



GBRMC

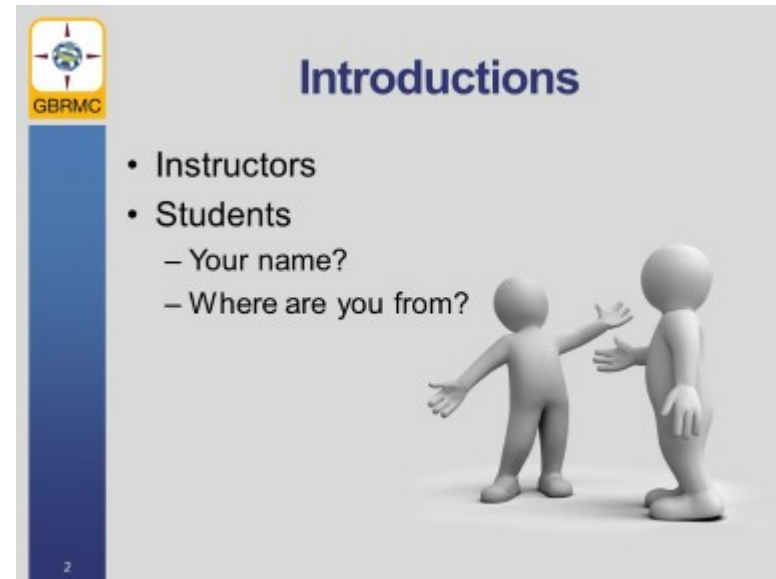
Biosafety Risk Assessment

Student Guide

2012



GLOBAL BIORISK MANAGEMENT CURRICULUM



Action Plan

By the end of this lesson, I would like to:

KNOW		FEEL		BE ABLE TO DO	
<i>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.</i>					
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?



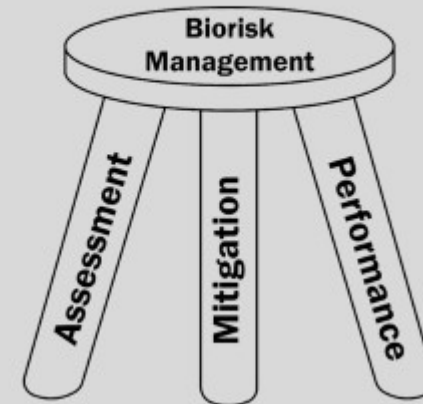
Key Messages

- A risk assessment is defined as a procedure that analyzes a particular process or situation in order to determine the likelihood and consequences of a certain adverse event and will be unique to each laboratory.
- To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.
- A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk.
- Risk Evaluation is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk and is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution

4



Biorisk Management: the AMP Model



5



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



6



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



7



Key Components of Biorisk Management

- **Biorisk Performance**
 - Improving biorisk management by recording, measuring, and evaluating organizational actions and outcomes to reduce biorisk.



8



Introduction to Biosafety Risk Assessment

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



9



Introduction to Biosafety Risk Assessment

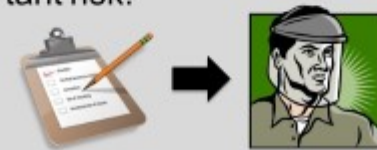
To be comprehensive:

A **biosafety risk assessment** should consider **every activity and procedure** conducted in a laboratory that involves **infectious disease agents**.

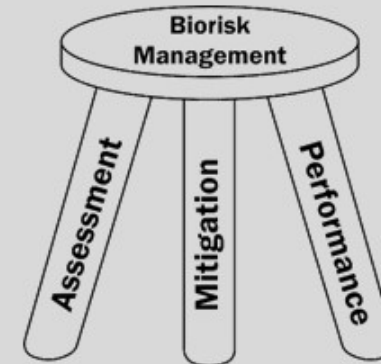
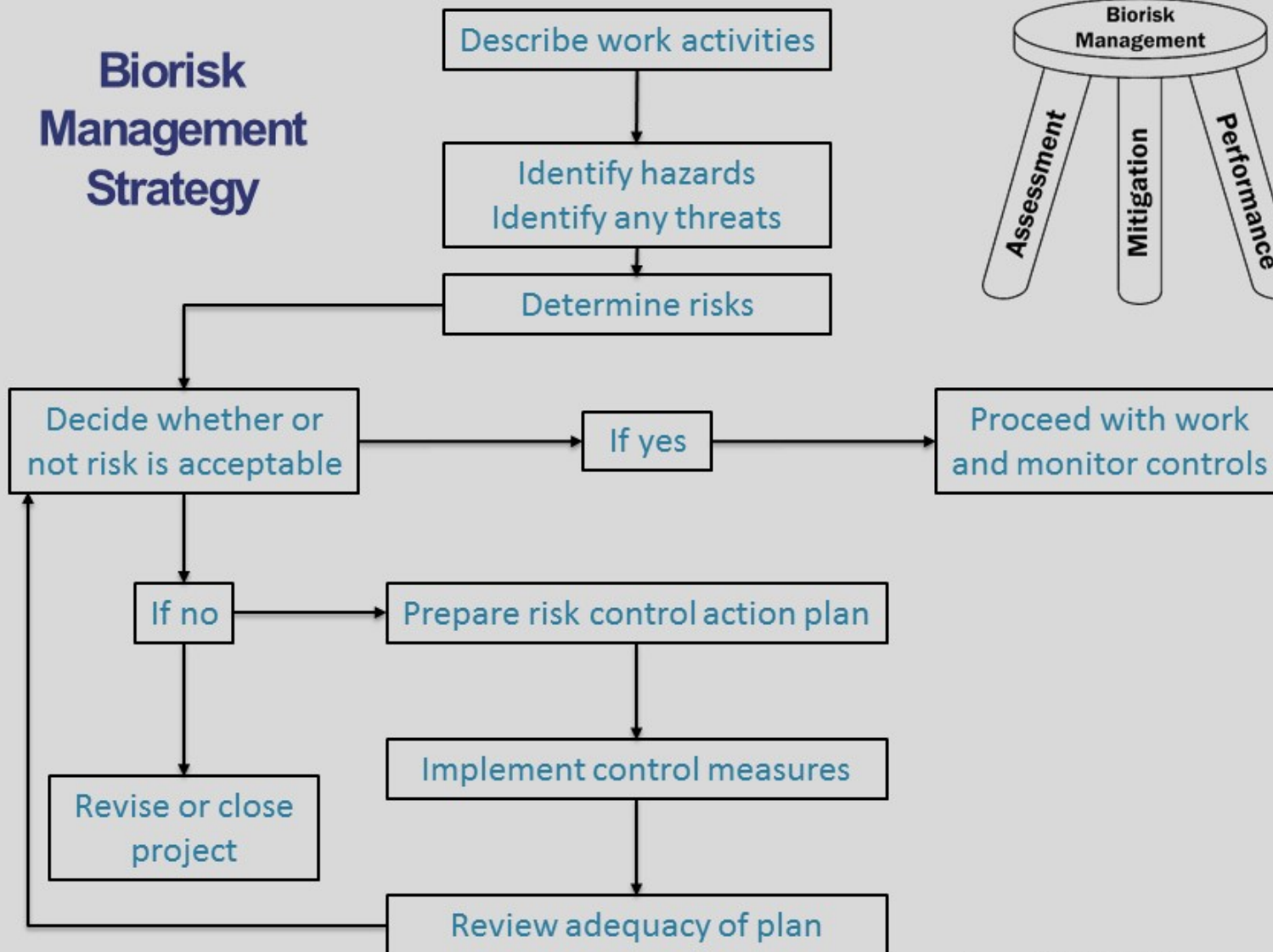


Introduction to Biosafety Risk Assessment

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.



Biorisk Management Strategy





Risk

Group Exercise:

Question:


What is “**risk**”?

In your groups, please spend **5 minutes** to develop a **definition** for “**risk**”. Choose someone from your group to share the definition with the class.

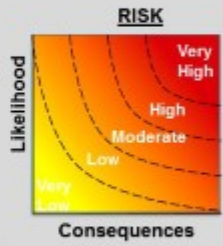
What did your group come up with?

13

What is Risk?

 **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



RISK

Likelihood

Very Low, Low, Moderate, High, Very High

Consequences

14

How can Risk be expressed?

What is risk a function of ?



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.

15

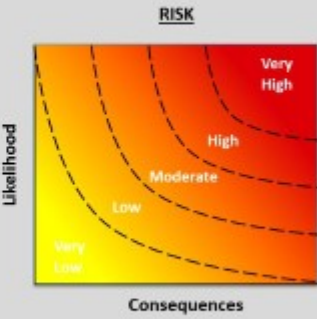
What is some information you would need to know the risk of being attacked by a tiger?



Risk

Let's consider the previous question in terms of **Likelihood** and **Consequences**, and the graph on the right.

R = f(L, C)



The graph is a 2D plot with 'Likelihood' on the vertical axis and 'Consequences' on the horizontal axis. The plot is divided into five regions by dashed lines, representing different risk levels. The regions are labeled from bottom-left to top-right: 'Very Low' (yellow), 'Low' (light orange), 'Moderate' (orange), 'High' (red-orange), and 'Very High' (red). The word 'RISK' is written at the top center of the graph area.

What is the likelihood of being attacked by a tiger?




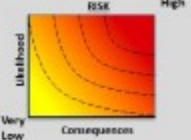
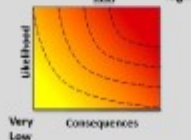
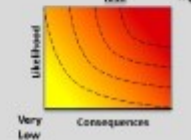
What are the consequences of being attacked by a tiger?

Biosafety Risk Assessment

What is Risk?

Risk

For the following scenarios, draw a STAR where the risk would fall on the graph.

<p>You are in an open field next to a very hungry, aggressive, adult tiger. The tiger is unrestrained and sees you as food.</p>  <p style="text-align: right;">Very High</p>	<p>You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.</p>  <p style="text-align: right;">Very High</p>	<p>You are holding a tiger cub with a playful temperament in your arms.</p>  <p style="text-align: right;">Very High</p>
 <p>Very Low Very High</p>	 <p>Very Low Very High</p>	 <p>Very Low Very High</p>

What is the risk for each Scenario?

Scenario #1

Rationale:

Risk:

Scenario #2


Rationale:

Risk:


Scenario #3

Rationale:

Risk:

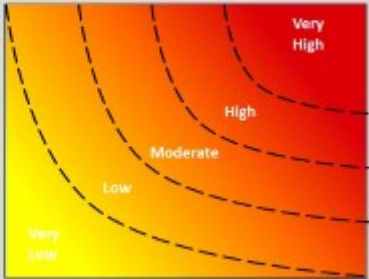
 GBRMC

You are at the zoo observing a mellow, tiger cub located behind a strong glass window.



Risk

RISK



Likelihood

Consequences

Very Low

Low

Moderate

High

Very High

18

What is the risk of being attacked in this scenario?

Biosafety Risk Assessment

Laboratory Biosafety Risk Assessment



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.

19

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

Biosafety Risk Assessment

Laboratory Biosafety Risk Assessment



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.

20

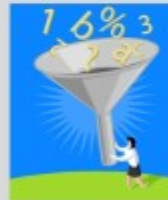
What are some factors that should be considered in a laboratory biosafety risk assessment?

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.

21




Risk Characterization

Exercise:

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

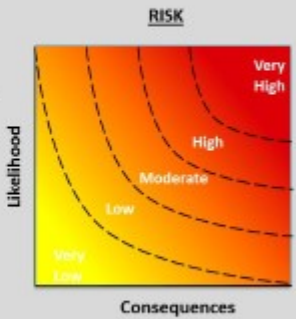


22

 **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?



RISK

Very High
High
Moderate
Low
Very Low

Likelihood

Very Low
Low
Moderate
High
Very High

Consequences


23

What is the likelihood of exposure?

Rationale:

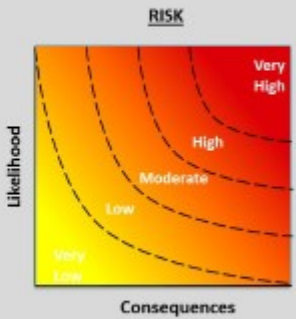
What are the consequences of exposure?

Rationale:

 **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?



The diagram is a risk matrix with 'Likelihood' on the vertical axis and 'Consequences' on the horizontal axis. The matrix is divided into five risk levels by dashed lines: 'Very Low' (bottom-left, yellow), 'Low' (bottom-middle, light orange), 'Moderate' (middle, orange), 'High' (top-middle, dark orange), and 'Very High' (top-right, red).

What is the likelihood of exposure?

Rationale:

What are the consequences of exposure?

Rationale:



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.

25

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**.

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/>

27

Biosafety Risk Assessment

Laboratory Biosafety Risk Assessment



BioRAM

Question:

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

28

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.

Risk Evaluation is the process of determining, subjectively, whether a risk is **high** or **low**, and whether it's **acceptable** or not.



29



Risk Evaluation

What is **“acceptable”** risk?



30



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**.



31



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**.



32



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.

33

Individual Factors:

Institution Factors:

Community Factors:



Risk Evaluation

If an **institution** finds a particular risk **unacceptable**, it will either **cease** the work resulting in that unacceptable risk, or it will **find ways to mitigate** that risk to a more acceptable level.



34

Risk Evaluation

The curves on this graph, called "**risk tolerance curves**", show different levels of risk, from **Very Low** to **Very High**.

It is important to recognize that the **precise locations** of these **risk tolerance curves** on the graph are in fact **arbitrary**. This is the essence of **Risk Evaluation**.

35

Risk Evaluation

Overall, two **institutions** with the **same computed risk "values"** for the risk characterization process may have **different risk evaluations (meanings of risk)**. For example, what is a moderate risk for one institution could be a high risk for another, depending on what each entity decides is moderate or high.

36



Risk Evaluation

An **institution** that considers a certain risk **high** might be motivated to spend a **large amount of resources** mitigating that risk.

Another **institution** that considers the **same** risk to be **moderate** might decide to spend a small **amount of resources** in mitigation instead.

37

How does risk evaluation influence risk mitigation strategies?




Review

Question:

What is **risk**?

38



Review

Question:

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

39



Review

Question:

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

40




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?

41




Final Review

For **10 minutes**, let's discuss what we have learned about **biosafety risk assessment**.

What did we learn?	What does it mean?	Where do we go from here?
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42



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43

Action Plan

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KNOW		FEEL		BE ABLE TO DO	
------	--	------	--	---------------	--

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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