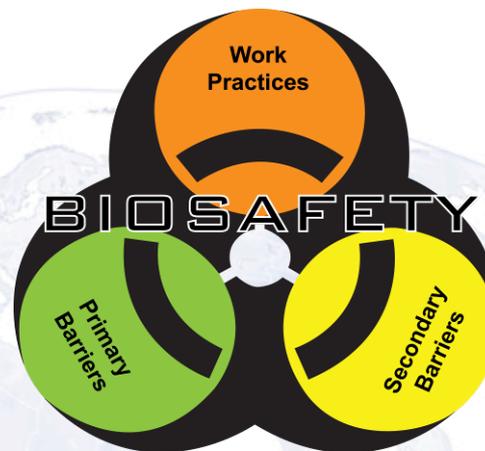
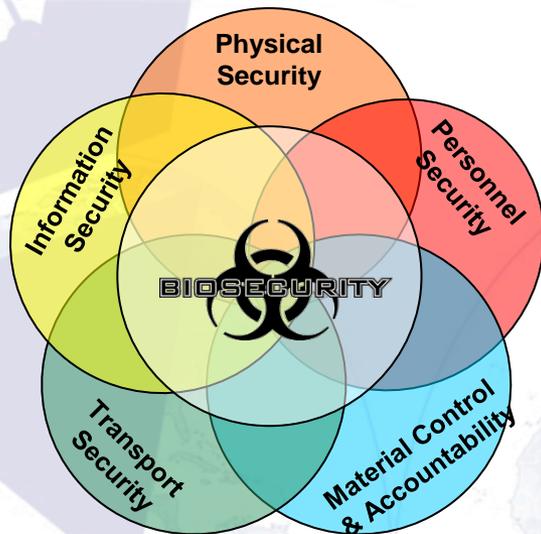




# Risk Assessment



## *Controlling Laboratory Biorisks Training Course*

**International Biological Threat Reduction Program**

**Global Security Programs**

**Sandia National Laboratories**

**Albuquerque, NM USA**



SAND No. 2008-0480P

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.





# Learning Objectives

- **By the end of the course, participants should be able to meet the following objectives:**
  - Be able to define risk.
  - Be able to explain the dependence of likelihood and consequences on the risk assessment.
  - Be able to describe the process of model development.
  - Be able to describe the advantages of a standard model.

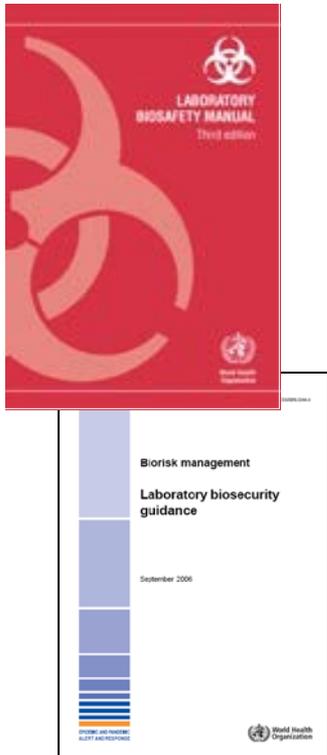


# Risk Assessment

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



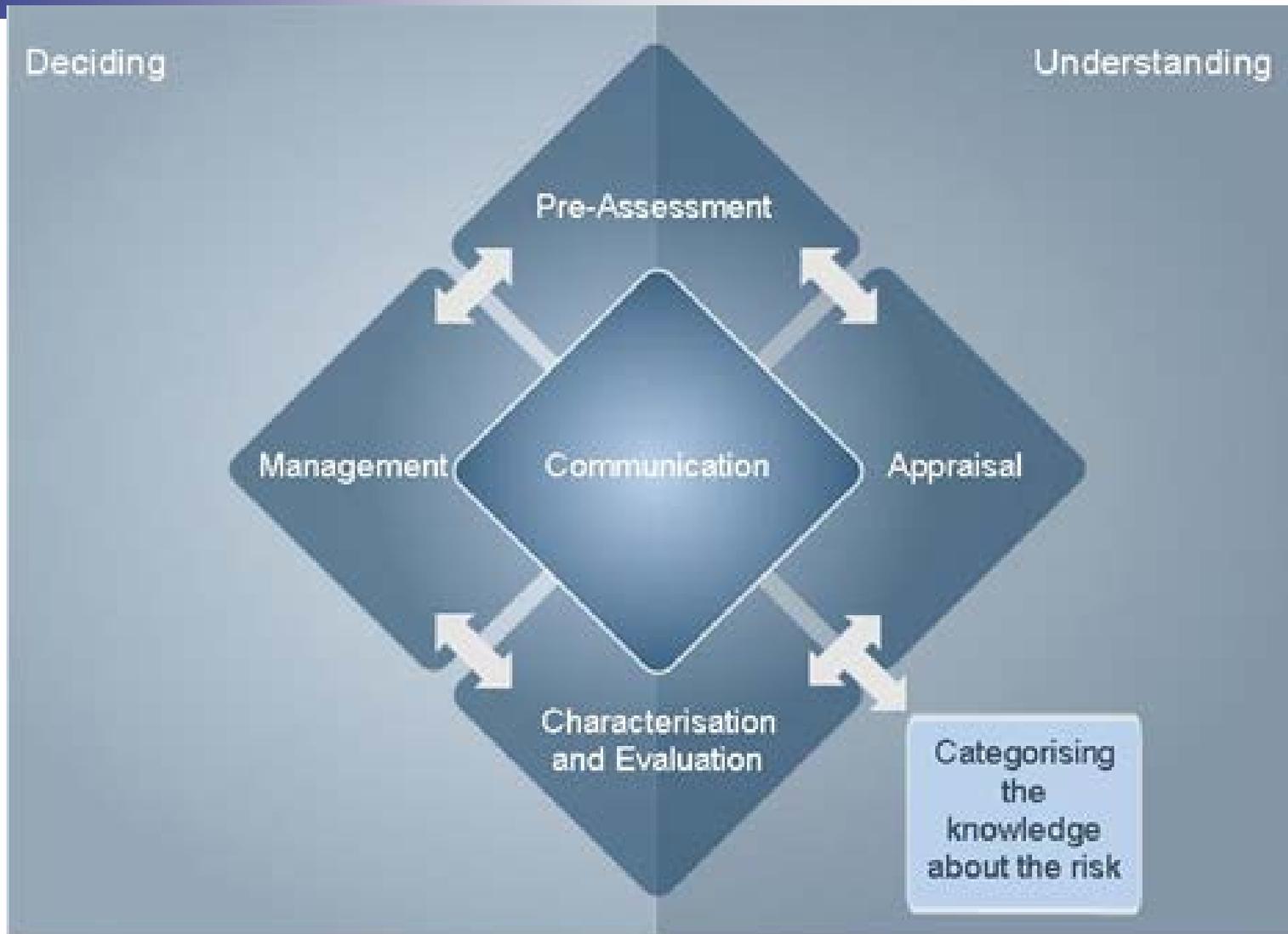
# Why Risk Assessment?



- **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 reasons
    - *E. coli* K-12
    - HIV
    - MDR-TB
    - *Shigella* sp.
    - *B. anthracis*
    - Ebolavirus



- **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.*

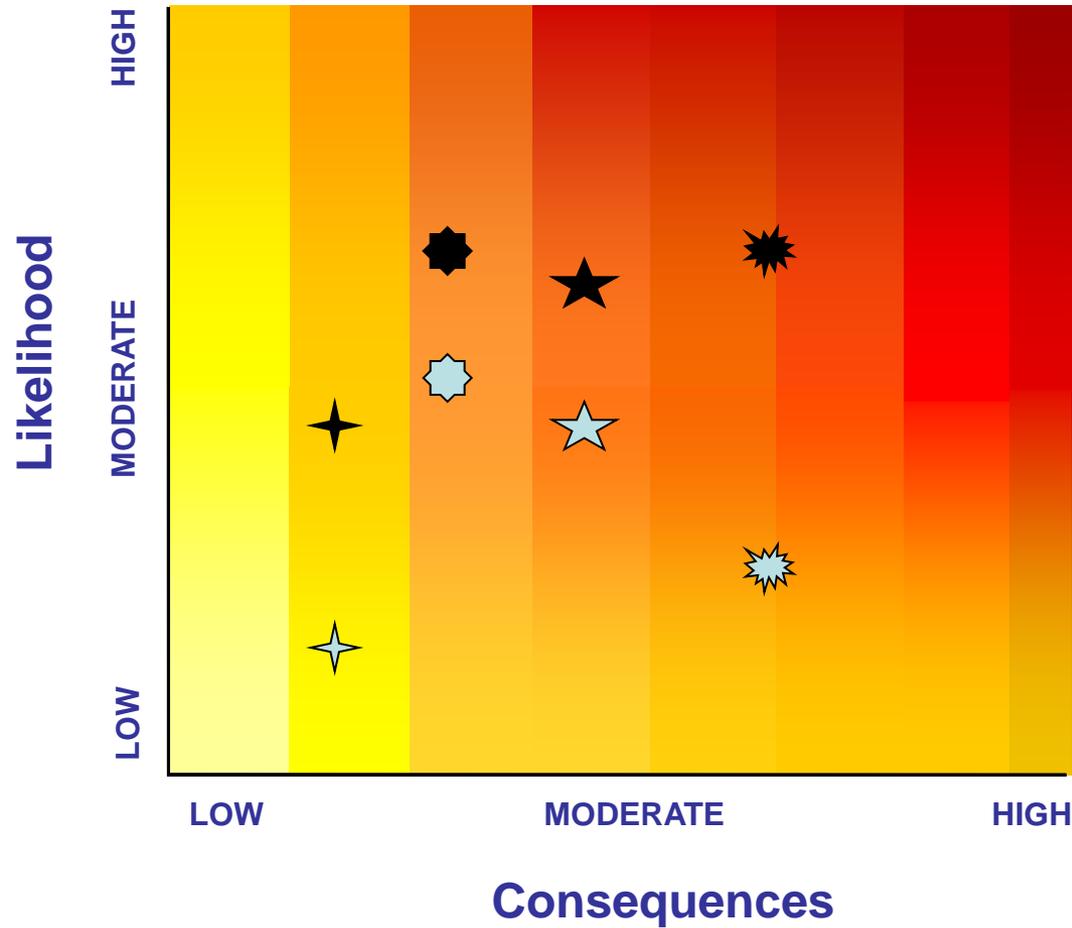
*A technician will hold the animals for the researcher during inoculation.*

*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



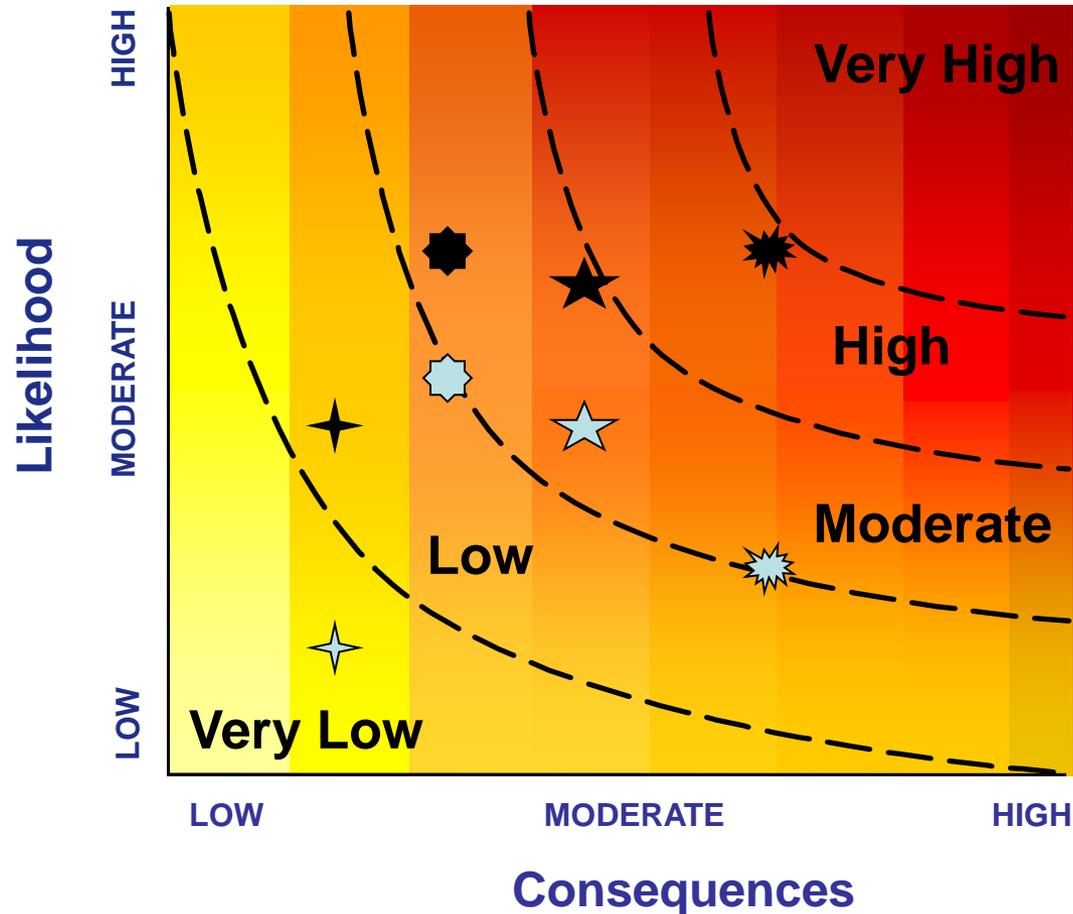
# Risk Characterization





# 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?**
  
  
  
  
  
  
  
  
  
  
- **When you think about conducting a risk assessment, what are some of the key messages you will take home and use?**



# 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