SAND2012-2826P

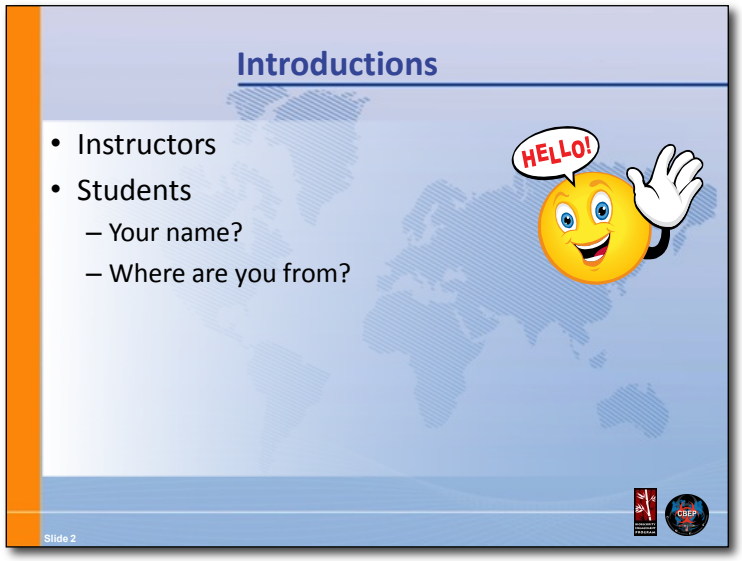
Biosafety Risk Assessment

Student Guide

BIOSECURITY ENGAGEMENT PROGRAM

CBEP
COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAM

Welcome to Biosafety Risk Assessment


Introductions
• Instructors
• Students
– Your name?
– Where are you from?
HELLO!
Slide 2

Action Plan

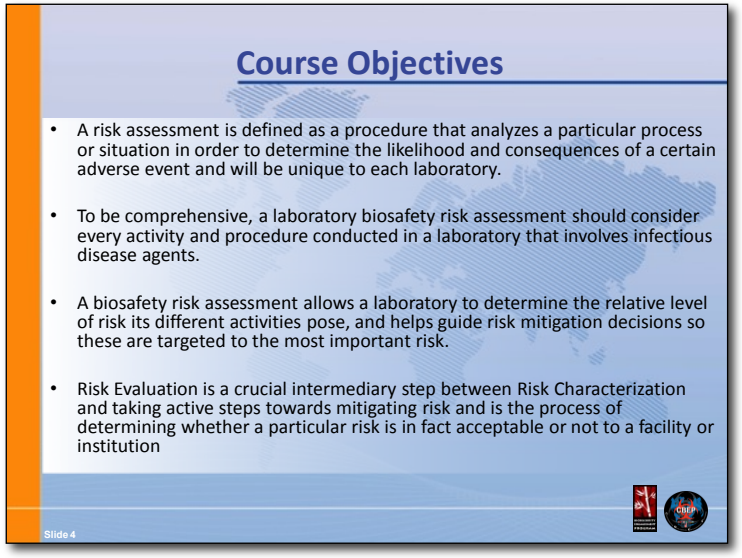
By the end of this lesson, I would like to:					
KNOW		FEEL		BE ABLE TO DO	

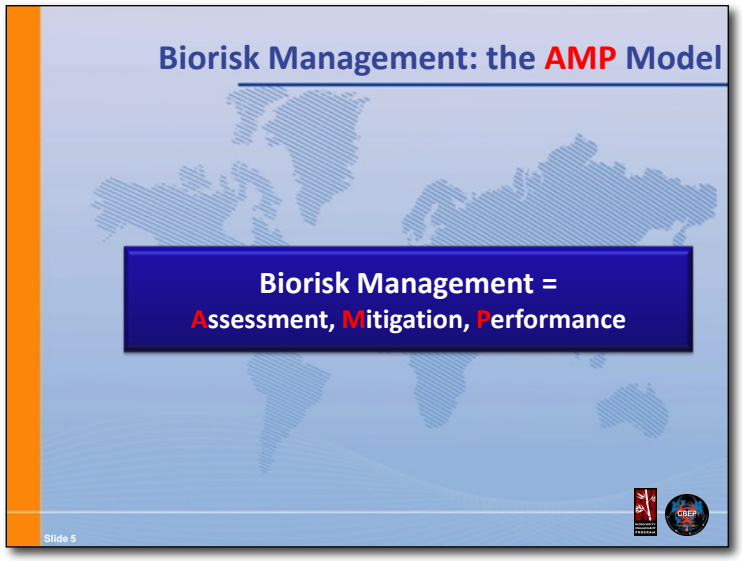
Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

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?

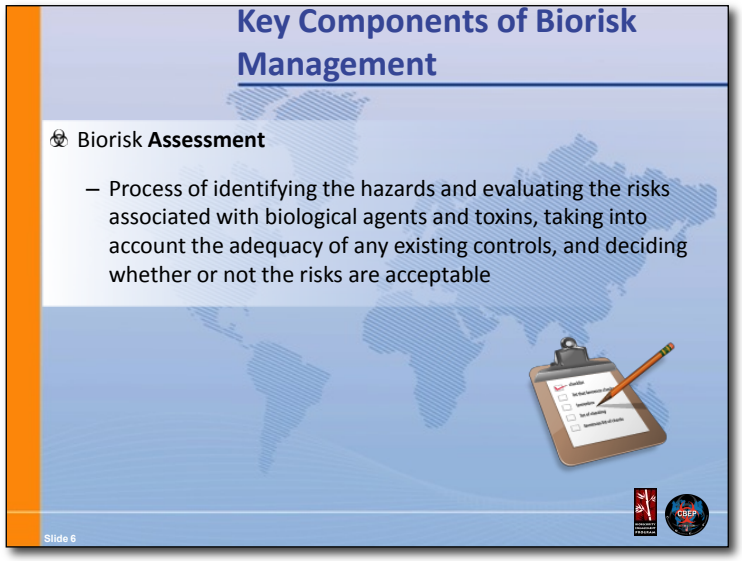
Use space on back, if needed

Slide 3


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
Slide 4

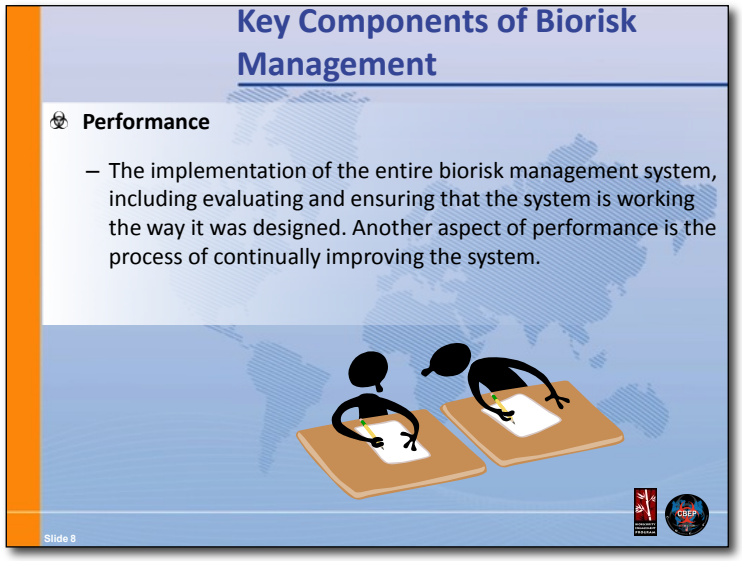


Record refresher notes on the AMP model and biorisk management.



Define Biorisk Assessment:

Define Biorisk Mitigation:



Define Performance:

Introduction to Biosafety Risk Assessment

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

Slide 9

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**.

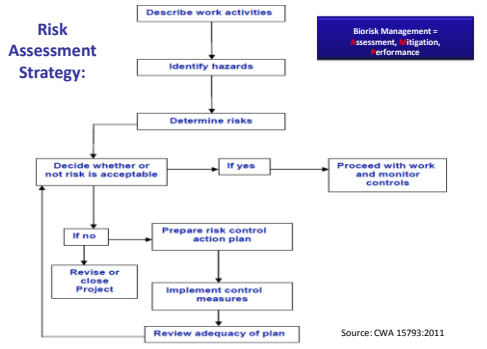
Slide 10

Introduction to Biosafety Risk Assessment

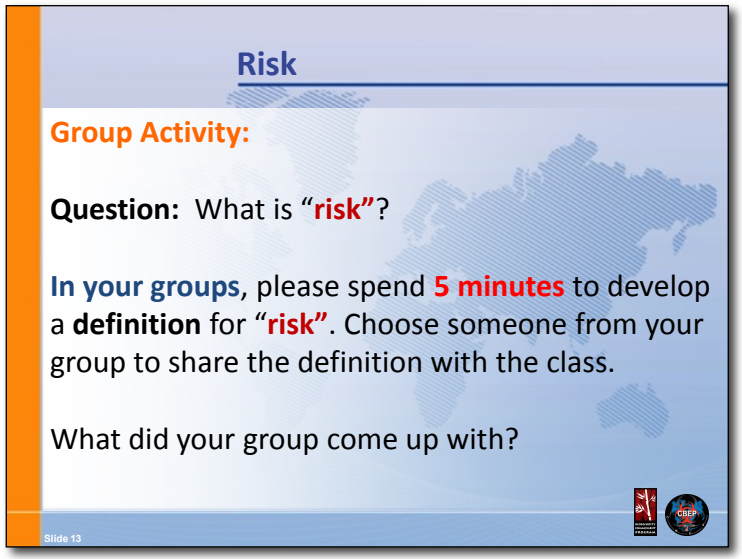
A **biosafety risk assessment** allows a laboratory to determine the relative level of risk its different activities pose, and helps guide **risk mitigation decisions** so these are targeted to the most important risk.

Slide 11

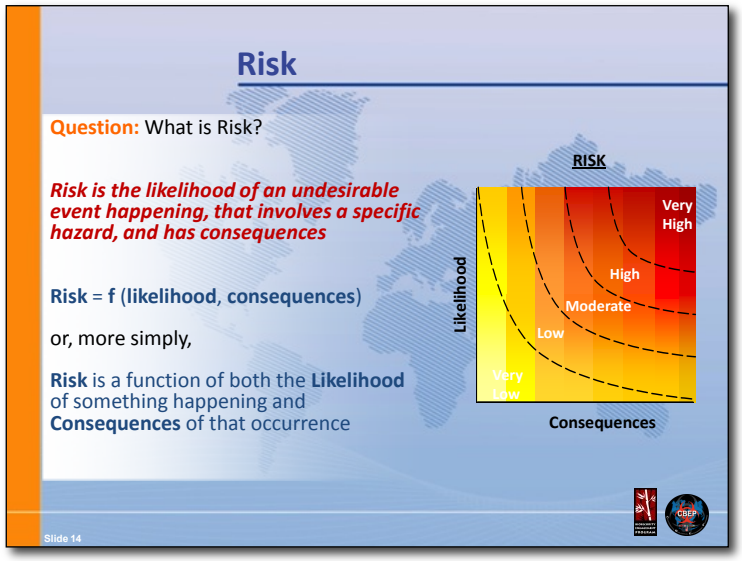
Risk Assessment Strategy



Slide 12

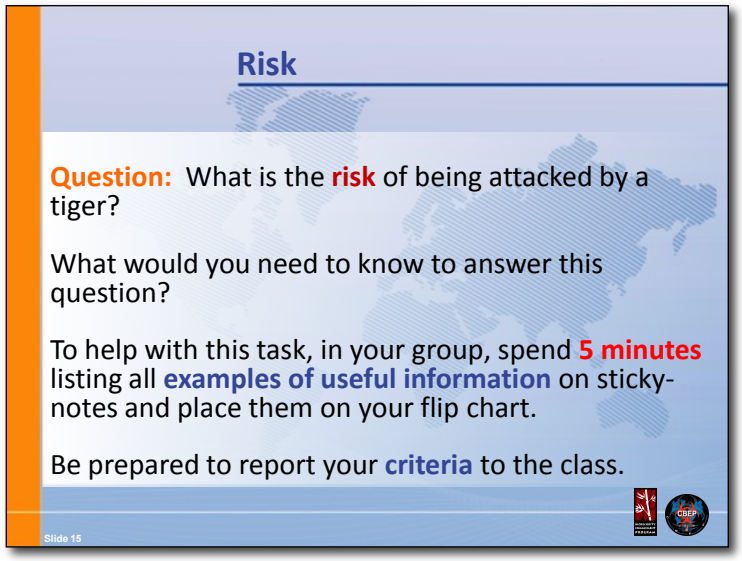

Risk
Group Activity:
Question: What is "risk"?
In your groups, please spend 5 minutes to develop a definition for "risk". Choose someone from your group to share the definition with the class.
What did your group come up with?
Slide 13

What is Risk?

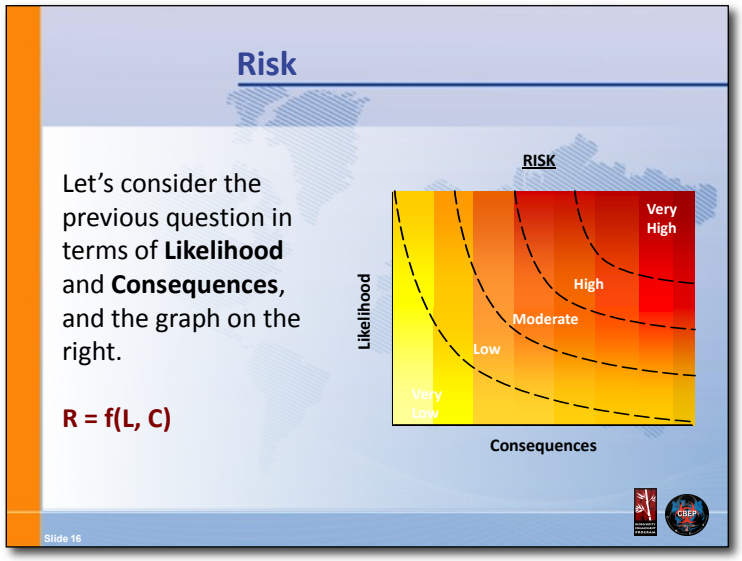


How can Risk be expressed?

What is risk a function of ?

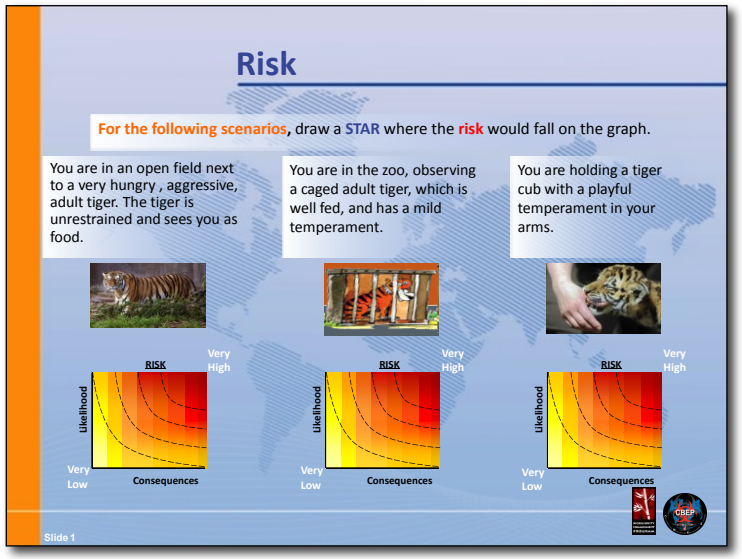


What is some information you would need to know the risk of being attacked by a tiger?



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

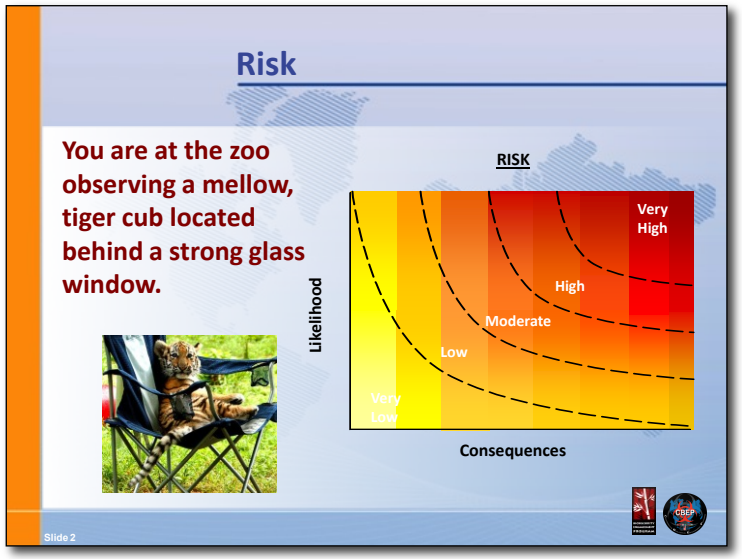
Rationale:

Risk:

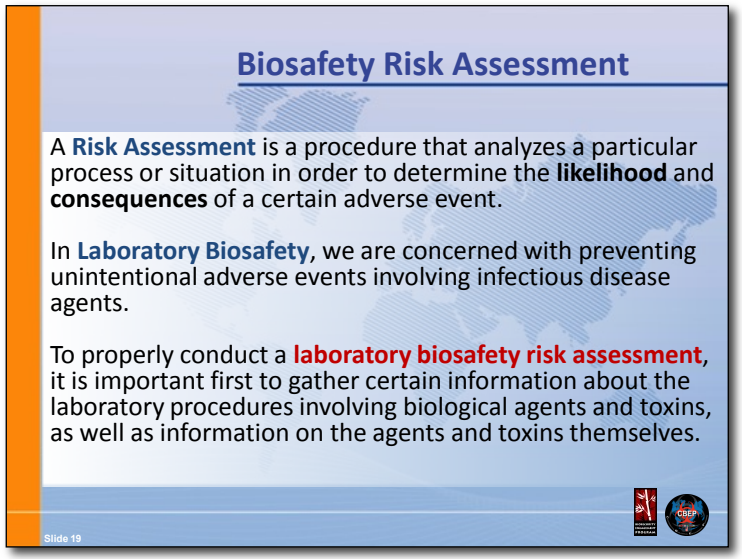
Scenario #3

Rationale:

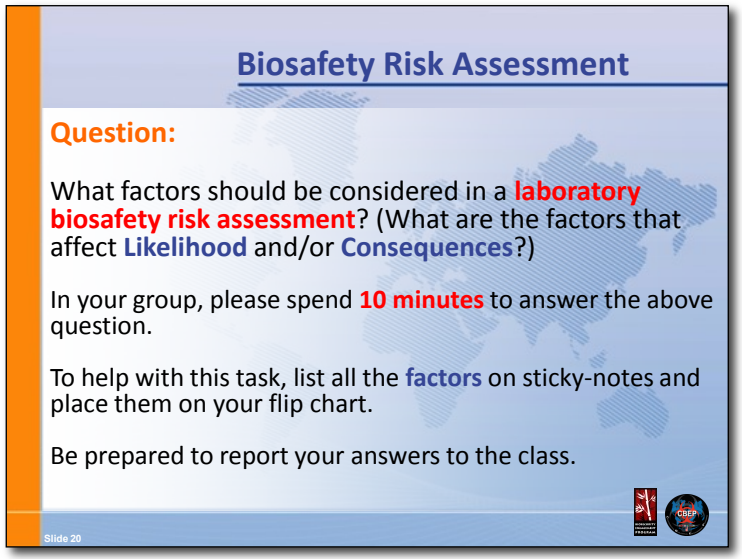
Risk:



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:

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

Activity:

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

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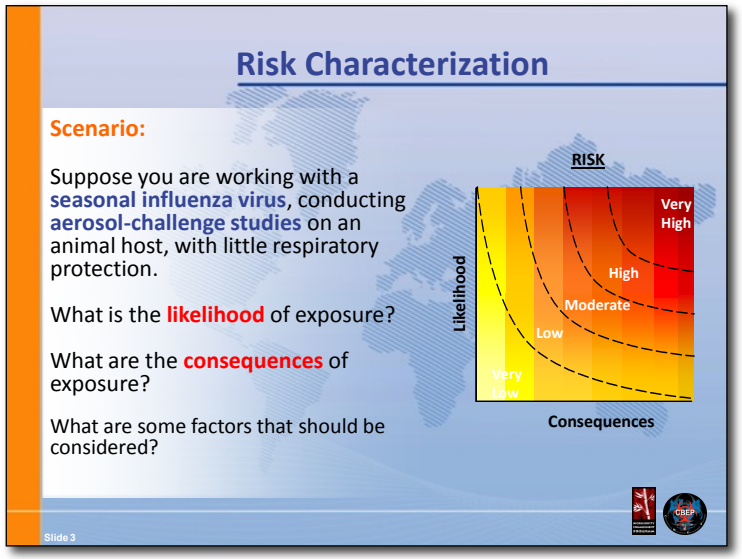
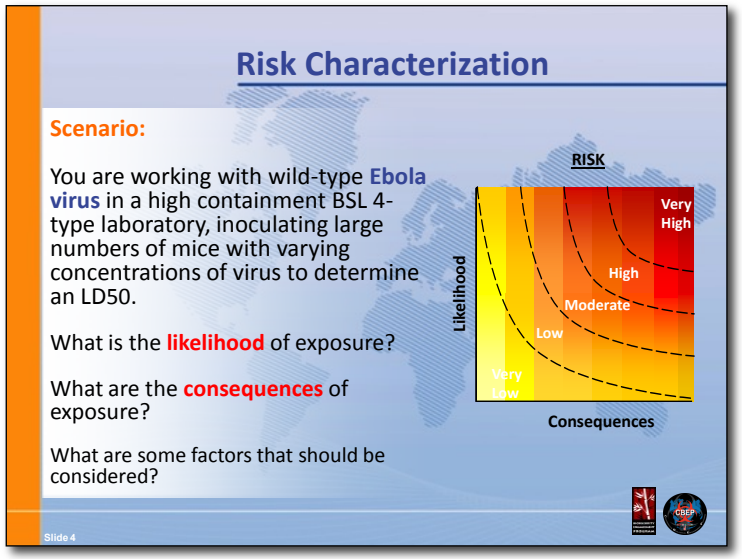


What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:



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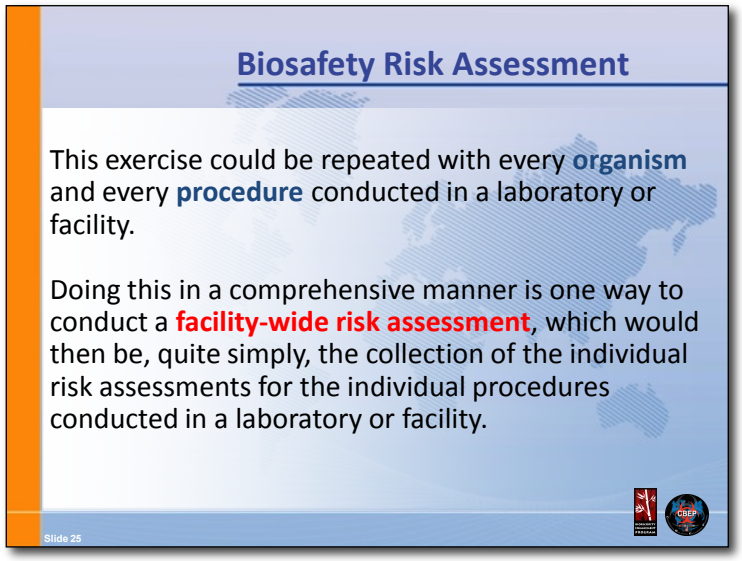
Biosafety Risk Assessment
This exercise could be repeated with every organism and every procedure conducted in a laboratory or facility.
Doing this in a comprehensive manner is one way to conduct a facility-wide risk assessment, which would then be, quite simply, the collection of the individual risk assessments for the individual procedures conducted in a laboratory or facility.
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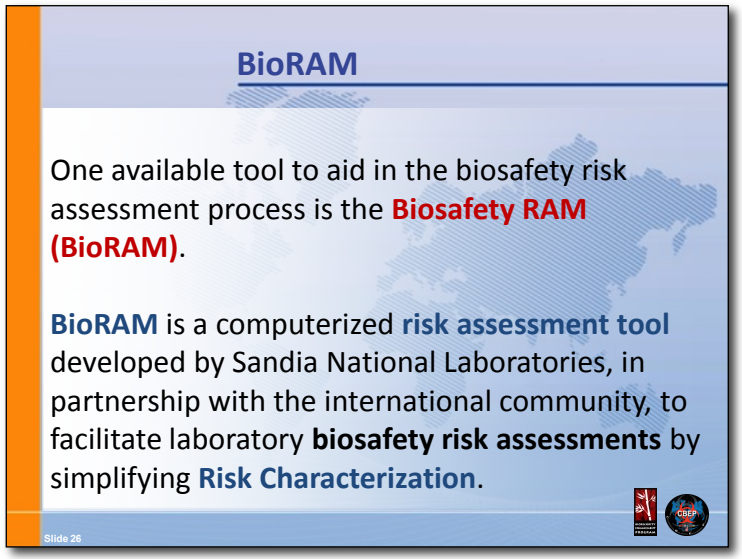
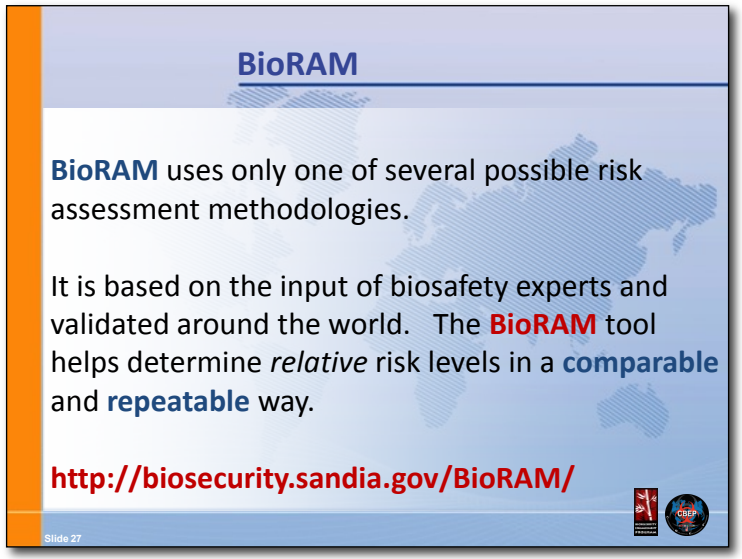
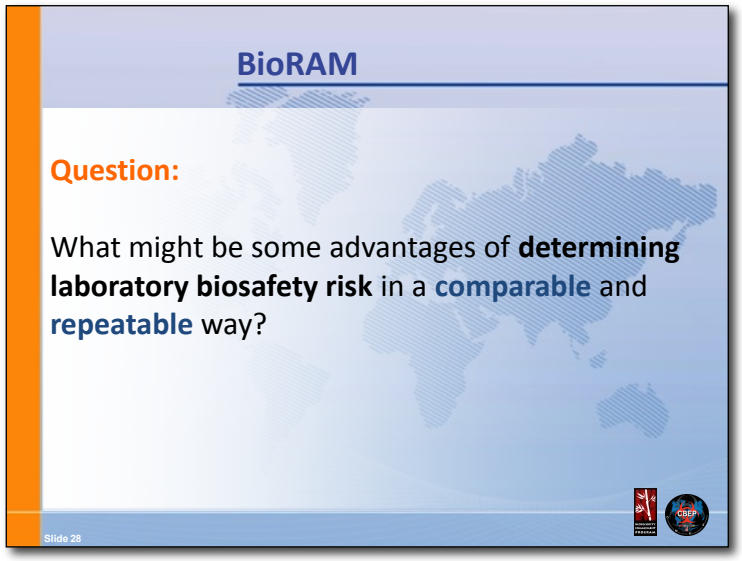
Notes:


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.
Slide 26

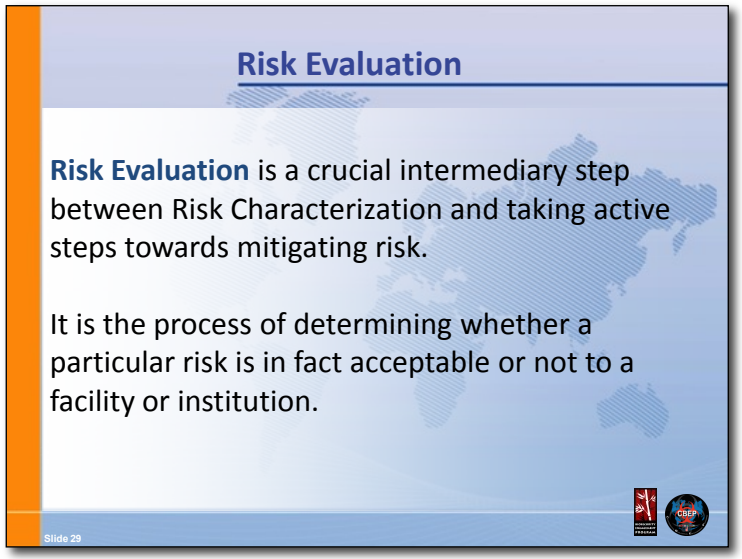

BioRAM
BioRAM uses only one of several possible risk assessment methodologies.
It is based on the input of biosafety experts and validated around the world. The BioRAM tool helps determine relative risk levels in a comparable and repeatable way.
http://biosecurity.sandia.gov/BioRAM/
Slide 27

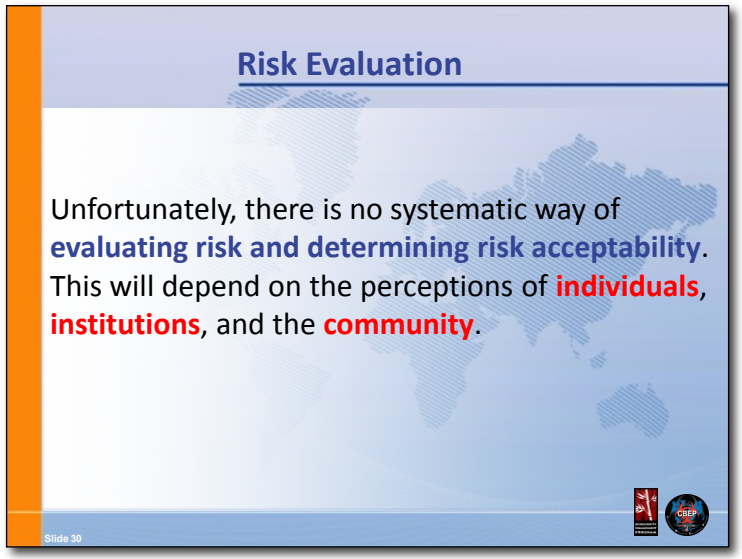


Laboratory Biosafety Risk Assessment:

Advantages:

Disadvantages:


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.
Slide 29


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:

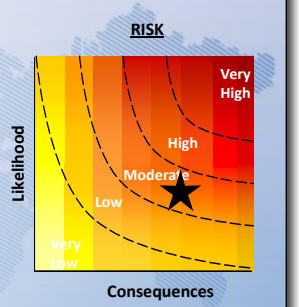
Institution Factors:

Community Factors:

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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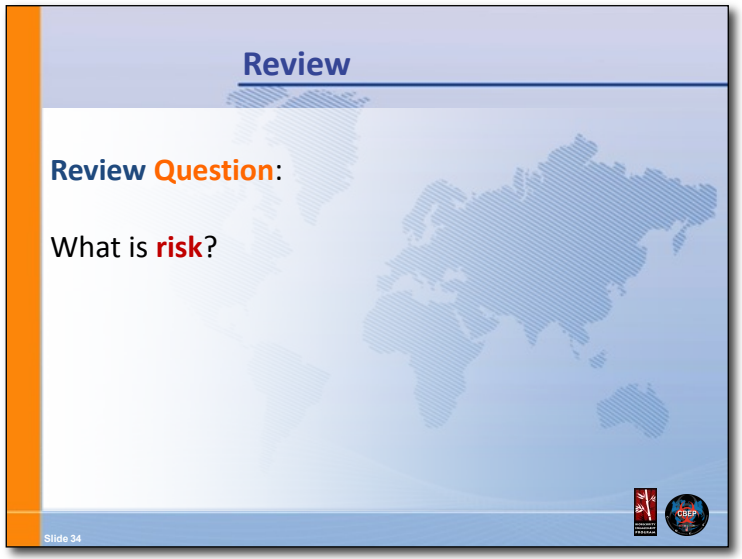
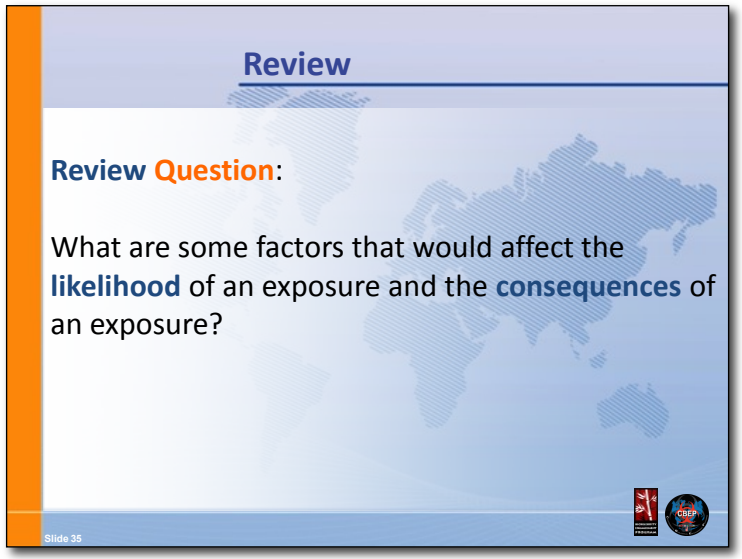
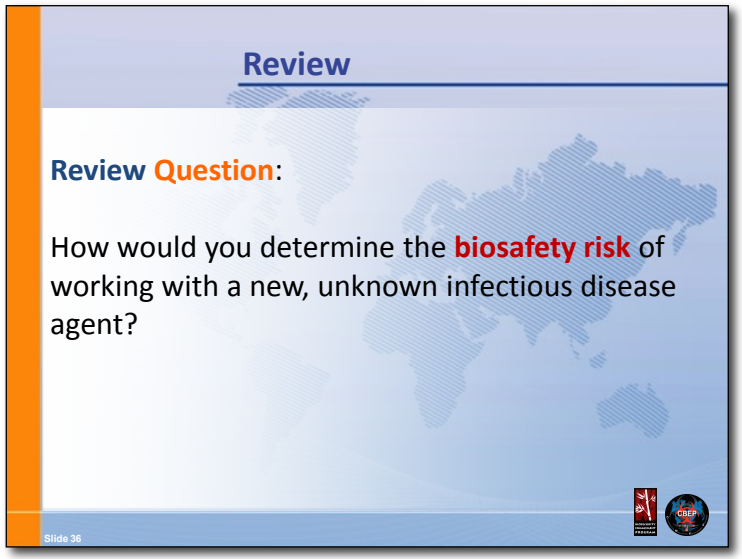
Risk Evaluation

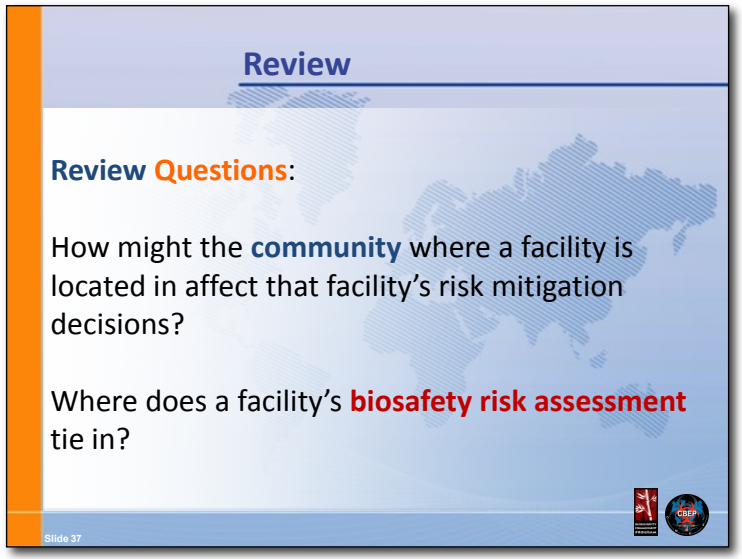
Risk Evaluation drives investment decisions in an institution. If an institution is particularly **risk-averse**, it will spend more resources attempting to reduce the risks it faces. If a similar institution faces the same risks but is **less risk-averse**, it might proceed with procedures others may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

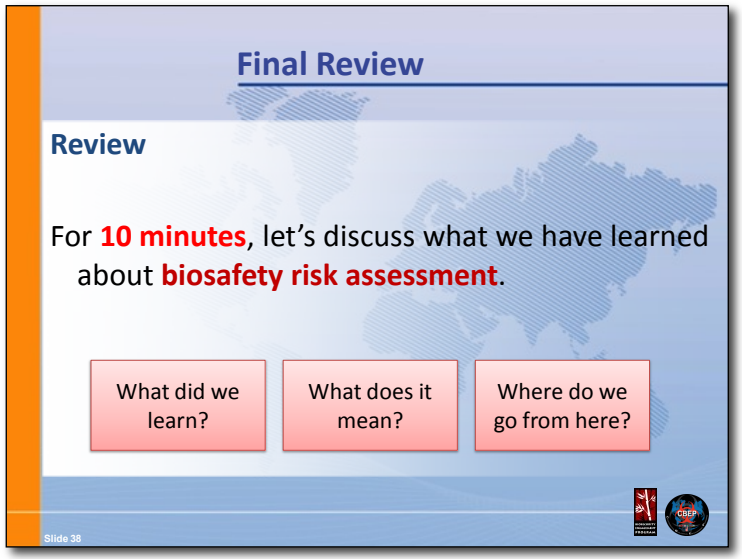
Slide 33

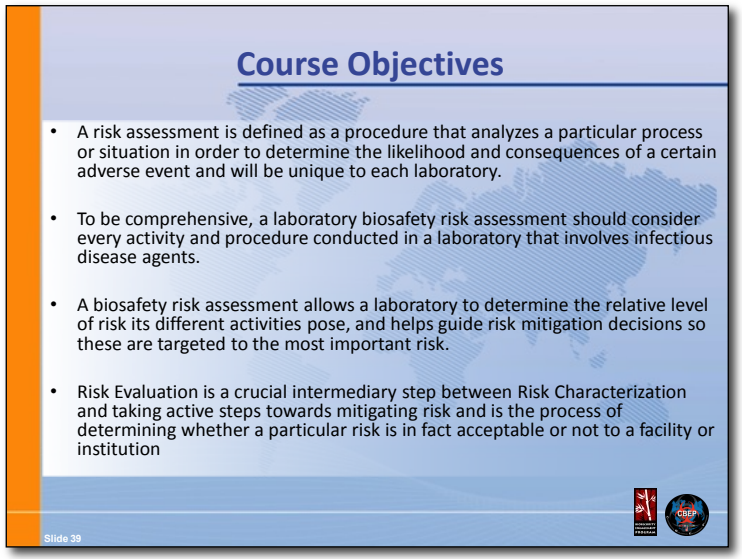

Review
Review Question:
What is risk?
Slide 34


Review
Review Question:
What are some factors that would affect the likelihood of an exposure and the consequences of an exposure?
Slide 35


Review
Review Question:
How would you determine the biosafety risk of working with a new, unknown infectious disease agent?
Slide 36


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?
Slide 37


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?
Slide 38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Slide 39


Thank You!
Don't forget to complete your evaluation!
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