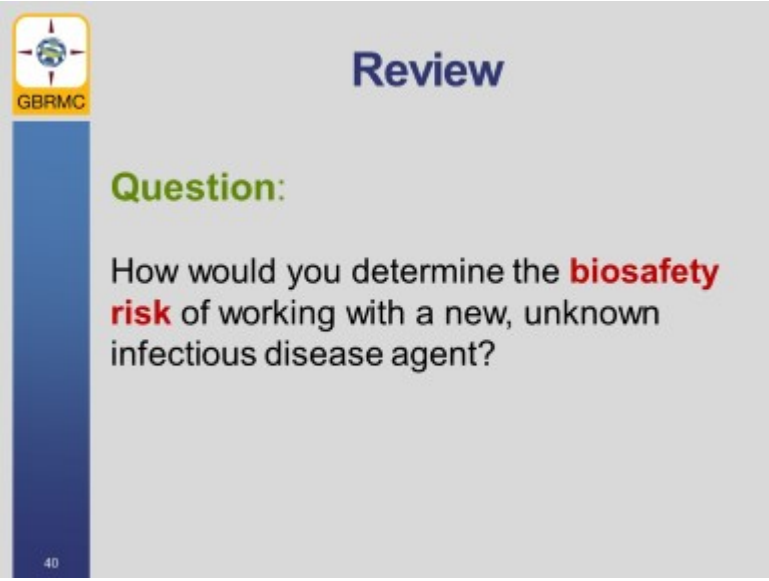
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Review
Question:
How would you determine the biosafety risk of working with a new, unknown infectious disease agent?
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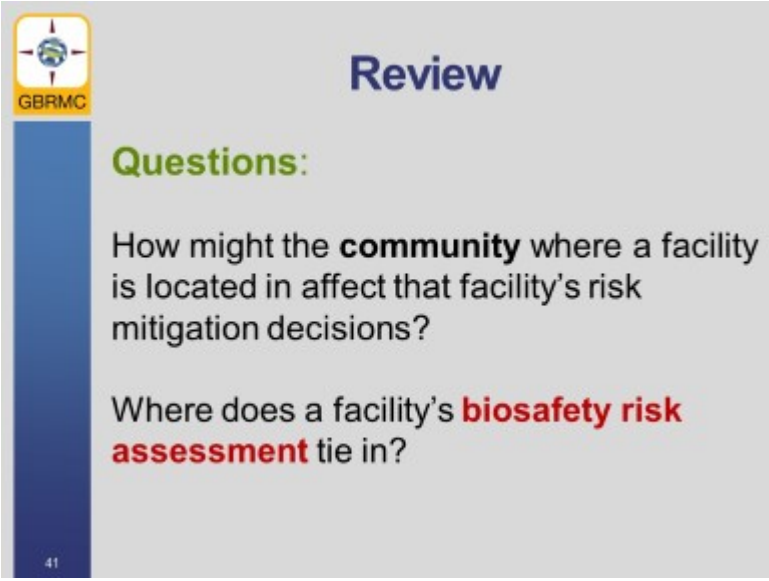
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Review
Questions:
How might the community where a facility is located in affect that facility's risk mitigation decisions?
Where does a facility's biosafety risk assessment tie in?
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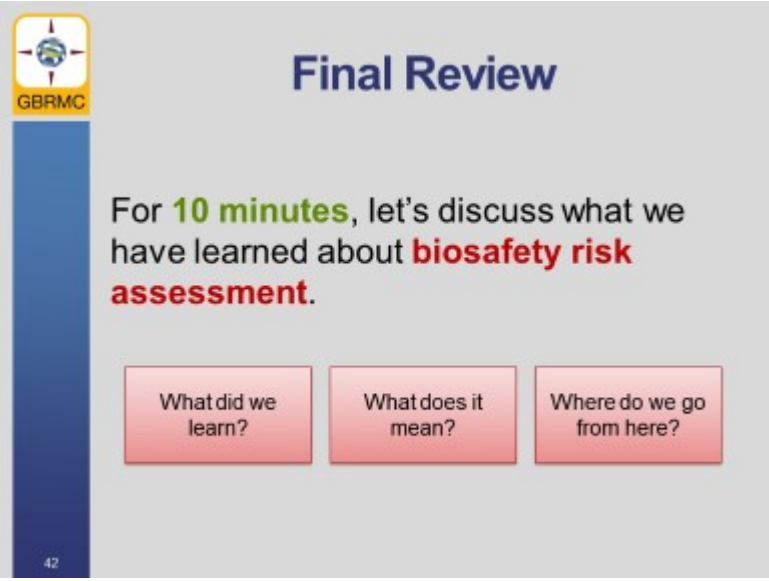
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Final Review
For 10 minutes, let's discuss what we have learned about biosafety risk assessment.
What did we learn?
What does it mean?
Where do we go from here?
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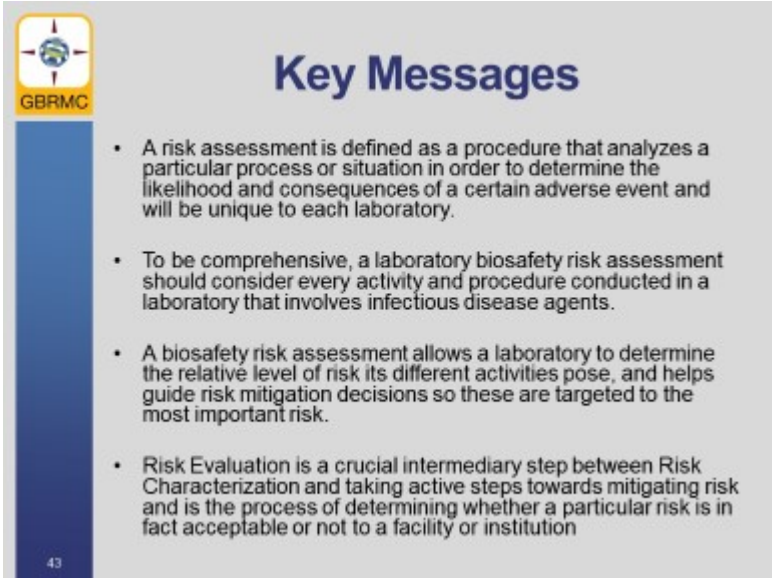
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Use space on back, if needed