

Biosafety Risk Assessment

Instructor Guide





Welcome & Introductions

Slide 1



Introduce Instructor(s):

[Introduce others associated with the training, as appropriate]

Name

Affiliation

Representation (I'm here on behalf of. . .)

Quick Experience Glimpse

Relevancy of the Course to your experience

Welcome & Introductions



Before you introduce yourselves, I'd like to provide some reminders about this facility and the training:

1. Restrooms are . . .
2. Exits are . . .
3. Evacuation procedures are . . .
4. [any escort or restricted access procedures]
5. We will have intermittent breaks during the course, but please feel free (or not) to take a quick break if you need to at other times during the course
6. Beverages and snacks will be available at (time) and at (location). You may/may not eat and drink in this room
7. Please silence any cell phones or other noise-making devices.
8. Others . . .

Slide 2



Introductions

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



Slide 2



Welcome & Introductions



Let's go around the room and let each of you introduce yourself. Please tell us your name, where you work (organization and/or title, as appropriate), and what you hope to gain from the course.



Ground rules

This will be a very interactive session and you will learn the most if you participate fully. We will not intentionally force any one to speak or to do an activity that embarrasses them – if you are uncomfortable, please speak to one of the leaders. For those of you who like to talk, please share your expertise but be aware of those around you who may be quieter and give them time to share their opinion as well. We ask that everyone respect the break times and report back promptly when asked to do so. But most of all, we want to make this a fun time to learn, so remember to smile and enjoy yourself!



Transition to Objectives



Goal

To review the Action Plan and Learning Objectives for the course and to solicit any additional learning goals from the participants.



Time

20 minutes

Welcome & Introductions



Key Messages for Instructor

1. 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.
2. To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.
3. 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.
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

Slide 3



Action Plan				
By the end of this lesson, I would like to:				
KNOW	FEEL		BE ABLE TO DO	
<p>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.</p>				
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

Welcome & Introductions



Instructions for the Action Plan handout:

- The Action Plan handout is on page __ of the student guide.
- It is designed to help you assess your learning of the material as we go through the course. It is also referred to as a learning contract.
- Go over each section of the Action Plan. . .
- The sections KNOW, FEEL and DO are designed to help outline personal learning objectives for this course.
- Ask each participant to think about what they would like to be able to KNOW, FEEL, and DO once this course is completed
- Tell the students that this is their own Action Plan. It does not need to be shared with anyone. It can be used during the course and after the course to help continually reach learning goals.
- Allow 5 minutes



Lecture

This course is intended to offer an understanding of the basic theory underlying a biosafety risk assessment.

We will first offer a brief introduction on risk and biosafety risk in particular. We will then discuss the process of assessing risk, and finally conclude with a deeper consideration of specific aspects of that process.

The goal is to offer a basic awareness of the importance of biosafety risk assessment within the overall process of laboratory biorisk management.

Welcome & Introductions

Slide 4



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



Lecture

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

One Principal Objective:

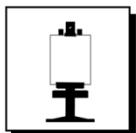
To learn the basic concept of a biosafety risk assessment, and explore its benefits and as well as the challenges involved in carrying it out.



Background Information for Instructor

Review the course objectives, these can be read from the slide. Check for understanding and verify that these objectives are consistent with student expectations.

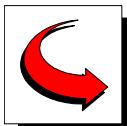
Welcome & Introductions



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 Biorisk Management Touchstone



Biorisk Management

Slide 5



Biorisk Management: the **AMP Model**

A world map in the background of the slide.

Biorisk Management =
Assessment, Mitigation, Performance

Slide 5

Two small circular logos in the bottom right corner.

Background Information for Instructor

- Review the AMP model of Biorisk Management with the participants.
- The following three slides provide specific definitions for A, M, and P.
- Integration of laboratory biosafety (protect people from pathogens) and laboratory biosecurity (protect pathogens from people)

Biorisk Management

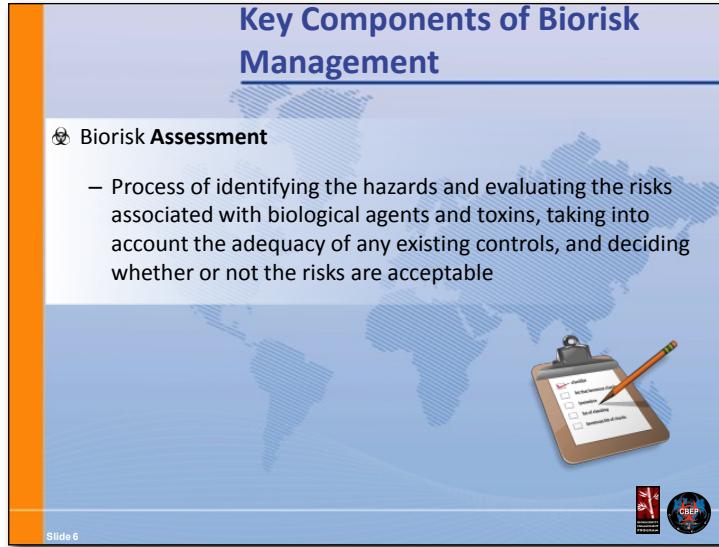
Slide 6



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



Slide 6



Background Information for Instructor

The instructor uses the following three slides: Biorisk Assessment; Biorisk Mitigation; and Performance to define key components of biorisk management

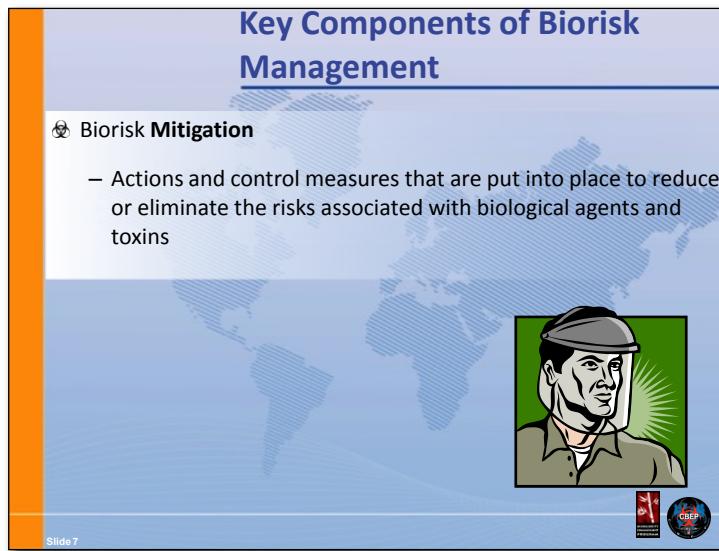
Slide 7



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



Slide 7



Biorisk Management



Background Information for Instructor

The instructor uses this slide and following slide (Performance) to define key components of biorisk management

Slide 8



Key Components of Biorisk Management

⌚ **Performance**

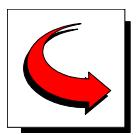
- The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Slide 8



Lecture

Taken together, the three elements of AMP constitute a complete biorisk management system. The elements of the AMP model also underpin CWA 15793:2011 – Laboratory Biorisk Management Standard



Transition to Introduction to Biosafety Risk Assessment

Introduction to Biosafety Risk Assessment

Slide 9



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



Lecture

The results of a biosafety risk assessment will be unique to each laboratory and each procedure conducted in that laboratory.

Slide 10



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

66
99

Lecture

The scale of biosafety risk assessment can vary from analyzing one particular procedure all the way up to performing a risk assessment on all the operations conducted in the facility.

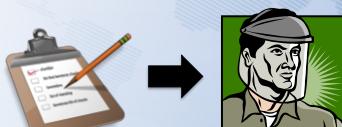
To be comprehensive, a biosafety risk assessment should consider every aspect of operations, including materials, equipment, and activities conducted that involves infectious disease agents or toxins.

Slide 11



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

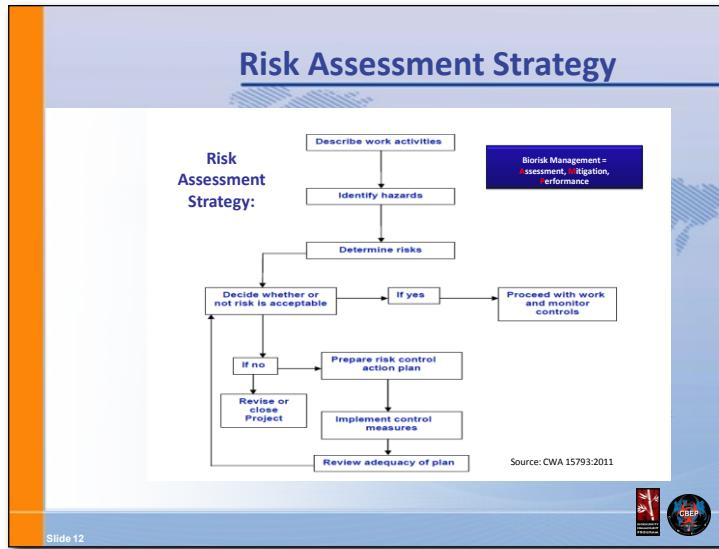


Background Information for Instructor

Tie information in the slide back to the AMP Model for Biorisk Management. In this course we will be focusing on the Assessment piece, but have students keep in mind that a thorough risk assessment is needed to implement appropriate mitigation measures.

Introduction to Biosafety Risk Assessment

Slide 12



Background Information for Instructor

This slide shows a standardized process from the CWA the outlines a risk assessment strategy. Talk through the flowchart and ask students if it makes sense to them.

We'll be breaking down this process to its components through the duration of this course.

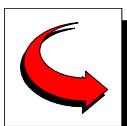


Take a Break (10 minutes)



Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.



Transition to What is Risk?

What is Risk?

Slide 13



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?



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 15 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.

What is Risk?

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 14



Risk

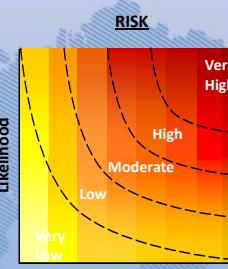
Question: What is Risk?

Risk is the likelihood of an undesirable event happening, that involves a specific hazard, and has consequences

$Risk = f(\text{likelihood, consequences})$

or, more simply,

Risk is a function of both the **Likelihood** of something happening and **Consequences** of that occurrence



CBEP

What is Risk?



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.

Slide 15



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.

Slide 15



What is Risk?



Small group activity (10 minutes).



Activity Instructions (to students)

1. You have 5 minutes, in your groups, to list all the information needed to know that answer the question, "What is the risk of being attacked by a tiger?"
2. To help with this task, list all examples of useful information on sticky-notes and place them on your flip chart
3. Be prepared to report your criteria to the class.



You have 10 minutes to complete this activity

Directions for Instructor:

- After 5 minutes, ask the students to stop working on the exercise
- Lead a 5-minute plenary discussion. Begin by asking for one group of students to report their information examples and have the students elaborate on what factors they considered.
- Continue around the room, asking other groups to report out, as time allows.
- Be sure to highlight any similarities, differences or unique answers.



What is Risk?

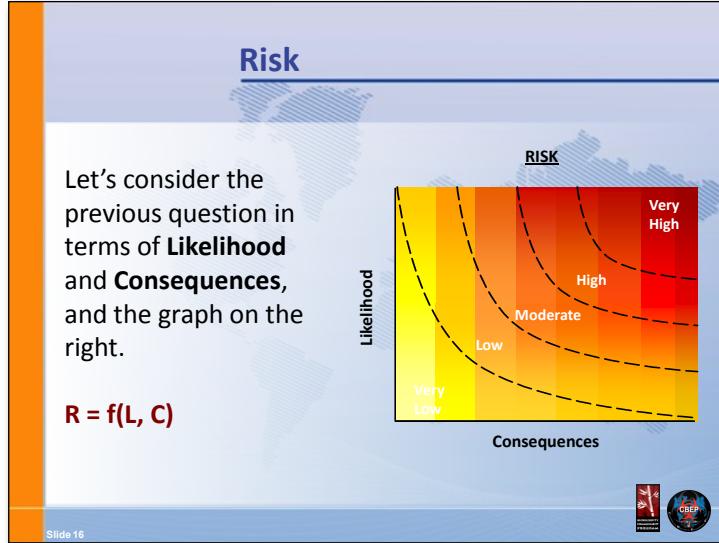
Expected Responses

- If the Tiger is hungry
- If Tigers are present in your surroundings
- The age of the Tiger
- The size of the Tiger
- The Tiger's temperament
- Has the Tiger been tamed?
- If the Tigers loose or caged?

New Responses from Students:

What is Risk?

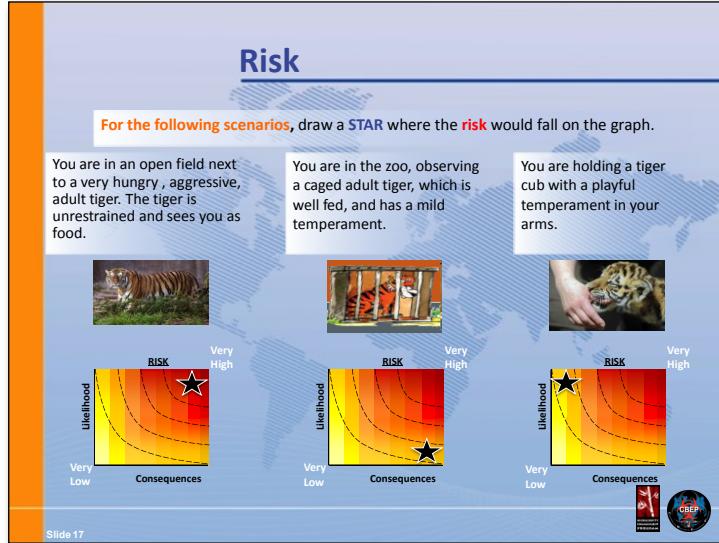
Slide 16



Background Information for Instructor

Use this slide to orient the students back to expressing risk as a function of likelihood and consequences.

Slide 17



What is Risk?



Small group activity (15 minutes).



Activity Instructions (to students)

1. You have 5 minutes, to work individually to draw a STAR where the risk would fall on the graph for each of the three scenarios.
2. After 5 minutes, discuss with your group your results.
3. Be prepared to report your criteria to the class.



You have 15 minutes to complete this activity

Directions for Instructor:

- After 5 minutes, ask the students to switch from working individually to work in their group to discuss their answers.
- Lead a 5-minute plenary discussion. Begin by asking for one group of students to report their answer for the first scenario and have them elaborate on where they graphed the risk for that scenario.
- Continue around the room, asking other groups to report out, moving through each scenario as time allows.

What is Risk?

Expected Responses

What is the risk of being attacked by a Tiger?

The risk is HIGH if:

- You are in an open field next to a very hungry, aggressive, adult tiger. The tiger is unrestrained and sees you as food.
- Rationale: There is a **high likelihood** that the tiger will attack you because it is unrestrained and hungry. There is also a **high consequence** if the tiger attacks – possible death.

The risk is LOW if:

- You are at the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.
- Rationale: The **likelihood** of being attacked by the tiger is decreased because it is contained in a cage; however, the **consequences** of being attacked by the tiger remain high because it is an adult tiger that can do a tremendous amount of harm if it does attack.
- Note: the tiger's cage is an example of a risk mitigation measure.

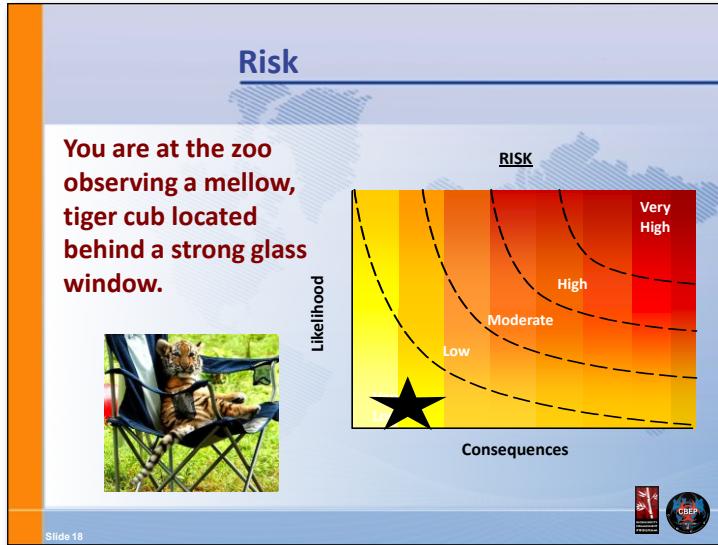
The risk is LOW if:

- You are holding a tiger cub with a playful temperament in your arms.
- Rationale: The **likelihood** that the tiger will attack is high because it is a cub that likes to play. The likelihood that the tiger will bite is high for the same reasons, however, the **consequences** of the tiger cub attacking are low because it is a cub instead of an adult tiger and cannot do as much harm as an adult tiger would be capable of doing.

New Responses from Students:

What is Risk?

Slide 18



Background Information for Instructor

The students should have the hang of assessing risk now in terms of likelihood and consequences. Use this slide to re-enforce the concept and make sure everyone is on the same page.



Lecture

Given your experience assessing risk, what is the risk of being attacked by a tiger in this scenario? You are at the zoo observing a mellow, tiger cub located behind a strong glass window.

Answer: Very Low



Ask: Any questions on what how to determine Risk?



Take a Break (10 minutes)



What is Risk?



Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.



Transition to Laboratory Biosafety Risk Assessment



Laboratory Biosafety Risk Assessment

Slide 19



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.



Slide 19

Slide 20



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.



Slide 20

Laboratory Biosafety Risk Assessment



Small group activity (15 minutes).



Activity Instructions (to students)

1. In your group, please spend 10 minutes to answer the question “What factors should be considered in a laboratory biosafety risk assessment? (What are the factors that affect Likelihood and/or Consequences?)”
2. To help with this task, list all the factors on sticky-notes and place them on your flip chart.
3. Be prepared to report your answers to the class.



You have 15 minutes to complete this activity

Directions for Instructor:

- After 10 minutes, ask the students to stop working on the exercise
- Gather the group at a location where there is a large space to post their sticky notes. You will guide the students through reviewing their answers while at the same time organizing their responses. Generally, the expected responses will fall out into two major categories: a. Agent Properties and b. Procedures, and sub-categories underneath each of these.
- Ask for one factor and post it in the space so everyone can see. Ask the rest of the group for any similar responses and post the sticky notes in the same area on the flip chart. Ask the students for a title for this category – write the title above the sticky-notes. Ask if the category can be subdivided into smaller categories. If so have the students rearrange the sticky notes to reflect all the categories.
- Repeat until all sticky notes are used up and all categories have been filled. Throughout the process, ask the students to justify their responses.

Laboratory Biosafety Risk Assessment

Expected Responses

Agent Properties:

- Pathogenicity – ability to cause disease
- Virulence – degree of pathogenicity
- Host range – restricted or broad, human, animals, plants
- Communicability – are there reports of epidemics? Of laboratory infections?
- Transmission – means (e.g., direct contact, vector borne) and routes (e.g., ingestion, inhalation)
- Environmental Stability
- Is there an alternate organism that could be used instead with lower risk associated with it?

Procedures

- What type of equipment is used – Biosafety Cabinets, centrifuges, containment laboratories
- What/if PPE is available and used correctly
- The training level of the laboratory staff with regard to biosafety and biosecurity
- How often dangerous procedures are performed
- What type of experiments are done – cell culture, radioactivity, genetic manipulation, animal studies, molecular biology, diagnostics, PCR, proliferation based (for example, involving large volumes of cultures)
- What are the waste disposal SOPs
- Is there an incident response plan in place?
- What are the consequences if the procedures are not performed?
- What types of disinfectants are available?

New Responses from Students:



Laboratory Biosafety Risk Assessment

Slide 21



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.



Slide 21



Slide 22



Risk Characterization

Activity:

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



Slide 22



Background Information for Instructor

Work through this series of slides, illustrating examples of how to determine the risk of exposure in the context of laboratory experiments.

Laboratory Biosafety Risk Assessment

Slide 23



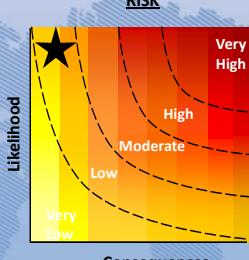
Risk Characterization

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?



Slide 23



In plenary, ask students:

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

Laboratory Biosafety Risk Assessment

Expected Responses

What is the likelihood of exposure?

- Factors: The type of virus, concentration of virus, volumes of aerosolized virus, stability of the virus
- Rationale: Without proper PPE the likelihood of exposure to the virus is high and seasonal influenza is easily transmissible.
- Answer: Likelihood is HIGH

What are the consequences of exposure?

- Factors: has the researcher been vaccinated?, are they immunocompromized?, volume and concentration of virus. Is there treatment available?
- Rationale: Seasonal influenza is a fairly common virus in the general population and many people are vaccinated on a yearly basis. Even without vaccination, the virus only causes flu like symptoms and typically does not kill its host, unless the person is immunocompromised.
- Answer: Consequences are LOW

New Responses from Students:

Laboratory Biosafety Risk Assessment



Background Information for Instructor

Risk in this case is the risk of exposure to the seasonal influenza virus.

Guide the students through the thinking process by first having them identify the factors relating to likelihood of exposure first and then assigning the level of risk based on a rationale. Repeat this process for identifying the factors contributing to the consequences of an exposure, and assigning the level of risk.

Have the students think about what the overall risk of exposure would be. If necessary, reference back to the Tiger example to help them through the process.

Overall, a combination of HIGH likelihood and LOW consequences equals a LOW overall risk.

Slide 24



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

Slide 24



In plenary, ask students:

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.

Laboratory Biosafety Risk Assessment

Expected Responses

What is the likelihood of exposure?

- Factors: The type of virus, concentration of virus, volumes of aerosolized virus, stability of the virus, researcher fatigue, using needles
- Rationale: The risk for exposure is increased because the researcher is inoculating many mice fatigue may be a big factor for a needle stick exposure. In addition, some mice will be inoculated with high concentration virus. Note: the BSL4 level lab will not protect against needle sticks.
- Answer: Likelihood is HIGH

What are the consequences of exposure?

- Factors: there is no vaccination for Ebola, no treatment, ~90% fatality rate.
- Rationale: The consequences are dire and must be weighed against the outcome of the research.
- Answer: Consequences are HIGH

New Responses from Students:

Laboratory Biosafety Risk Assessment



Background Information for Instructor

Risk in this case is the risk of exposure to Ebola virus.

Similar to the previous example, guide the students through the thinking process by first having them identify the factors relating to likelihood of exposure first and then assigning the level of risk based on a rationale. Repeat this process for identifying the factors contributing to the consequences of an exposure, and assigning the level of risk.

Have the students think about what the overall risk of exposure would be. If necessary, reference back to the Tiger example to help them through the process.

Overall, a combination of HIGH likelihood and HIGH consequences equals a HIGH overall risk.

Slide 25



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.

Slide 25





Laboratory Biosafety Risk Assessment



Background Information for Instructor

In plenary ask the following questions:

What might be some challenges to conducting biosafety risk assessments for every procedure conducted with every agent in a facility?

What might be other limitations of this approach to conducting risk assessments?

(For example, will you always be able to gather all the relevant information?)

The hope here is for students to think about why a risk assessment is difficult. They may say several things, like this approach might take a long time, a lot of work, and it may be difficult to gather all the information that is needed and be on top of every small change in procedure.

Despite the challenges, it is important for students to recognize the advantages of thinking about risk, and assessing risk, in a systematic way, and is as complete a manner as possible.



Laboratory Biosafety Risk Assessment

Slide 26



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



Background Information for Instructor

The following slides discuss the BioRAM risk assessment tool. The objective is not to pitch the BioRAM to the students, but instead to let them know that there are resources available to assist with laboratory biosafety risk assessments, and what the advantages of a standardized risk assessment methodology (RAM) are.

Laboratory Biosafety Risk Assessment

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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/>

Slide 27



Background Information for Instructor

It is important to emphasize that BioRAM is only one of several potential methodologies that could be used to assess risk. The “methodology” forms the basis for the questions asked in the tool as well as how the answers to those questions are combined to form risk assessment results displayed in terms of likelihood and consequences.

BioRAM uses a scoring matrix to help assign values to particular procedures in relation to the agent, to model the risk on the Likelihood Consequences graph. It also allows for comparison between mitigated and un-mitigated activities to show how risk is affected.

Keep in mind that the information entered into BioRAM is entered by a person and might be associated with some error. In general, BioRAM helps determine *relative* risk levels in a comparable and repeatable way.

Laboratory Biosafety Risk Assessment

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BioRAM

Question:

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

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Background Information for Instructor

This question is a follow up to the BioRAM slides, attempting to get students to think why having a methodology that allows for comparable and repeatable risk assessments is desirable.

Comparable and repeatable risk assessments are useful because they provide a basis for determining improvements in risk mitigation.



Ask: Any questions on Laboratory Biosafety Risk Assessment?



Take a Break (10 minutes)



Time Check

You should be approximately __ hour and __ minutes into the course.
You have __ hours of the course remaining.



Laboratory Biosafety Risk Assessment



Transition to Risk Evaluation

Risk Evaluation

Slide 29



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



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

Slide 30



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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Background Information for Instructor

Risk evaluation is the process of analyzing the risk data to determine the risk acceptability. People, institutions and communities play a very important role in risk evaluation, because their concerns will factor into the overall risk rating.



Risk Evaluation

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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.

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Background Information for Instructor

The objective of this slide is to get students to think about what acceptability is in the real world, and to focus on the potential differences between individuals, institutions, and communities.



Small group activity (10 minutes).



Activity Instructions (to students)

1. You have 5 minutes, in your groups; to consider: What factors might drive differences in risk acceptability between individuals, institutions, and communities?
2. Be prepared to discuss share your ideas with the rest of the class.

Risk Evaluation



You have 15 minutes to complete this activity

Directions for Instructor:

- After 5 minutes, ask the students to stop working on the activity.
- Lead a 5-minute plenary discussion. Begin by asking for one group to discuss individual factors. Move on to other groups to report out answers for institutions and communities.
- Be sure to highlight any similarities, differences or unique answers.

Risk Evaluation

Expected Responses

- Professional goals
- Financial goals
- Educational goals
- Notoriety
- Personal health

Individual

- Same as above
- Note: Institutions have a lot to loose if an agent is released from the laboratory or someone gets sick from working with a pathogen.
- Legal issues
- Rules/Regulations Compliance

Institution

- Health and well being of the community
- Educational/professional opportunities

Community

New Responses from Students:

Risk Evaluation

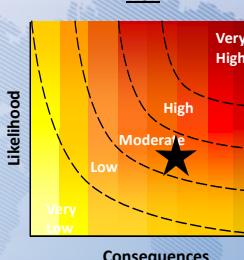
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Risk Evaluation

Overall, two **institutions** with the **same computed risk “values”** for the risk characterization process may have **different risk evaluations (meanings of risk)**. 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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Background Information for Instructor

The key message for this slide is that the factors that the students identified in the previous exercise will contribute to the overall risk assessment value because they will affect the risk evaluation process. The evaluation process is based on the risk characterization data, but overall, where the risk lies on the graph will be somewhat arbitrary.

The line distinctions on the graph that indicate the risk categories (called isoquants). An isoquant is a line representing the same level of a certain thing, in this case risk, across the line. Thus, if you are located on any point on the line, your overall risk is the same. The actual shape and location of the lines is arbitrary, and is determined by the individual, the institution, and/or the community – whoever has risk preferences.

Risk Evaluation

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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”.

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Three small decorative icons in the bottom right corner: a red square with a white 'X', a blue circle with a white 'CBER', and a green circle with a white 'CBER'.



Ask: Any questions on Risk Evaluation?

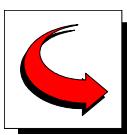


Take a Break (10 minutes)



Time Check

You should be approximately hour and minutes into the course.
You have hours of the course remaining.



Transition to Review

Review & Wrap-Up



Goal

The purpose and goal of this section is to recap the key messages of the course and to conduct a “What? So What? Now What?” review of the course and key messages.



Time

Allow 20 minutes to get through the Review section.

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Review

Review Question:

What is **risk**?

Slide 34

CBEP

University of Texas at Austin



Background Information for Instructor

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.

Review & Wrap-Up

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Review

Review Question:

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

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Background Information for Instructor

Refer back to the scenario exercises above for factors that would affect likelihood and consequences of an exposure.

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Review

Review Question:

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

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Review & Wrap-Up



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.

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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?

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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.

Review & Wrap-Up

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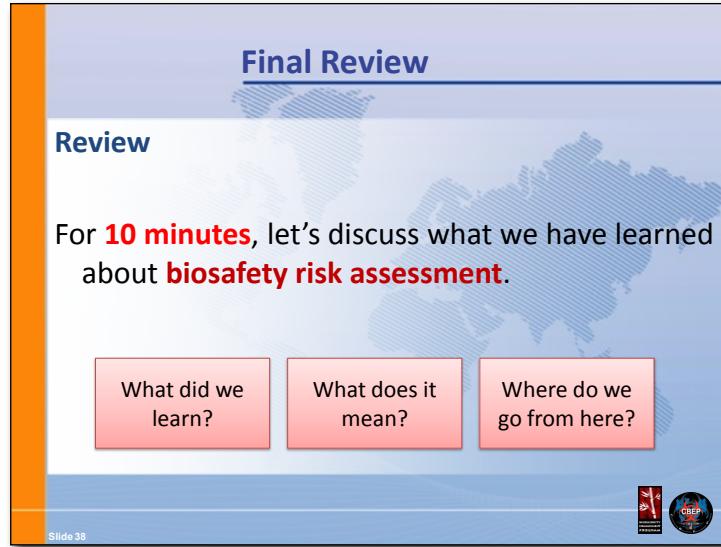
Final Review

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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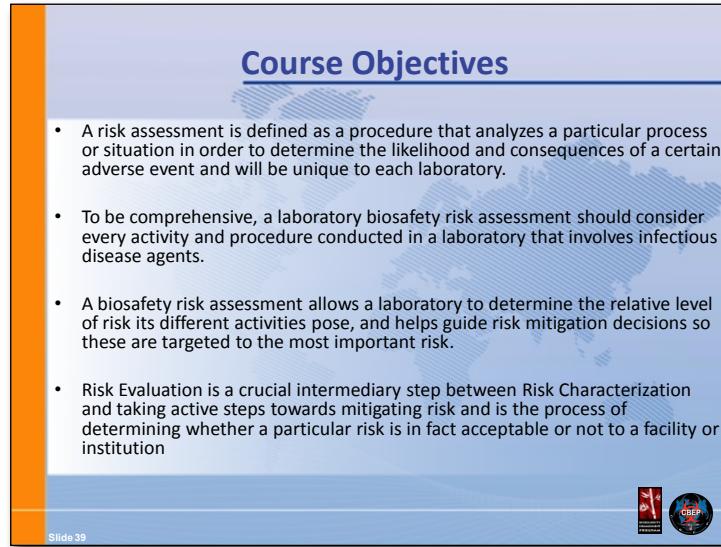
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Course Objectives

- 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

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Review & Wrap-Up



Review Key Messages

Include discussion on how activities/examples relate to the Key Messages of the course and how the messages can be applied.

- 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

Review & Wrap-Up

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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?

Use space on back, if needed

CBEP

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

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Review & Wrap-Up



Level 1 Evaluation

- Ask students to complete the course evaluation and to put it in the evaluation box (alternately, give students instructions for completing the evaluation on-line).
