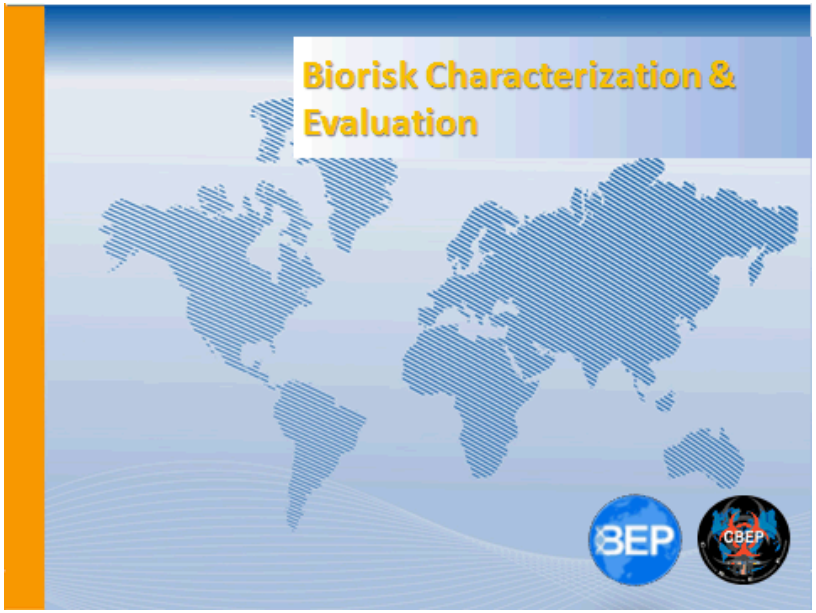
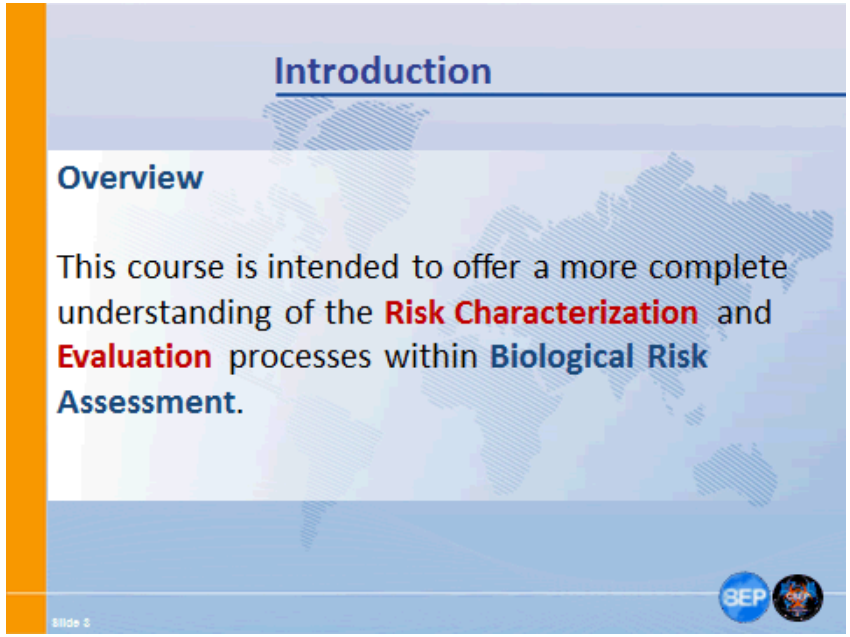
SAND2013-6725P

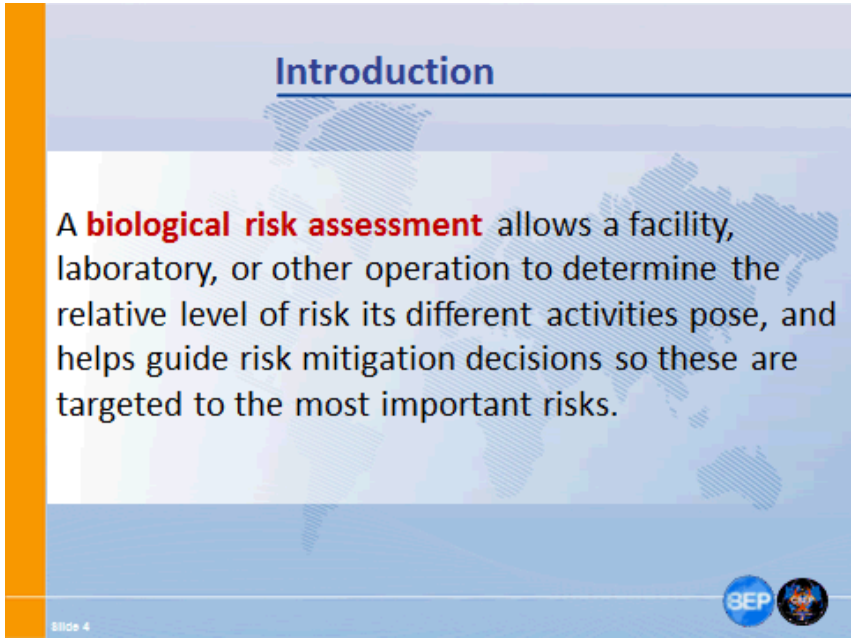
Biorisk Characterization & Evaluation

Student Guide



Welcome to Biorisk Characterization & Evaluation!


Introduction
Overview
This course is intended to offer a more complete understanding of the Risk Characterization and Evaluation processes within Biological Risk Assessment.
Slide 3


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.
Slide 4

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**

Slide 6

Introduction

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

Slide 8

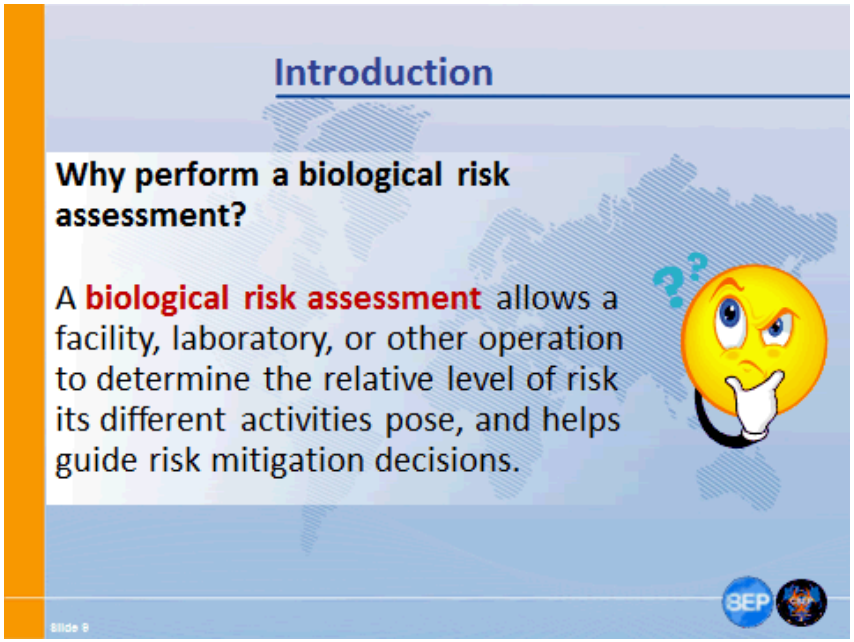
Introduction

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

Introduction

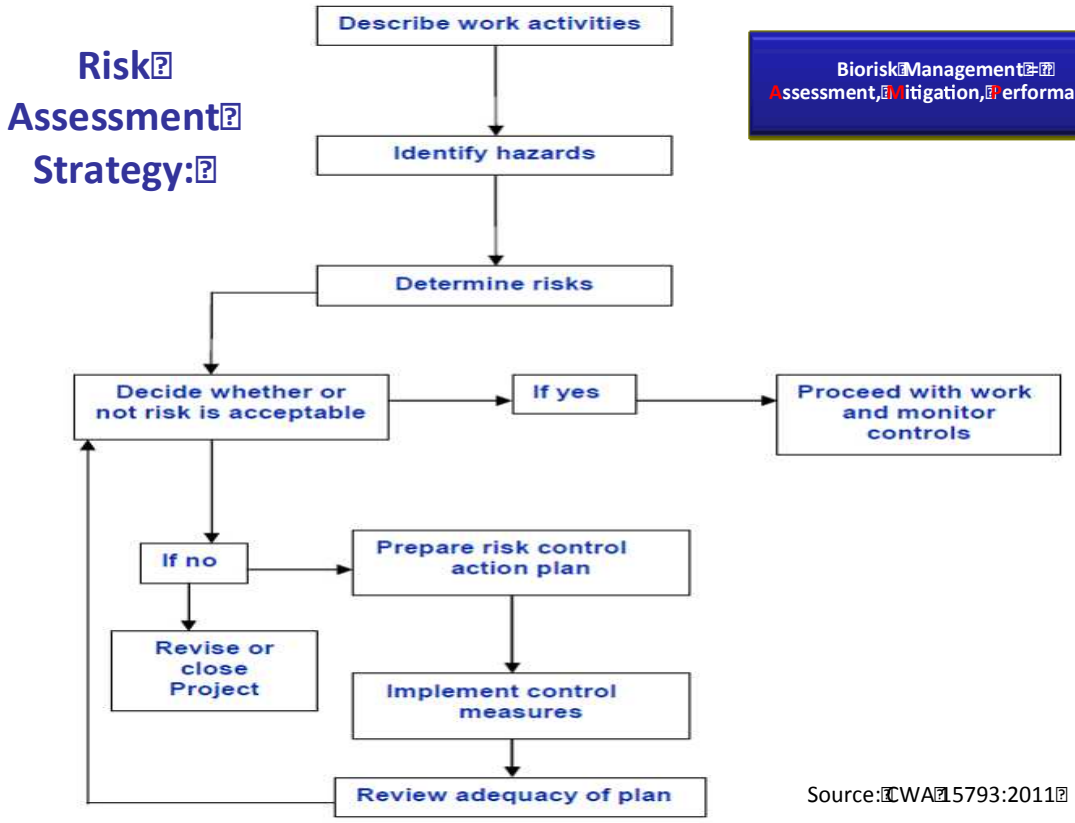
To be comprehensive:
A **biosafety risk assessment** should consider every aspect of operations, including materials, equipment, and activities conducted that involves infectious disease agents or toxins.

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?

Slide 11

Risk

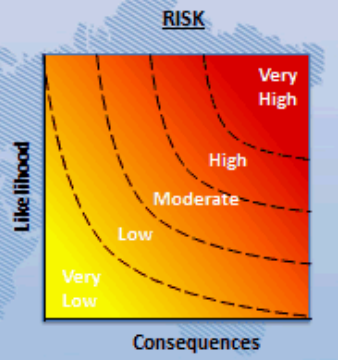
Question: What is Risk?

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



Slide 12

Risk Assessment

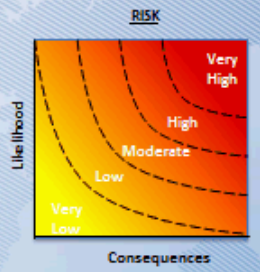
A **risk assessment** could be defined as a procedure that analyses a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

R = f(L, C)

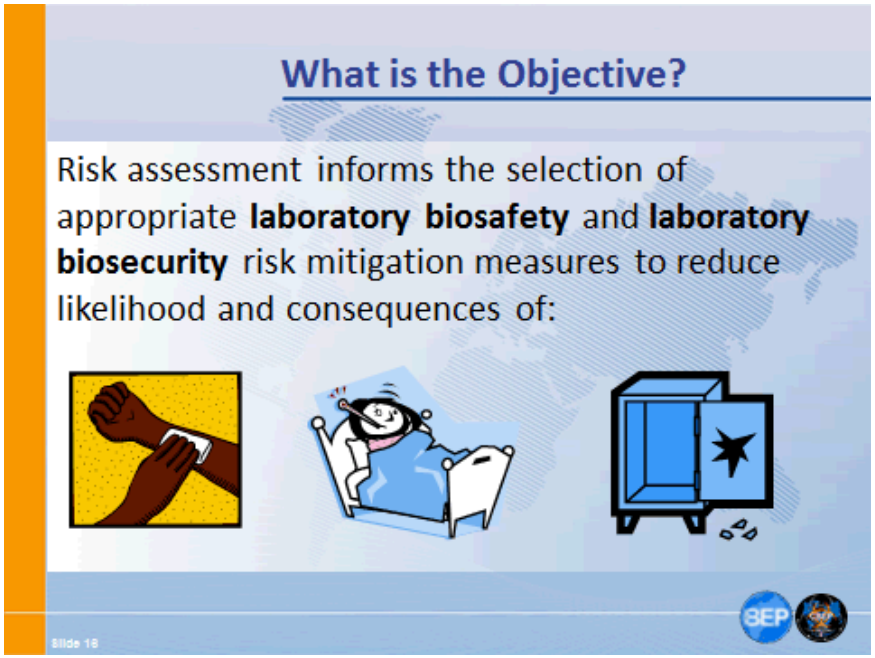
Slide 13

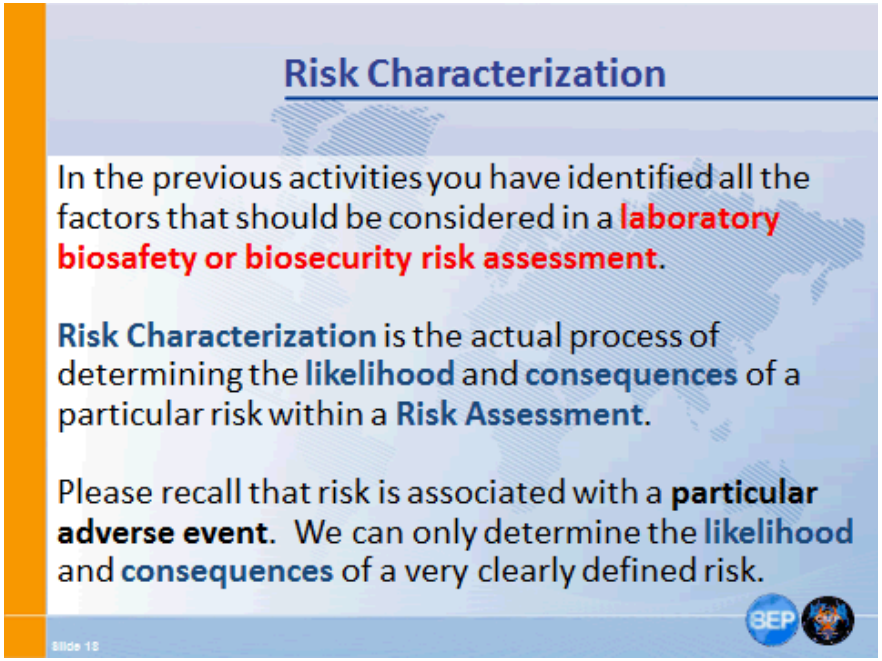
Risk Assessment

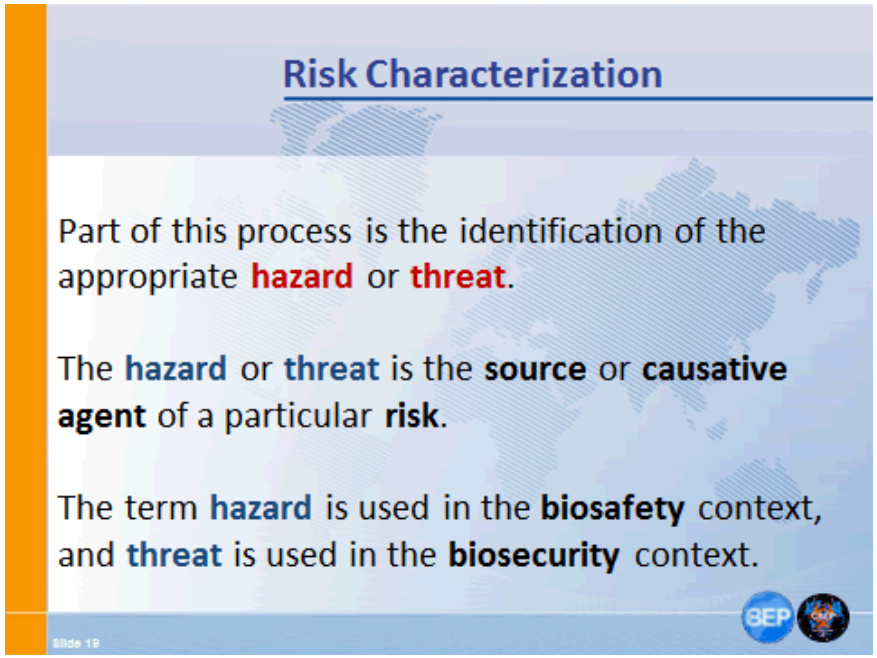
A **risk assessment** assigns values for **likelihood** and **consequences**, which allows us to represent the risk of a particular adverse event on a graph.



Slide 14


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:
Slide 18


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.
Slide 18


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.
Slide 19

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.

Slide 20

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**.

Slide 21

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**.

Slide 20

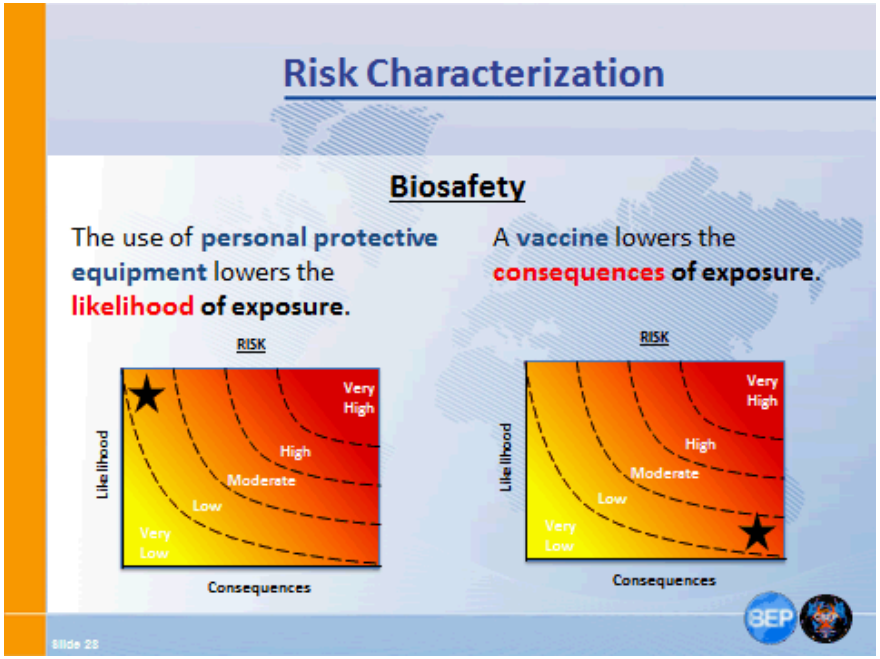
Risk Characterization

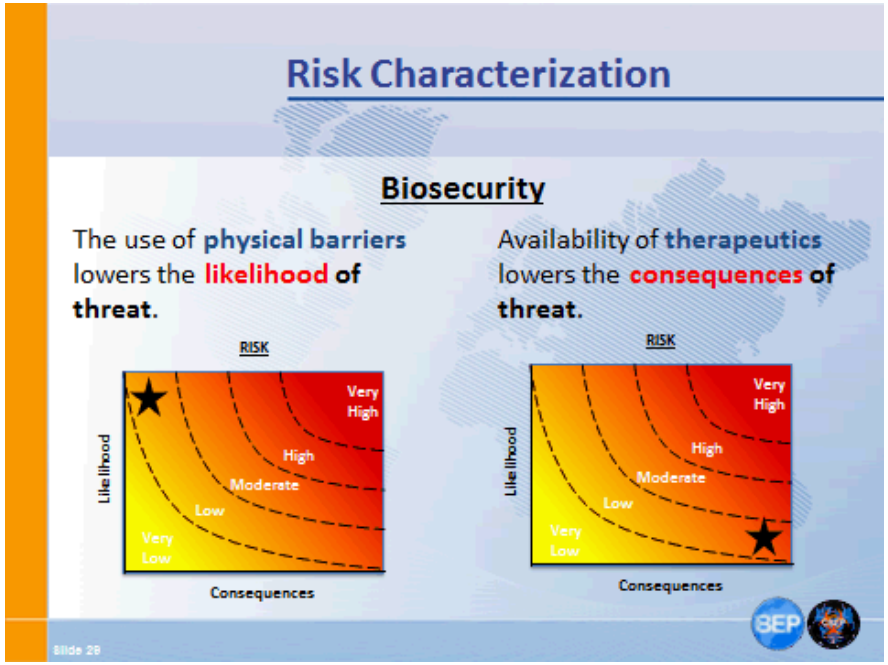
Activity:

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

Slide 22


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.
Slide 26


Risk Characterization
Biosafety
The use of personal protective equipment lowers the likelihood of exposure.
A vaccine lowers the consequences of exposure.
RISK
Likelihood
Very High
High
Moderate
Low
Very Low
Consequences
RISK
Likelihood
Very High
High
Moderate
Low
Very Low
Consequences
Slide 28


Risk Characterization
Biosecurity
The use of physical barriers lowers the likelihood of threat.
Availability of therapeutics lowers the consequences of threat.
RISK
Likelihood
Very High
High
Moderate
Low
Very Low
Consequences
RISK
Likelihood
Very High
High
Moderate
Low
Very Low
Consequences
Slide 29

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.

Slide 32

Risk Evaluation

What is "**acceptable**" risk?

Slide 33

Risk Evaluation

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

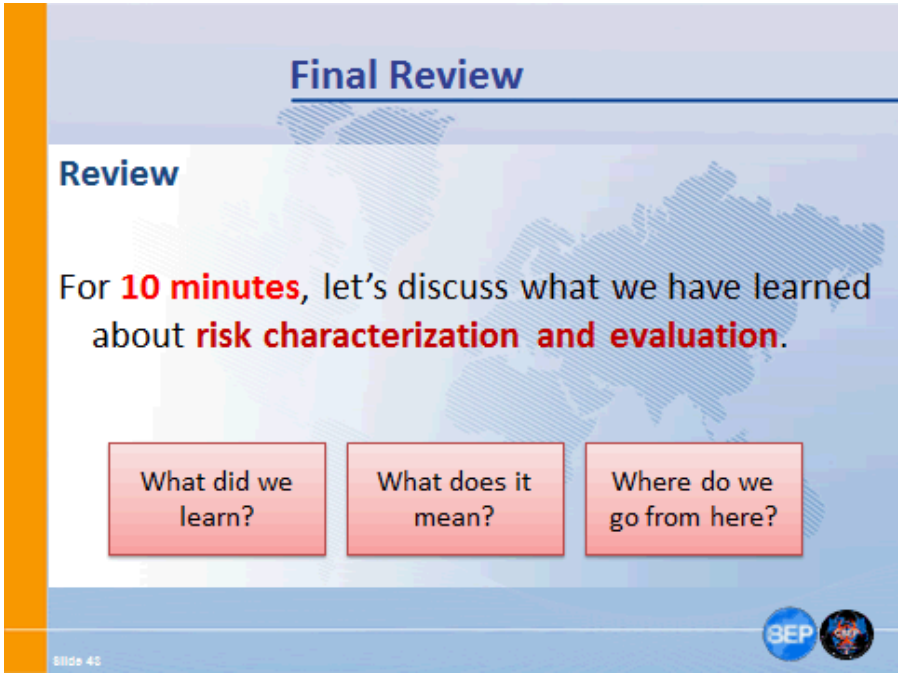
Risk evaluation and **acceptance** can vary with **culture, experience, resources, management,** and even **current events**.

Slide 54

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**.

Slide 55


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?
BEP
Slide 48