



## ***Biorisk Assessment***

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Course  
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- **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 course 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

- *CWA 15790 Laboratory Biorisk Management Standard, Feb 2008*



- **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 + Mitigation + Performance



Hazard ID  
Risk Assessment



Biorisk Control Measures  
Risk Management



Processes  
QA/QC  
Objectives



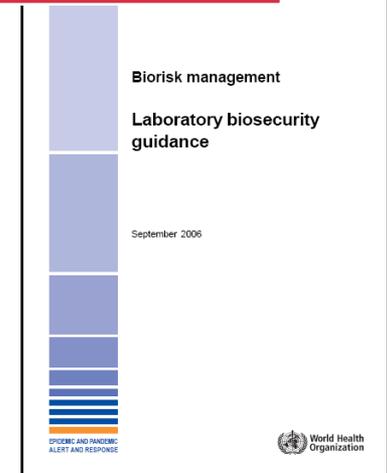
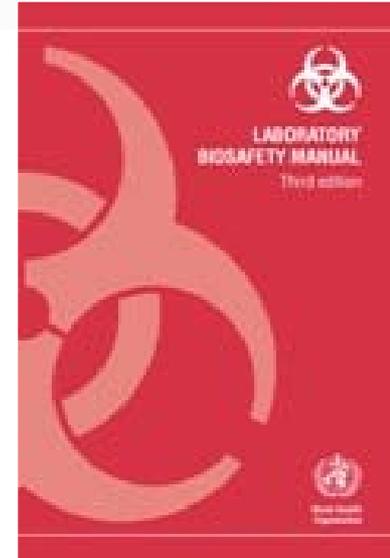
# Risk Assessment

- **Why is risk assessment so important?**
  
- **Think about this question:**
  - *Is conducting a risk assessment simple? Why or why not?*



# 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**





- **What is the risk of being attacked by a tiger?**
  - Work in your group to identify factors that would help you determine this risk.
    - Write these factors on the sticky notes. (Put one factor per sticky note)





# Characterize the factors

- **By looking at all the factors your group defined, are there any natural groupings?**
  - What are the natural groupings you see?
  - Place all your factors into natural groupings



# Characterize the factors (part II)

- **Factors that influence the potential for a tiger attack (likelihood)**

- Place all the factors you defined which influence the potential for a tiger attack under likelihood
- (place an L next to the factor on the sticky note)

- **Factors that influence the impact of a tiger attack (consequences)**

- Place all the factors you defined which influence the impact of a tiger attack under consequences
- (place a C next to the factor on the sticky note)



# Risk

- **Is a function of Likelihood and Consequence**





# Risk Assessment Principles

- **Define the problem**
  - Think about how the factors would change if you were assessing the risk of someone stealing a tiger?
- **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 (I)

- **Example 1: A laboratory researching resistance factors for *Mycobacterium tuberculosis***
- **Work in your group to determine:**
  - What is/are the risk(s) you need to assess?
  - What are the key factors needed to conduct a risk assessment?
    - Write each factor down one per sticky note
    - Characterize these factors into likelihood and/or consequence factors?
  - For each factor, identify if it is low, medium, or high for this example
    - Use another color sticky note, write either low, medium, or high and place it next to the factor
    - Mark unknowns
    - Mark any key factors



# Laboratory Biorisk Assessment (II)

- **Example 2: A clinical laboratory conducting diagnostic tests for diarrheal diseases**
- **Work in your group to determine:**
  - Using the same factors as before, identify if it is now low, medium, or high for this example
    - Use another color sticky note, write either low, medium, or high and place it next to the factor
    - Mark unknowns
    - Mark key factors
  - What is/are the biorisk(s) you need to assess for this example?
- **Do the factors you defined work to assess biorisks for this example?**



- **Is conducting a risk assessment simple? Why or why not?**
  
- **What are some of the benefits to a structured process for conducting a biorisk assessment?**



# 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



# Likelihood of infection

- **Routes of infection of the agent (and infectious dose via that route)**
  - Inhalation
  - Ingestion
  - Contact
  - Percutaneous
  - Vector-Borne
- **Infection mitigation measures (existence of prophylaxis)**



# Likelihood of exposure

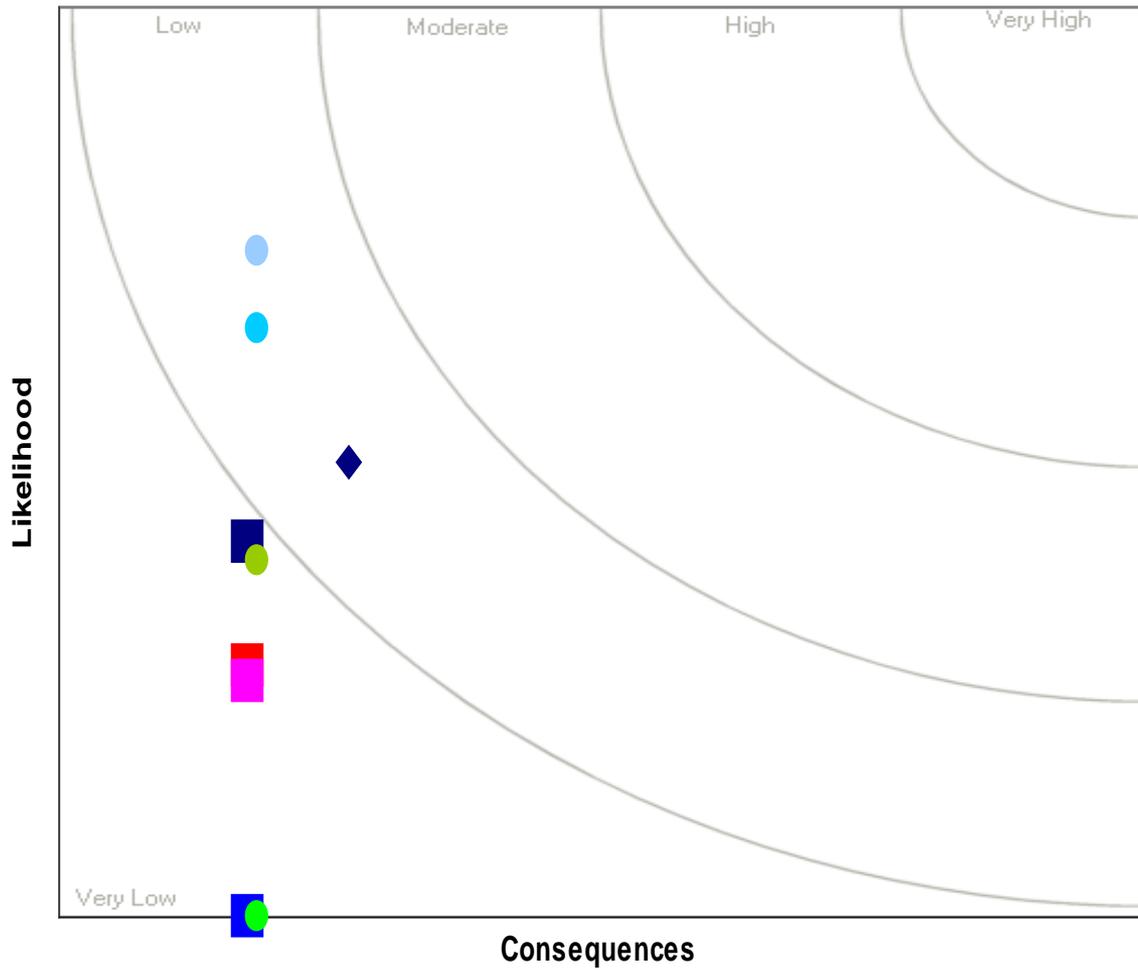
- **Potential of inhalation exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of ingestion exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of percutaneous exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of contact exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures



# Consequence of disease

- **Agent properties**
- **Morbidity**
- **Mortality**
- **Consequence mitigation measures**
- **Potential for secondary transmission**
  - Communicability (host to host)
  - Transmissibility (route of infection between hosts)

## Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community of example diagnostic laboratory reviewing potential aerosol transmitted agent



- Inhalation Risk to Ind
- Percutaneous Risk to Ind
- Contact Risk to Ind
- Ingestion Risk to Ind
- Inhalation Risk to Community
- Percutaneous Risk to Community
- Contact Risk to Community
- Ingestion Risk to Community
- ◆ Inhalation Secondary Infection Risk



# 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

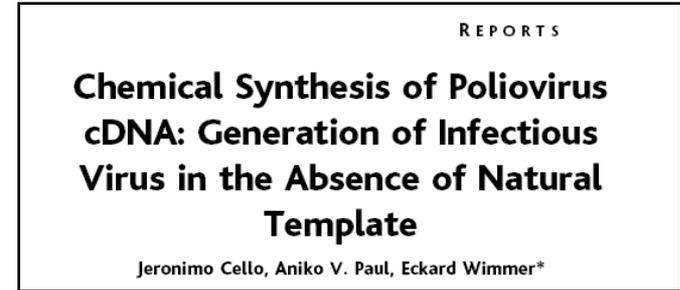
- **Risks**

- Persons in area of attack
- Persons in larger community from secondary exposure
- Animals in area of attack
- Animal in larger community from secondary exposure

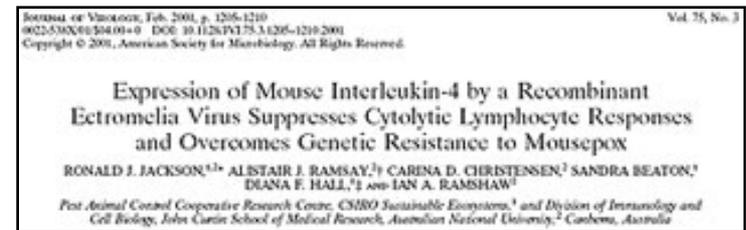


# Characterize the Biological Agents

- Agents potential as a biological weapon
  - **Biological Agent Properties**
    - Transmissibility
    - Stability
    - Awareness of agent's BW potential
  - **Production and dissemination**
- Consequences of a bioattack with agent
  - **Disease consequences**
  - **Socioeconomic consequences**
  - **Secondary exposure consequences**



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# Characterize the Adversaries



- **Adversary Classes**

- Should be defined in design basis threat
  - Terrorist
  - Extremist
  - Criminal



- **Insiders**

- Authorized access to the facility, dangerous pathogens, and/or restricted information
- Distinguish Insiders by level of authorized access
  - Site
  - Building
  - Asset

- **Outsiders**

- No authorized access

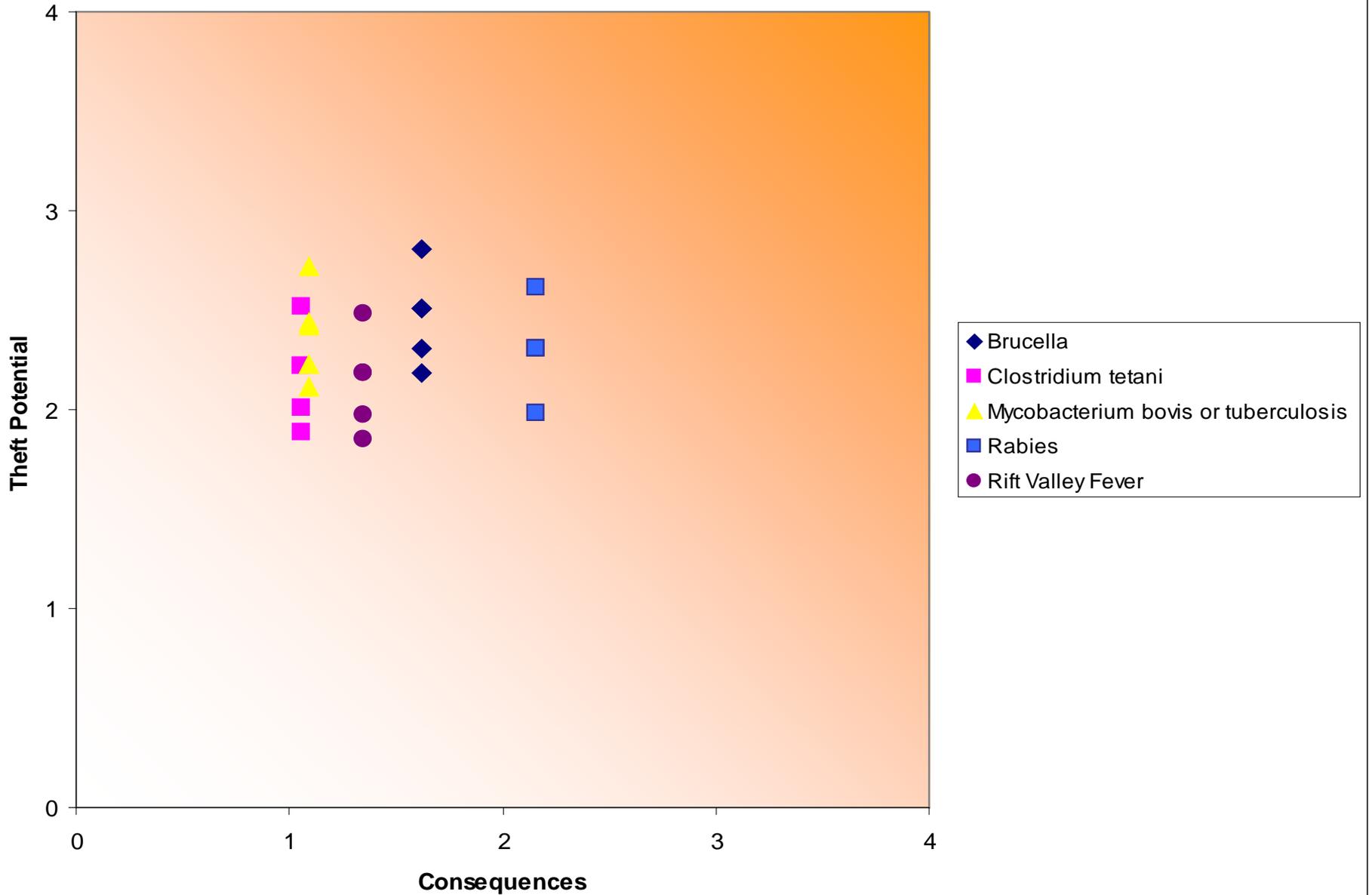




# Characterize the Facility

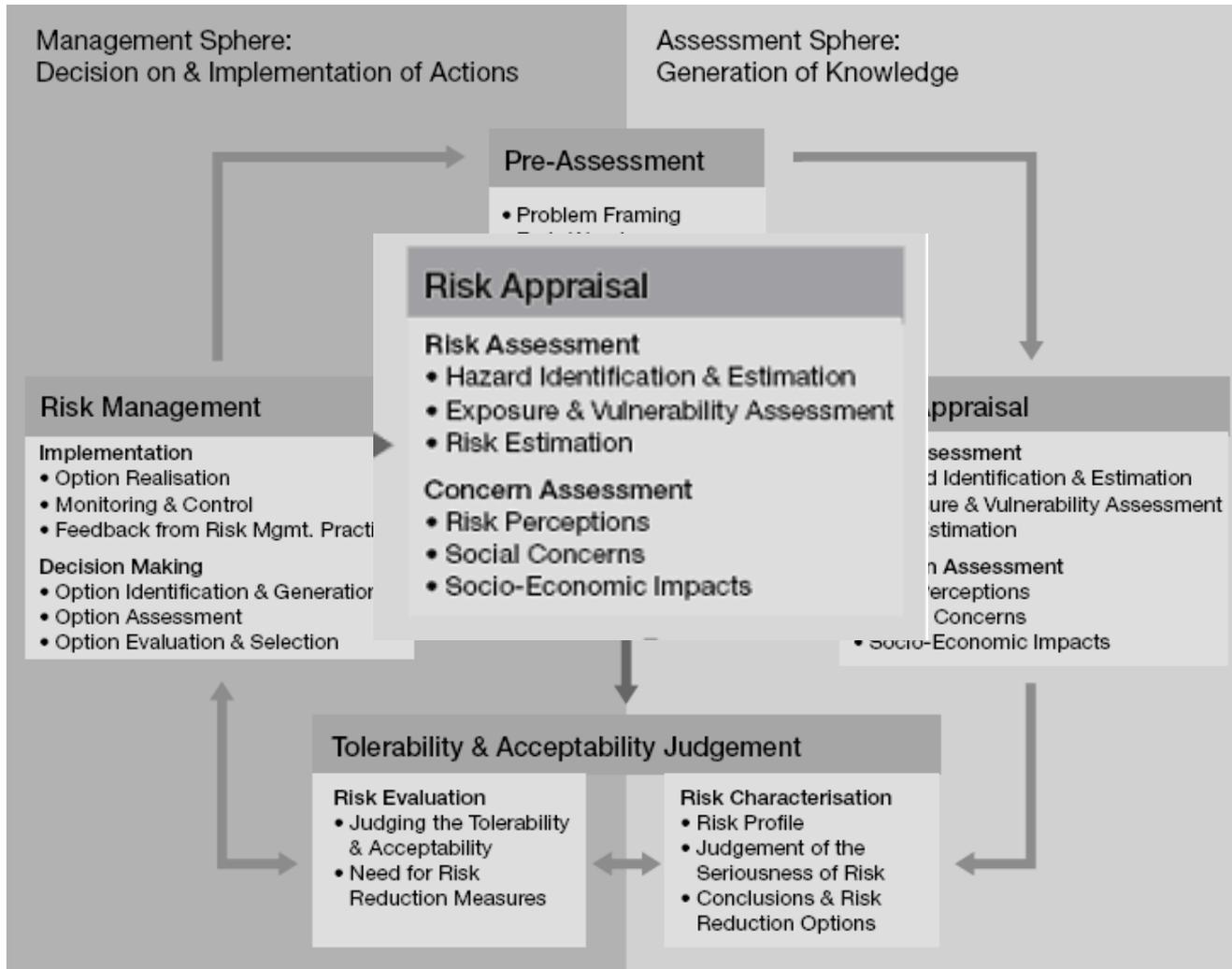
- **Identify “specific adversaries”**
  - Operational Means
  - Opportunity
- **Identify “specific assets”**
  - Uniqueness of asset at facility
  - Location of asset
  - State of asset (e.g. in long-term storage, in active research, type of research, quantity, ...)
- **Facility vulnerabilities**

# Example Human Biosecurity Risk





# Risk Governance





# Risk Assessment vs. Concern Assessment

- **Technical risk assessments are typically based on scientific data, observations, and/or expert opinion**
- **Concern assessments are based upon risks “perceived” by the general public**
  
- **Are concern assessments important in assessing biorisks? Why or why not?**
  
- **Work in your group and identify what factors you should consider for conducting a concern assessment?**



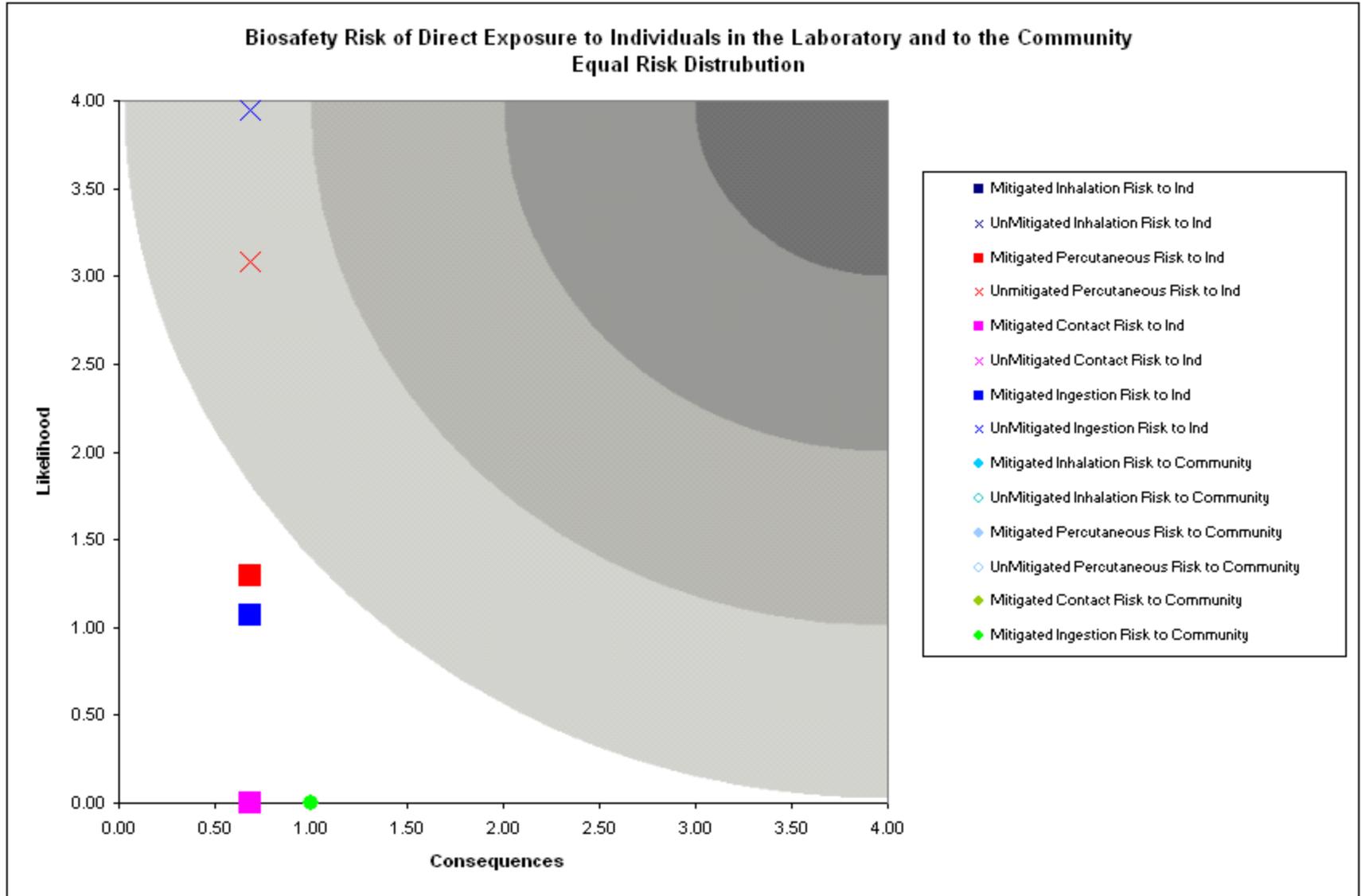
# Characterizing the factors

- **Factors that would characterize the public's dread regarding the situation**
- **Factors that characterized the public's ability to know or understand the situation**

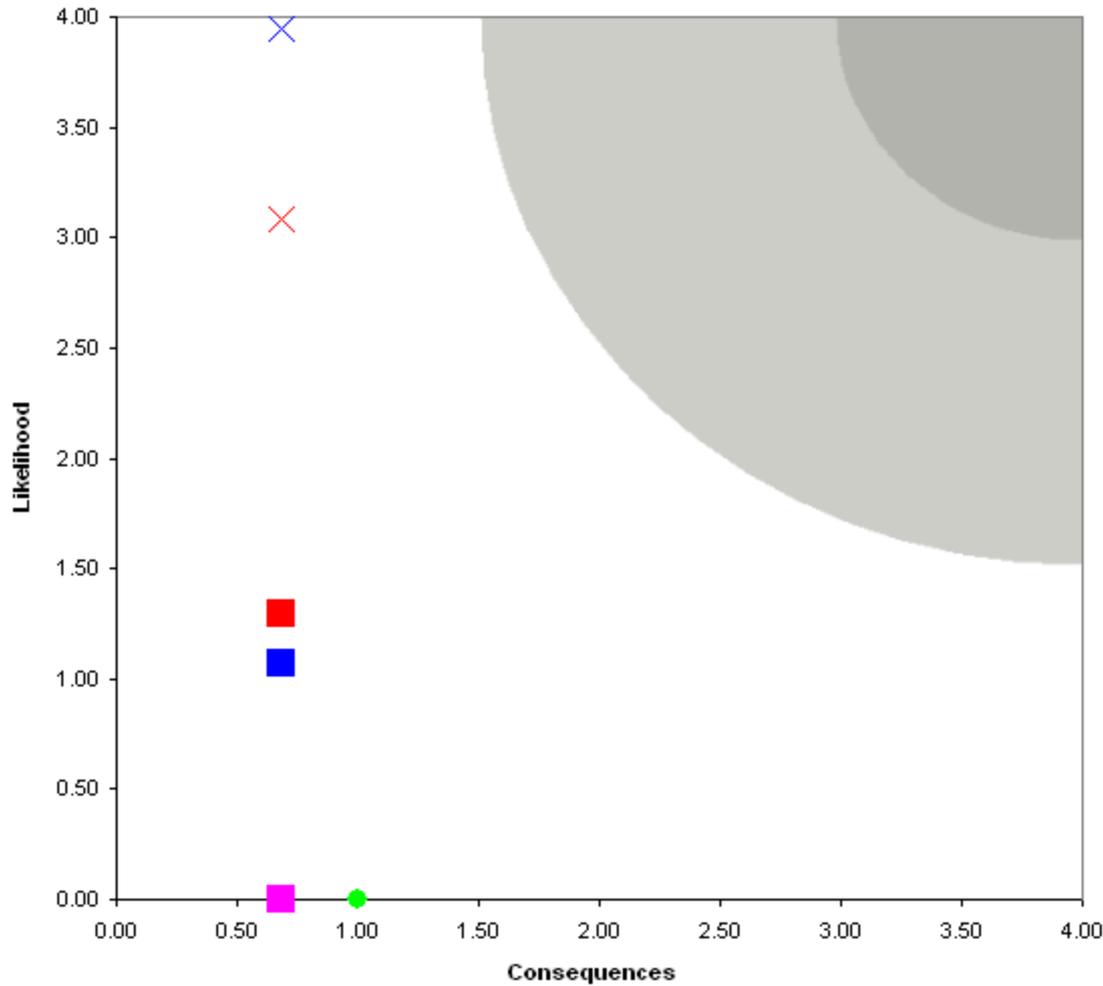


# Risk Acceptance

- **How should the concern assessment be reflected in the technical risk assessment? Which, if either, is more important?**
- **How much risk mitigation is enough?**
- **How should you balance safety risks vs. security risks?**
- **Do the assessments help to determine level of acceptance?**



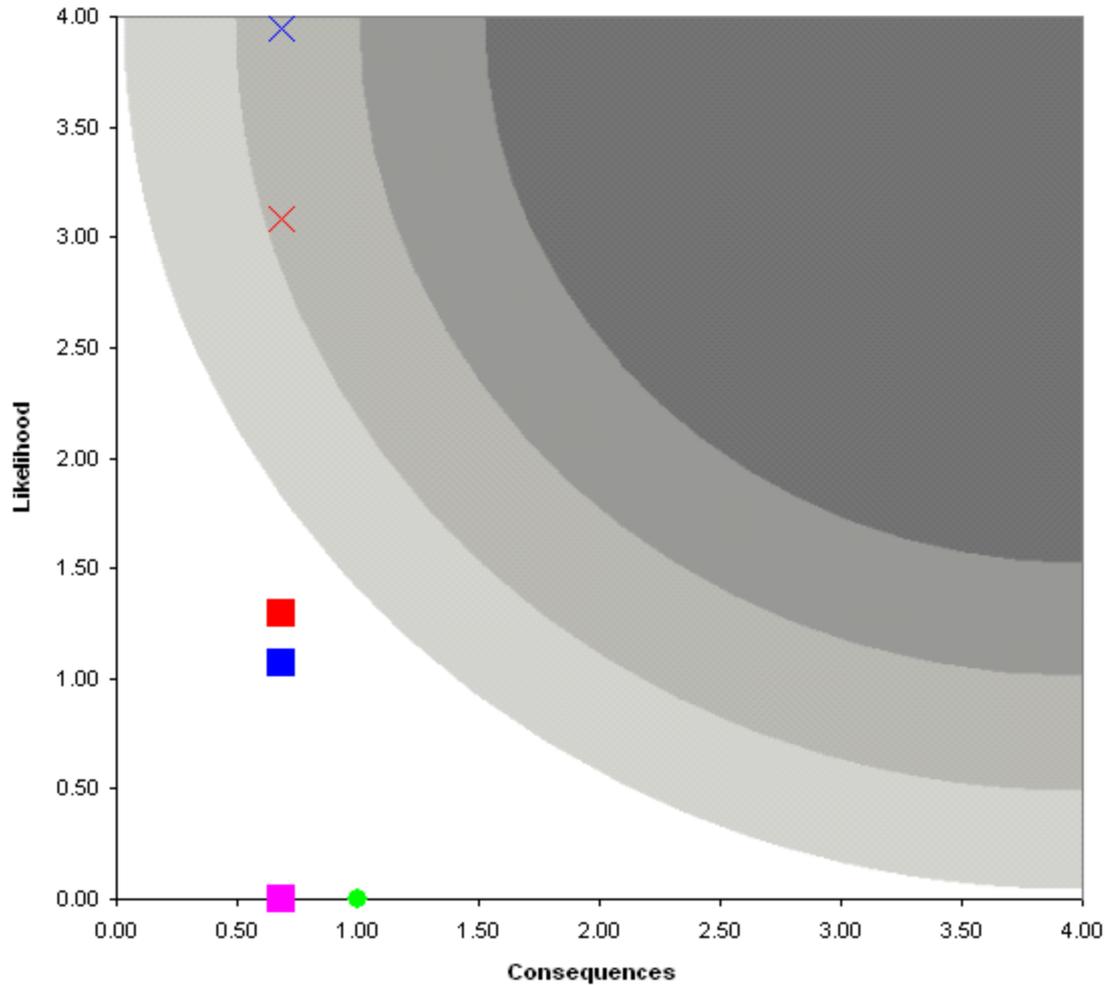
### Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community Risk Tolerant



- Mitigated Inhalation Risk to Ind
- × UnMitigated Inhalation Risk to Ind
- Mitigated Percutaneous Risk to Ind
- × Unmitigated Percutaneous Risk to Ind
- Mitigated Contact Risk to Ind
- × UnMitigated Contact Risk to Ind
- Mitigated Ingestion Risk to Ind
- × UnMitigated Ingestion Risk to Ind
- ◆ Mitigated Inhalation Risk to Community
- ◇ UnMitigated Inhalation Risk to Community
- ◆ Mitigated Percutaneous Risk to Community
- ◇ UnMitigated Percutaneous Risk to Community
- ◆ Mitigated Contact Risk to Community
- ◆ Mitigated Ingestion Risk to Community



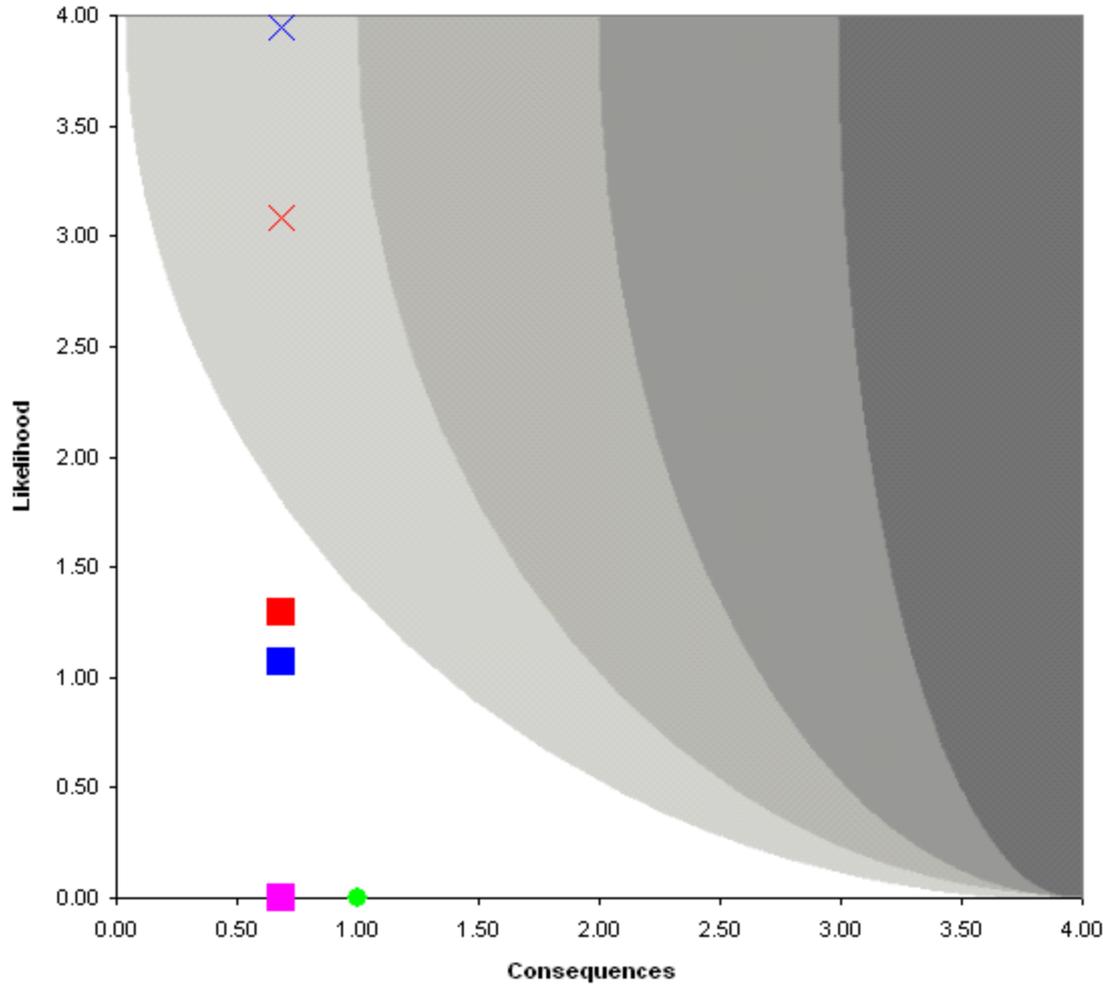
### Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community Risk Adverse



- Mitigated Inhalation Risk to Ind
- × UnMitigated Inhalation Risk to Ind
- Mitigated Percutaneous Risk to Ind
- × UnMitigated Percutaneous Risk to Ind
- Mitigated Contact Risk to Ind
- × UnMitigated Contact Risk to Ind
- Mitigated Ingestion Risk to Ind
- × UnMitigated Ingestion Risk to Ind
- ◆ Mitigated Inhalation Risk to Community
- ◇ UnMitigated Inhalation Risk to Community
- ◆ Mitigated Percutaneous Risk to Community
- ◇ UnMitigated Percutaneous Risk to Community
- ◆ Mitigated Contact Risk to Community
- ◆ Mitigated Ingestion Risk to Community



### Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community Consequence Driven





# Conclusions

- **What is AMP? And why is assessment important?**
- **What is risk?**
- **What are the benefits of a systematic, standardized risk assessment process?**
- **What is a concern assessment and why would you do one?**
- **How can your risk assessment help to communicate risk acceptance?**