

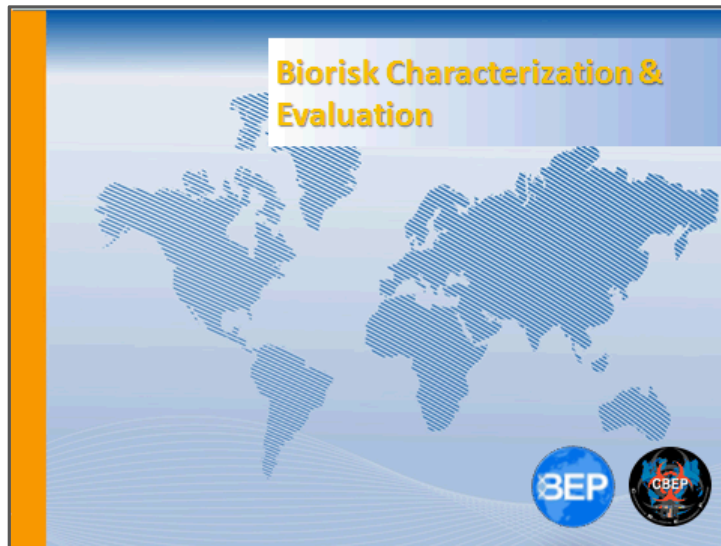
# Biorisk Characterization & Evaluation

## *Instructor Guide*



# Welcome & Introductions

## Slide 1



## Key Messages for Instructor

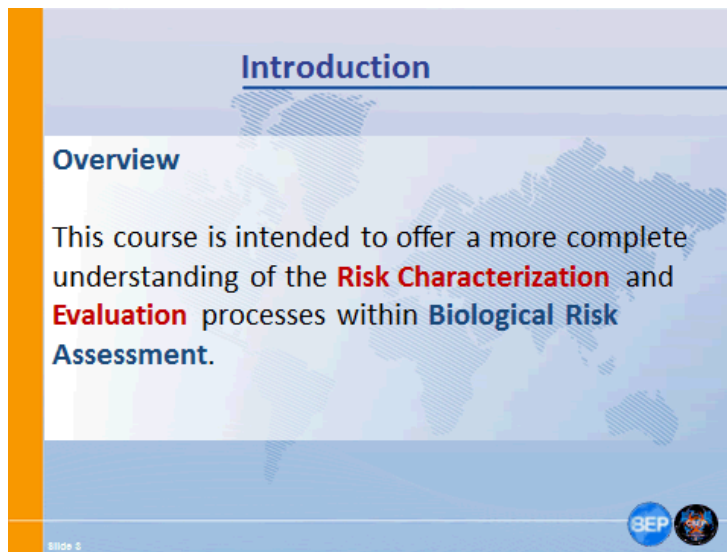
1. A biosafety and biosecurity risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk.
2. Risk Characterization is the process of identifying the factors that contribute to risk and determining the likelihood and consequences that contribute to risk.
3. Complete and thorough analysis of the different hazards, threats and situations that can affect risk will increase the robustness of the risk characterization process.
4. 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.

# Welcome & Introductions

## Slide 2




---



**Introduction**

**Overview**

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

SEP 

Slide 2



## Lecture

This outlines the topics that we will focus on today in the Biorisk Characterization and Evaluation course.



## Lecture

Question: What would you like to take home from this course?

One Principal Objective:

To understand risk characterization and evaluation within risk assessment, in order to better choose and implement risk mitigation strategies.



## Background Information for Instructor

Check for understanding and verify that these objectives are consistent with student expectations.

# Welcome & Introductions

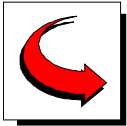
---



## **Capture any additional KNOW, FEEL, or DO or other learning goals**

Capture any learning goals that will supplement course objectives and address any that are outside the scope of the course.

This course is flexible in nature. If there is a learning goal that is easily incorporated into the course, feel free to add it. Please note successful additions and consistently requested learning goals in the evaluation portion of this course and/or to GBRMC administrators.



## **Transition to Basics of Risk Assessment**

---

# Basics of 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 12



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 12




# Basics of Risk Assessment

Slide 5





**Introduction**

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



Slide 14

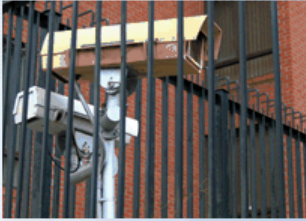


Slide 6





**Introduction**

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



Slide 15



# Basics of Risk Assessment

Slide 7





**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.

Slide 16




Slide 8





**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.



Slide 17



# Basics of Risk Assessment



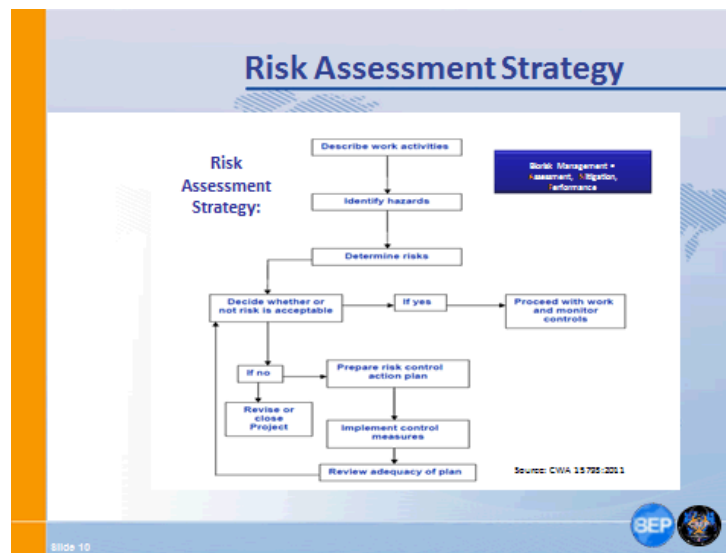
## In Plenary, ask students:

Why is it important to perform a biological risk assessment?

Ask the students if they have any examples to share about instances when performing a biological risk assessment was necessary.

Or as an instructor, include your own example.

## Slide 9



## Background Information for Instructor

Walk through this flow chart, from the CWA 15793:2011 (Laboratory Biorisk Management Standard), that is used as a strategy to assess risk. Highlight the progression of identifying the risks and hazards and then deciding whether the risk is acceptable or not and what to do in either case.

# Basics of Risk Assessment

Slide 10



---

**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 10



# Basics of Risk Assessment

---



**Small group activity (10 minutes).**



## **Activity Instructions (to students)**

1. What is “risk”?
2. In your groups, please spend 5 minutes to develop a definition for “risk”.
3. Choose someone from your group to share the definition with the class.
4. What did your group come up with?



**You have 10 minutes to complete this activity**

### ***Directions for Instructor:***

- Allow students 5 minutes to come up with answers to the question: What is “risk”?
  - Instructor fills out plenary flip-chart
  - Spokesperson from each group report in plenary. Reporting time of 10 minutes.
-

# Basics of Risk Assessment

## Expected Responses

- Chance of an adverse event happening
- Examples that may focus on consequence
- Examples that may be biased towards discussing likelihood/consequence

New Responses from Students:

---

---

---

---

---

---

---

## Slide 11



**Risk**

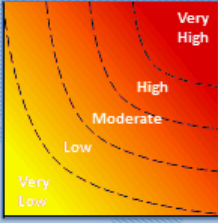
**Question:** What is Risk?

*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**



The diagram is a 2D matrix with 'Likelihood' on the vertical axis and 'Consequences' on the horizontal axis. The matrix is divided into five color-coded regions: 'Very Low' (yellow), 'Low' (orange), 'Moderate' (light red), 'High' (red), and 'Very High' (dark red). Dashed lines separate these regions. The word 'RISK' is written above the matrix.

Slide 11



# Basics of Risk Assessment

---



## Background Information for Instructor

A risk can be defined in several ways, but for our purposes we could say that risk is the likelihood of an adverse event of some consequence happening.

Thus, risk is thus a function of the Likelihood a particular adverse event will occur, and the Consequences of that event.

$$R = f(L, C)$$

One way to visualize risk is to graph it. Shown on the left is a 2-dimensional graph, with Likelihood in the y-axis and Consequences in the x-axis. This graph allows us to fully determine the risk associated with something by assign values to both likelihood and consequences.

For example, there are some risks with very low likelihood, but high consequences and vice versa. To become more familiar with this concept of risk we will work through the following example.

---

# Basics of Risk Assessment

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 24



## Background Information for Instructor

These next three slides tie in the concept of risk (in terms of likelihood and consequences) into the framework of a risk assessment.

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 25

# Basics of Risk Assessment


## 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 27  

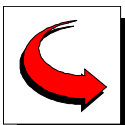


### In Plenary, ask students:

What is the objective of a risk assessment? It helps with selection of appropriate mitigation measures to reduce the likelihood and consequences of: What?

Expected Responses:

Exposure, sickness, theft, diversion, misuse, accidents, incidents, mistakes, etc.



### Transition to Risk Characterization

---

# Risk Characterization

## Slide 15





---

**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 15



---

## Lecture

We have now identified all the factors that will be assessed in determining the likelihood and consequences of risk. This whole process is known as Risk Characterization.

---

# Risk Characterization

## Slide 16





**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 22



## Background Information for Instructor

The next few slides will more clearly define hazard and threat in the context of biosafety and biosecurity, respectively.

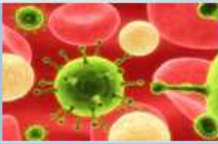
## Slide 17





**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 23



# Risk Characterization



## Lecture

This slide explains the association of hazard to biosafety risk.

For example, to determine a biosafety risk, we must consider very carefully, and specifically, the activity being conducted and the potentially dangerous biological material being manipulated.

We must ask a risk question: What is the risk of exposure to this material if I conduct that procedure?

## Slide 18



**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**.

A simple line-art icon of a robot's face with a neutral expression, located at the bottom center of the slide.

Slide 14

A small circular logo with the letters 'BEP' inside, located at the bottom right of the slide.

## Lecture

This slide explains the association of threat to biosecurity risk.

For biosecurity risk, we must consider very carefully, and specifically, the adversary with the intent to steal, the actual manner of theft, and the biological material being targeted.

We must ask a risk question: What is the risk of this material being stolen in this way by that adversary?

# Risk Characterization

## Slide 19





**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 19



## Slide 20





**Risk Characterization**

**Activity:**

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



Slide 20



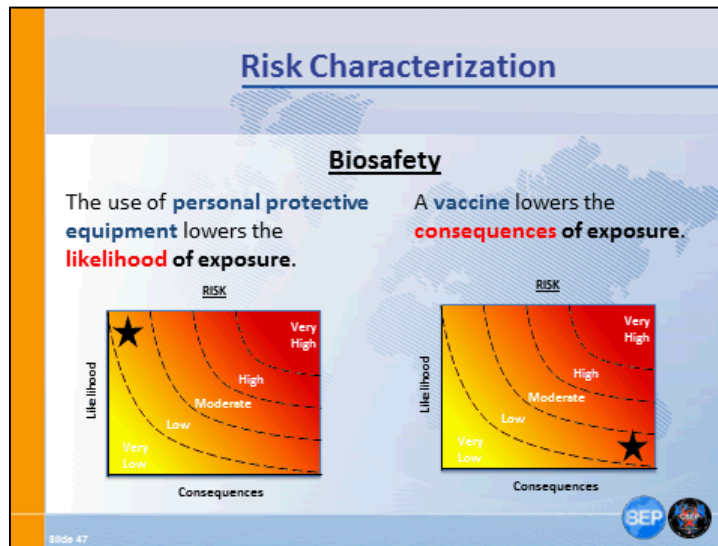
### Background Information for Instructor

Hazard (or agent) characteristics, and Threat (or adversary) characteristics are thus crucial for biological risk characterization.

But characterizing risk is incomplete without also analyzing the situation.

# Risk Characterization

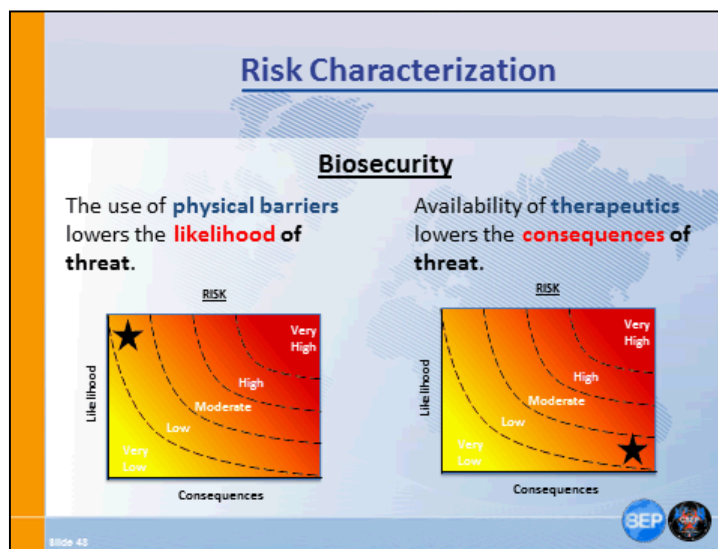
## Slide 21



## Background Information for Instructor

Watch how the likelihood and consequences in a biosafety scenario can change dependent on the use of PPE and an available vaccine, respectively.

## Slide 22



# Risk Characterization



## Background Information for Instructor

Watch how the likelihood and consequences in a biosecurity scenario can change dependent on the use of physical barriers and an available therapeutics, respectively.

### Slide 23



**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 23

BEP



## Background Information for Instructor

Risk evaluation is the final section of the course. It is an intermediary step between risk characterization and mitigation because it allows for the interpretation of characterized risks based on the uniqueness of each laboratory or institution's preferences.

Risk evaluation, and risk acceptance, remain crucial components of a risk assessment. Without the *interpretation* of a characterized risk through risk evaluation, mitigation decisions cannot be made.

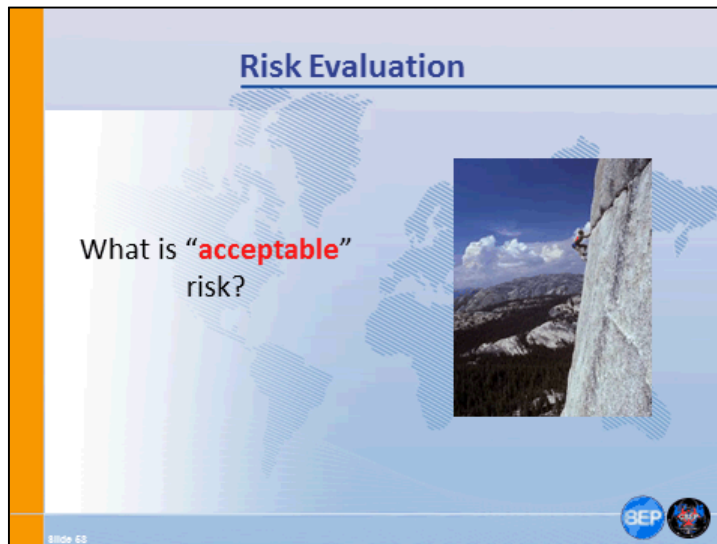
This slide underlines the importance of risk evaluation and acceptance, because without these steps, risk characterization would have little practical use.

# Risk Characterization

## Slide 24



---



The slide features a blue header with the title "Risk Evaluation". Below the title, the text "What is "acceptable" risk?" is displayed in black, with the word "acceptable" in red. To the right of the text is a photograph of a person rock climbing a vertical rock face. The background of the slide is a light blue world map. In the bottom right corner, there are two circular logos: one with the letters "BEP" and another with a globe icon. The text "Slide 24" is visible in the bottom left corner of the slide frame.



### Background Information for Instructor

This slide highlights the concept of "acceptable" risk. In just about every situation there will be an amount of risk that will need to be accepted and it is often up to the institution to determine the level of acceptable risk.

Ask the students if the picture on the right depicts acceptable risk or not to them. Likely the level of acceptable risk will take into account the mitigation measures that are put into place – in this case ropes and harnesses. Some people may feel ok with using ropes and harnesses to keep them safe while rock climbing, to others, the risk is still to high..

---

# Risk Characterization

## Slide 25




---



**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 25



## Background Information for Instructor

This slide emphasizes the point that neither risk evaluation or acceptance can be determined through a formula, nor can either be determined in a robust. If you have time, discuss this point with the students. What do they think?

# Risk Characterization


Slide 26



---

**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.**



© 2004 BFP



## Background Information for Instructor

Risk Acceptance is how tolerable or acceptable a particular risk is to an institution, the community, or a person.

# Risk Characterization

Slide 27



## 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?

Slide 22

Slide 28



## 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 24



Ask students to spend a few minutes reviewing and completing their action plan.

# Risk Characterization

Slide 29



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



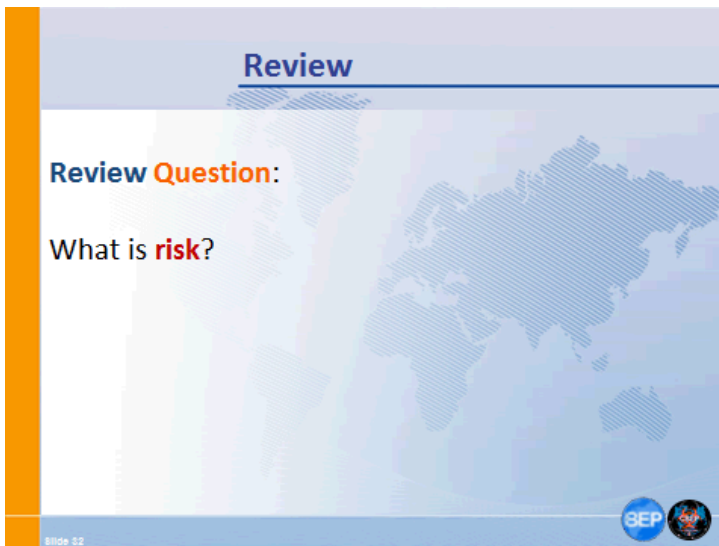
BEPP CBEP

Slide 30



**Review**

**Review Question:**  
What is **risk**?



Slide 32 BEPP CBEP

# Risk Characterization



## Background Information for Instructor

This is the first of the review questions. These are a series of questions which are meant to jog the students memories and in this manner review the key concepts of the course.

The instructor can choose the best way to conduct these sessions, though general discussion is likely to be the fastest way.

In this slide, students should come up with a definition of risk like they did in the beginning of the course, recognizing:

- 1) risk is composed of likelihood and consequences, and
- 2) it is based on a very specific scenario, with a particular agent, set of procedures, and mitigation measures already in place.

## Slide 31

A presentation slide titled 'Review' with a world map background. The slide contains a 'Review Question' and logos for SEP and a globe in the bottom right corner. The text on the slide reads: 'Review Question: What are some factors that would affect the likelihood of an exposure and the consequences of an exposure?'

**Review**

**Review Question:**

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

SEP

Slide 31

# Risk Characterization

---



## Background Information for Instructor

This question is intended to remind students about likelihood and consequences, and underline the point that one factor can influence both.

In this case, route of exposure may increase the likelihood of exposure because a particular agent may prefer that route for infecting hosts. Procedures that generate risks associated with that route will increase the likelihood of exposure. Depending on the route of exposure, the consequences may also change. Certain routes of exposure are more likely to lead to infection (percutaneous versus contact, for example), and some routes of exposure cause more serious disease than others (subcutaneous anthrax versus inhalational anthrax).

---

## Slide 32

A presentation slide titled 'Review' with a world map background. The slide contains a 'Review Question' about determining biosafety risk. It includes a 'BEP' logo and a small globe icon in the bottom right corner.

**Review**

**Review Question:**

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

Slide 32

BEP

# Risk Characterization



## Background Information for Instructor

This is a complicated question, with no right answer per se, but intended to have students think about how to apply risk assessments.

The difference with a known disease comes in agent characterization. We don't know much about the agent so we won't know how to determine whether a particular procedure will result in exposure and infection, or not. To determine the biosafety risk, one would have to do what one does to determine biosafety risk for a known agent, and for the unknown factors, potentially assume the worst until more information is gathered.

## Slide 33



The slide has a light blue background with a faint world map. At the top, the word "Review" is written in blue. Below it, the text "Review Questions:" is in blue. The first question is "How might the **community** where a facility is located in affect that facility's risk mitigation decisions?". The second question is "Where does a facility's **biosafety risk assessment** tie in?". In the bottom right corner, there are two circular logos: one with the letters "BEP" and another with a globe. In the bottom left corner, the text "Slide 33" is visible.

# Risk Characterization

---



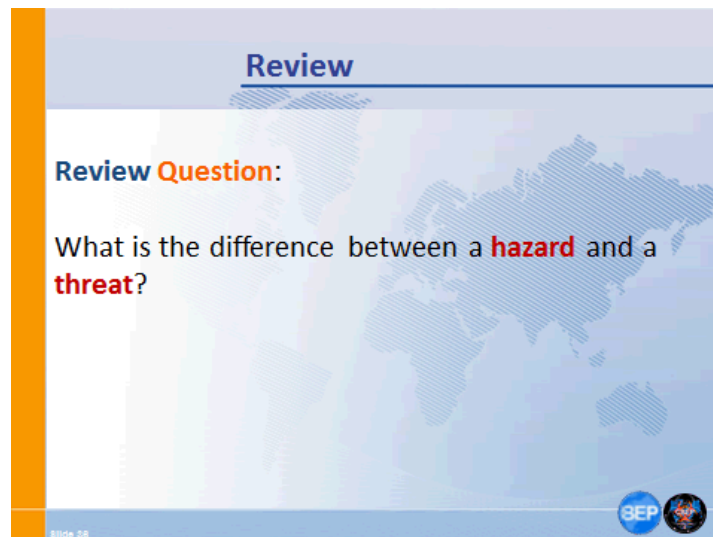
## Background Information for Instructor

This question is meant to remind students of the role of communities in risk evaluation, and that risk characterization is only part of the answer.

A community can put obstacles in the proper functioning of a facility if they feel its operations put them at risk. Thus, the opinions of the community have to be taken into account when developing risk mitigation decisions. A biosafety risk assessment includes risk characterization and risk evaluation... the decision to employ risk mitigation decisions is based on both.

---

## Slide 34

A presentation slide titled "Review" with a world map background. The text on the slide reads: "Review Question: What is the difference between a hazard and a threat?". The slide also features a "BEP" logo and a small globe icon in the bottom right corner, and "Slide 34" in the bottom left corner.

**Review**

**Review Question:**

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

Slide 34

BEP



## Background Information for Instructor

The difference between a hazard and a threat is that a hazard is used in the biosafety context and usually refers to biological material that has no intent, whereas threat is used in the security context and usually refers to a human being or a group of human beings with intent.

---

# Risk Characterization

Slide 35




---

**Review**

**Review Question:**

Neither a **hazard** or a **threat** are a **risk** without a \_\_\_\_\_ ?

Slide 37



## Background Information for Instructor

The answer here is situation. Other acceptable answers could be “procedures” or “context”. It is meant to emphasize an important point about hazards and threats, and potentially, how to change the situation so that they no longer pose as much of a risk.

---

# Risk Characterization

## Slide 36




---

**Review**

**Review Question:**

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

Slide 36



## Background Information for Instructor

This question is from the biosecurity risk assessment module. It is a complicated question, with no right answer per se, but intended to have students think about how to apply risk assessments. The difference with a known disease comes in agent characterization. We don't know much about the agent so we won't know how to determine whether an adversary will be interested. An adversary will not know either, so he or she will be less likely to risk taking it; at the same time, because it is new, it may be in the news, in people's minds, and thus in a potential adversary's mind. In general, a biosecurity risk assessment will proceed as normal, except that some of the information may be unknown, and one will have to take into account the potentially higher profile the asset will have.

---