



Risk Assessment

*AMERICAN BIOSAFETY ASSOCIATION PRECONFERENCE COURSE
OCTOBER 2010*

www.biosecurity.sandia.gov



Learning Objectives

- **By the end of the course, participants should be able to meet the following objectives:**
 - Understand the value of assessment
 - Define risk
 - Develop a risk model for biosafety and/or biosecurity
 - Compare the differences between technical assessments and concern assessments



- **What are the risks of working with biological material?**
 - Work in your group to:
 - **Identify some of these risks**
 - **Use these risks to develop a definition for biorisk**



- **Biorisk is the combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological toxin or agent**
 - The source may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.
 - Biorisk is the integration of biosafety and biosecurity



- **How do you identify risks?**
- **How do you manage risks?**
- **How do you know your management strategy is working?**



The Biorisk AMP Model

Biorisk Management =
Assessment **M**itigation **P**erformance



Hazard ID
Risk Assessment



Biorisk Control Measures
Risk Management



Processes
QA/QC
Objectives



Biorisk Assessment



Risk Assessment

- **Why is risk assessment so important?**



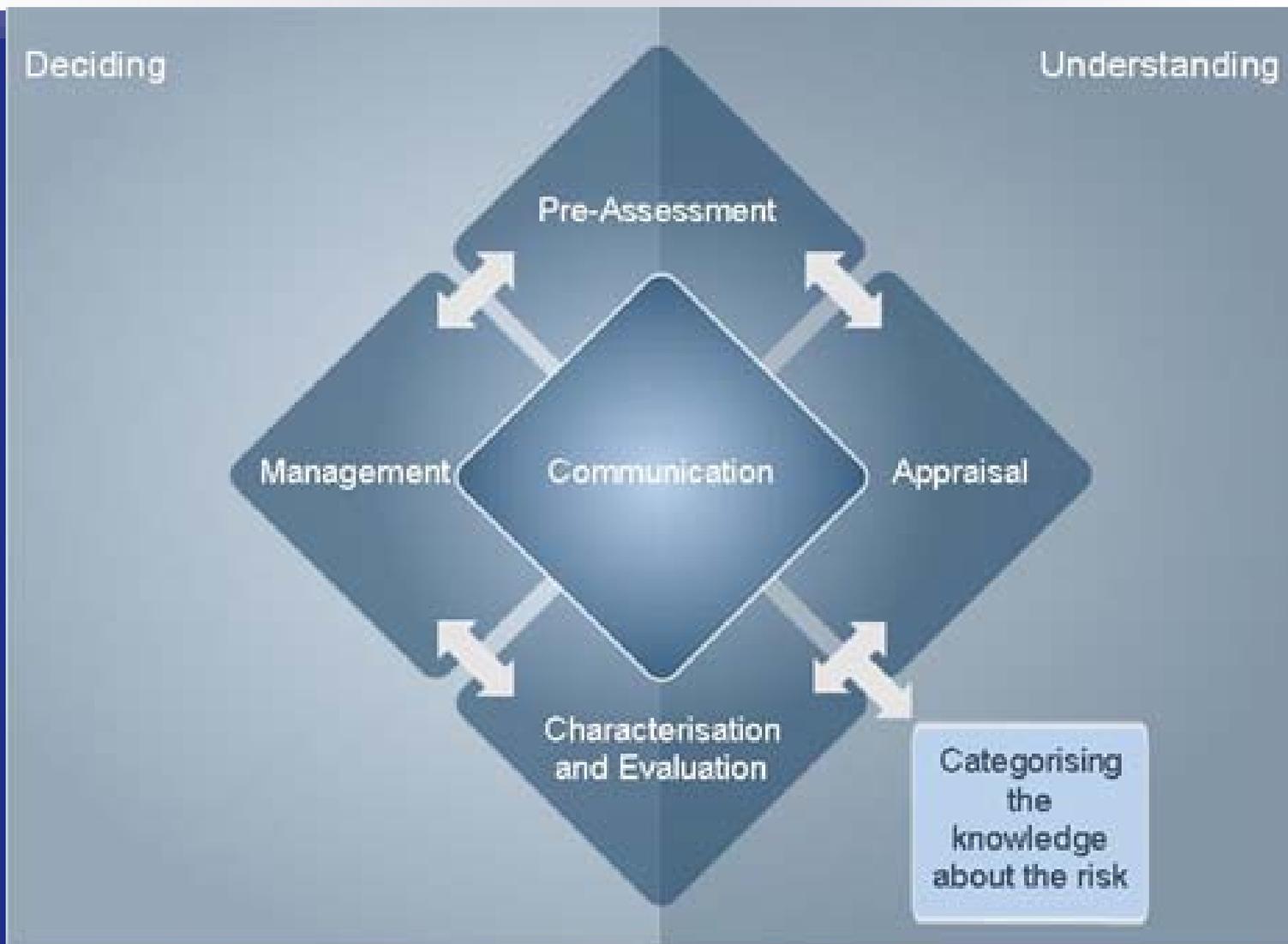
Why Risk Assessment?



- **Laboratory Biosafety**
A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent
- **Laboratory Biosecurity**
A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm
- **Identification of preventive measures is determined by the RISK ASSESSMENT**



Risk Analysis Process





- **Why do we handle the following agents differently in the laboratory?**
 - Work in your group to identify some of the generalized reasons behind the differences
 - **Ecoli K-12**
 - **HIV**
 - **MDR-TB**
 - ***Shigella***
 - ***B. Anthracis***
 - **Ebola**



- Can you place your reasons into one of these two categories?
 - **How the agents gets into a host**
 - **What that agent does to the host**
- Based on these characterizations, how would you define risk?



Risk

Is a function of Likelihood and Consequence





Risk Assessment Principles

- **Define the problem**
 - What is the question you are trying to answer with your risk assessment?
- **The risk assessment method should be as simple as possible**
 - Elaborate when needed
- **Those conducting risk assessments should be explicit about uncertainties**
- **Risk assessment methods can incorporate one or more approaches**



Laboratory Biorisk Assessment

Example:

A researcher is working to create a new animal model for HIV studies.

Using mice, he plans on injecting HIV.

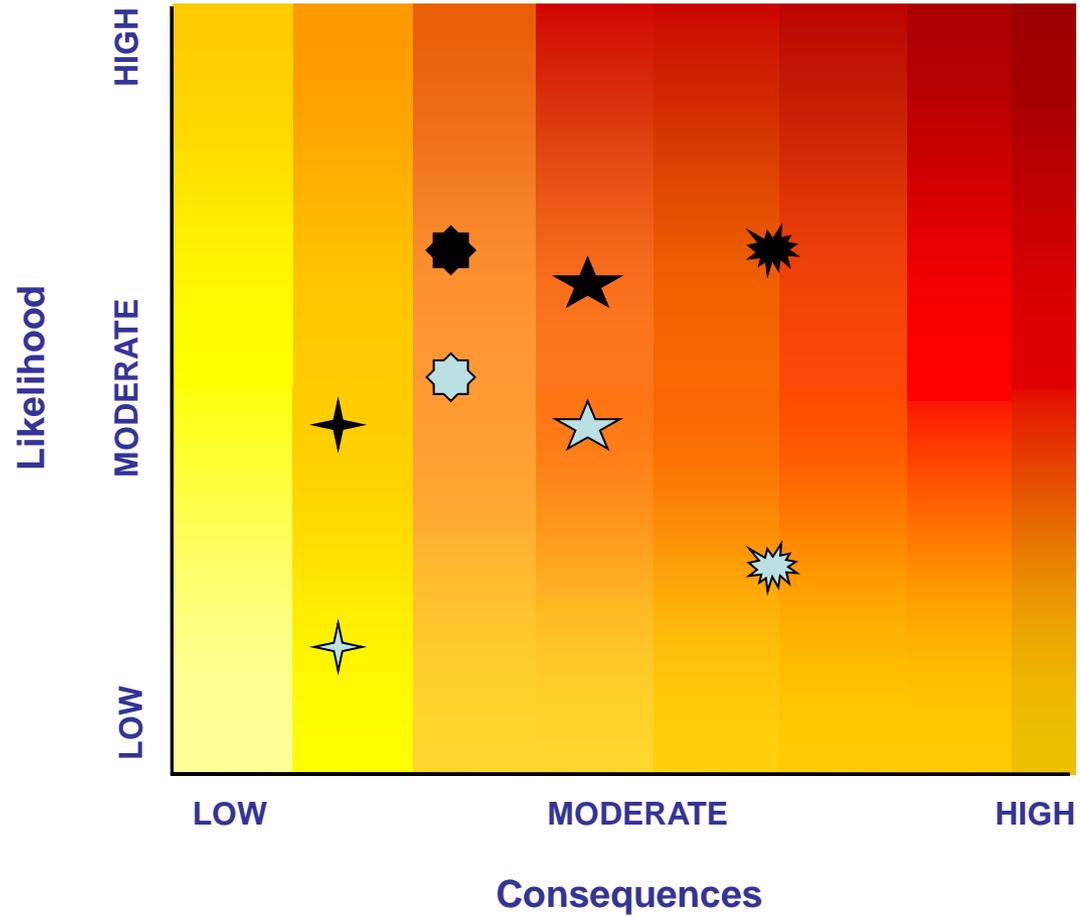
A technician will hold the animals for the researcher during inoculation.

Researcher has been acting odd and keeping notes to himself.

- **Work in your group to determine:**
 - What is/are the risk(s) you need to assess?
 - **Write down the risk(s) you are going to assess**
 - What are the key questions you need to answer to define the likelihood for one of the risks you defined?
 - What are the key questions you need to answer to define the consequences for one of the risks you defined?
 - For each question, define what would be considered okay and what would be considered bad



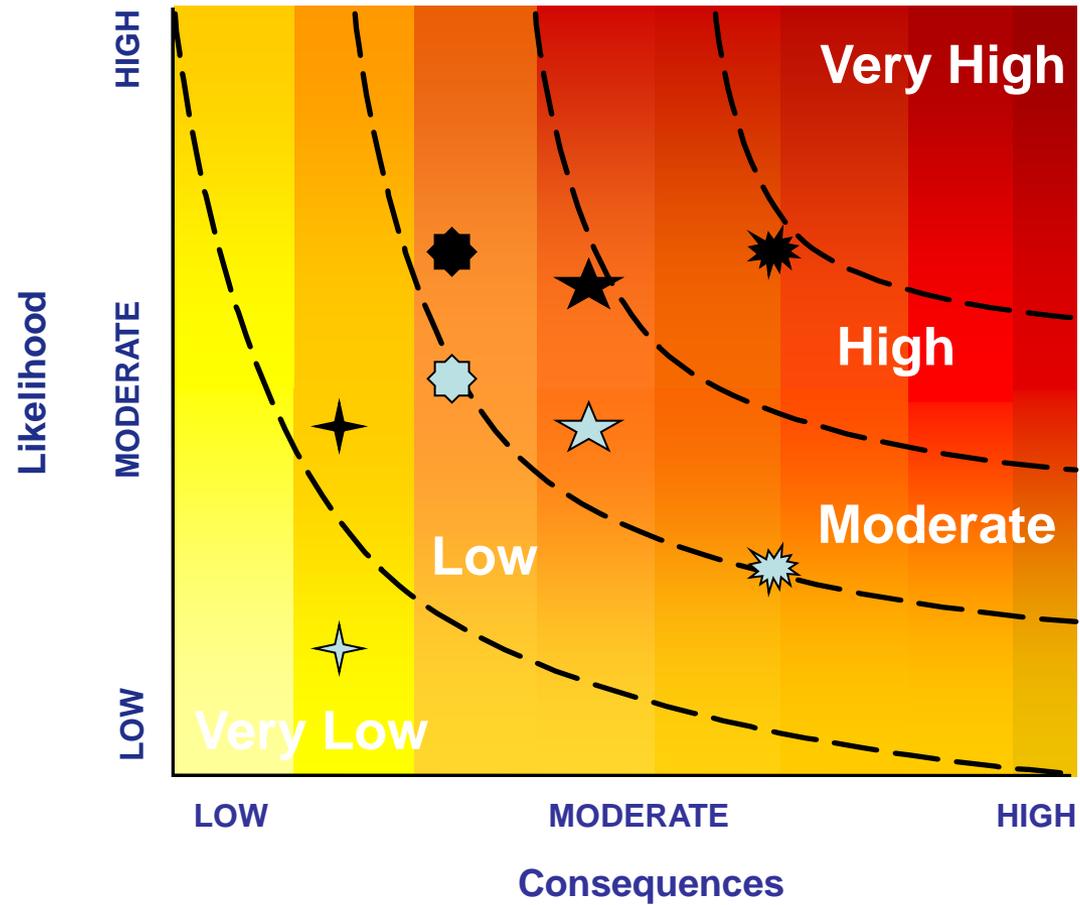
Risk Characterization





Risk Evaluation

What is acceptable, tolerable, and intolerable?





Laboratory Biosafety Risk Assessment Methodology (Biosafety RAM)

$$\text{Risk} = f(\text{Likelihood, Consequence})$$

- **Likelihood**

The likelihood of infection by the agent and the likelihood of exposure through an infectious route based on the procedures and work practices

- **Consequences**

Of disease from accidental exposure

- **Risks**

To laboratory workers

- Researchers
- Animal care workers
- Technicians
- Engineers

Risk of accidental exposure to community

Risk of accidental exposure to animal community

Risks of secondary exposure to human and animal community



- **In your group, conduct a biosafety risk assessment based upon the example(s) provided.**
 - Define the likelihood
 - **What are the routes of infection?**
 - **What are the possible routes of exposure?**
 - What are the consequences of disease and to whom?
 - Is this risk high, moderate, or low? Acceptable? Why?



Laboratory Biosecurity Risk Assessment Methodology (Biosecurity RAM)

$$\text{Risk} = f(\text{Likelihood, Consequence})$$

- **Likelihood**
 - The likelihood of theft from a facility and the likelihood an agent can be used as a weapon
- **Consequences**
 - Of a bioattack with the agent
- **Risks**
 - Persons in area of attack
 - Persons in larger community from secondary exposure
 - Animals in area of attack
 - Animal in larger community from secondary exposure



- **In your group, conduct a biosecurity risk assessment based upon the example(s) provided.**
 - Define the likelihood:
 - **What is the potential for misuse of the agent?**
 - **What are the possible areas an adversary could acquire the agent?**
 - What are the consequences of misuse and to whom?
 - Is this risk high, moderate, or low? Acceptable Why?



- **What are some of the benefits to a structured process for conducting a biorisk assessment?**



Summary

- **Biorisk assessment is the first step in biorisk management**
- **Assessing the risk by determining likelihood and consequence will allow for strategic decisions on control measures**
- **A structured approach will allow for:**
 - Relative risk comparison
 - Improved risk communication
 - Repeatability of the assessment