



Biorisk Assessment

Biosafety Management Systems in Laboratories

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Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
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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 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

• *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?

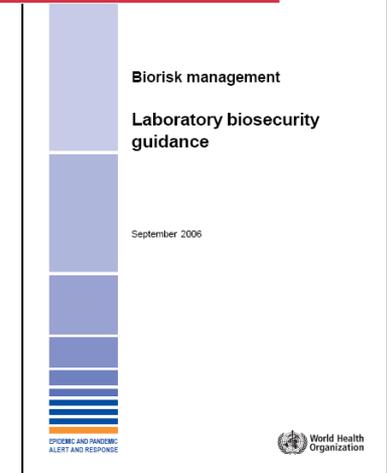
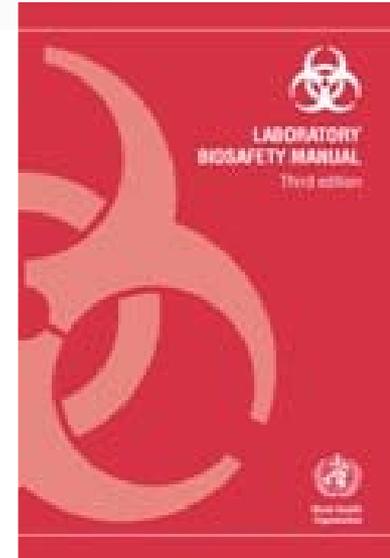
- **Laboratory Biosafety**

- 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



- **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





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?
 - **Write down the risk(s) you are going 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

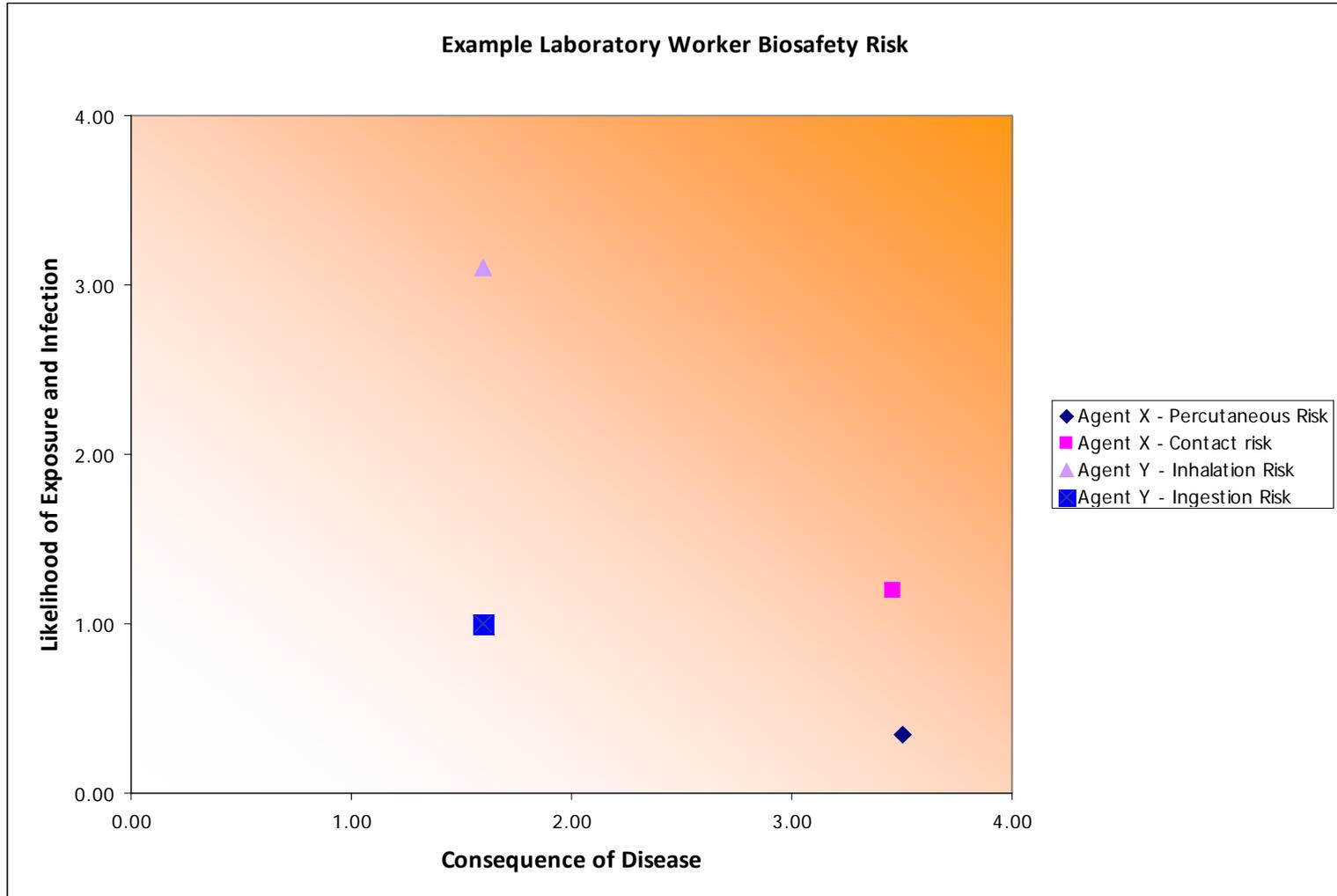


Consequence of disease

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



Example Laboratory Worker Biosafety 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**

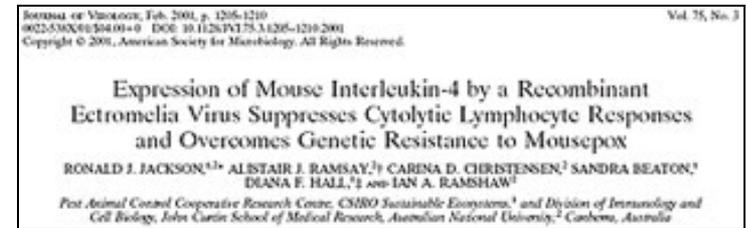
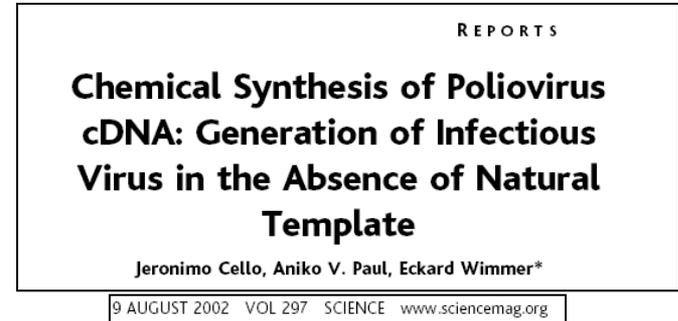
- Of a bioattack with the agent

- **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**



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

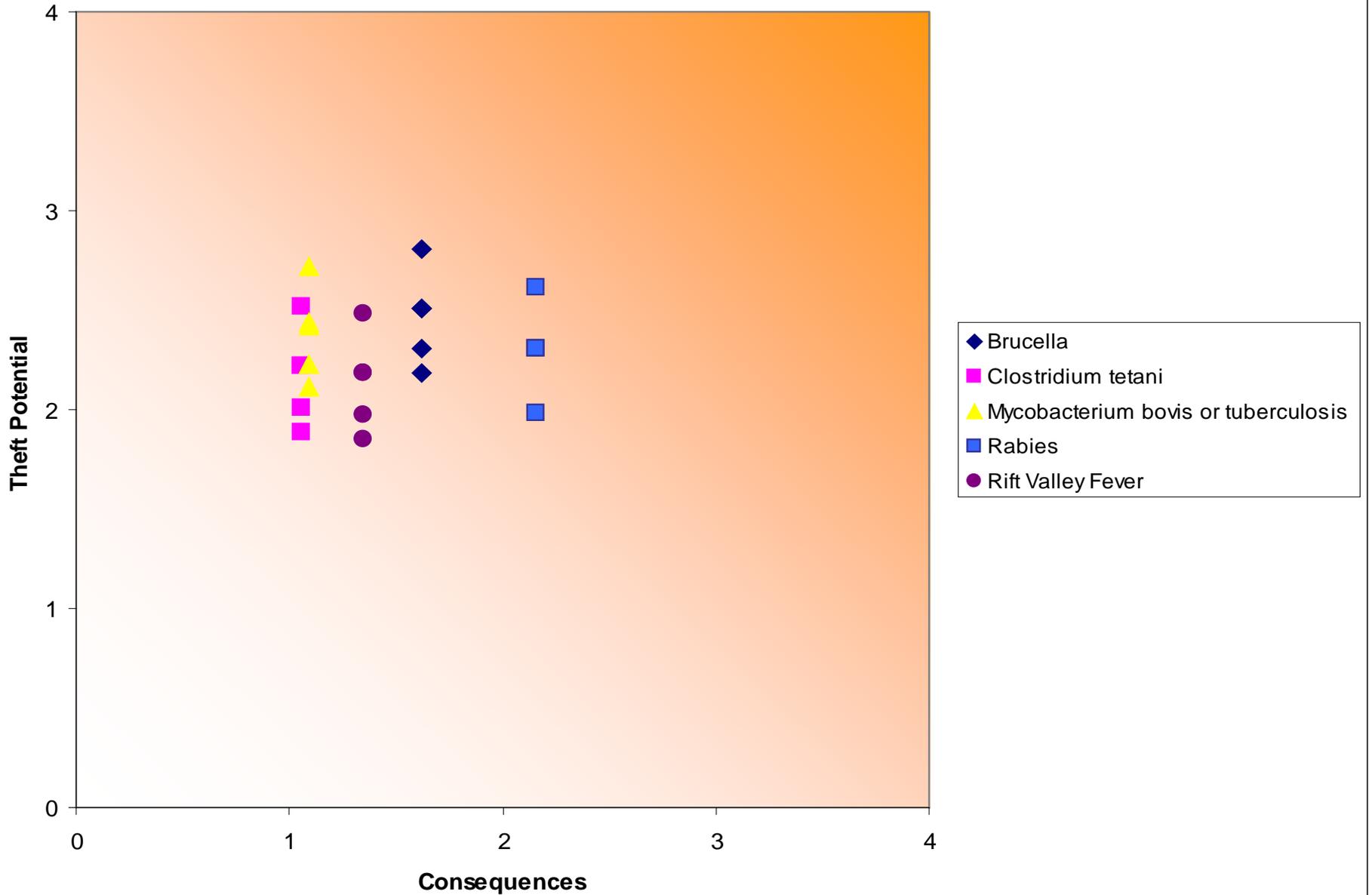




Characterize the Facility

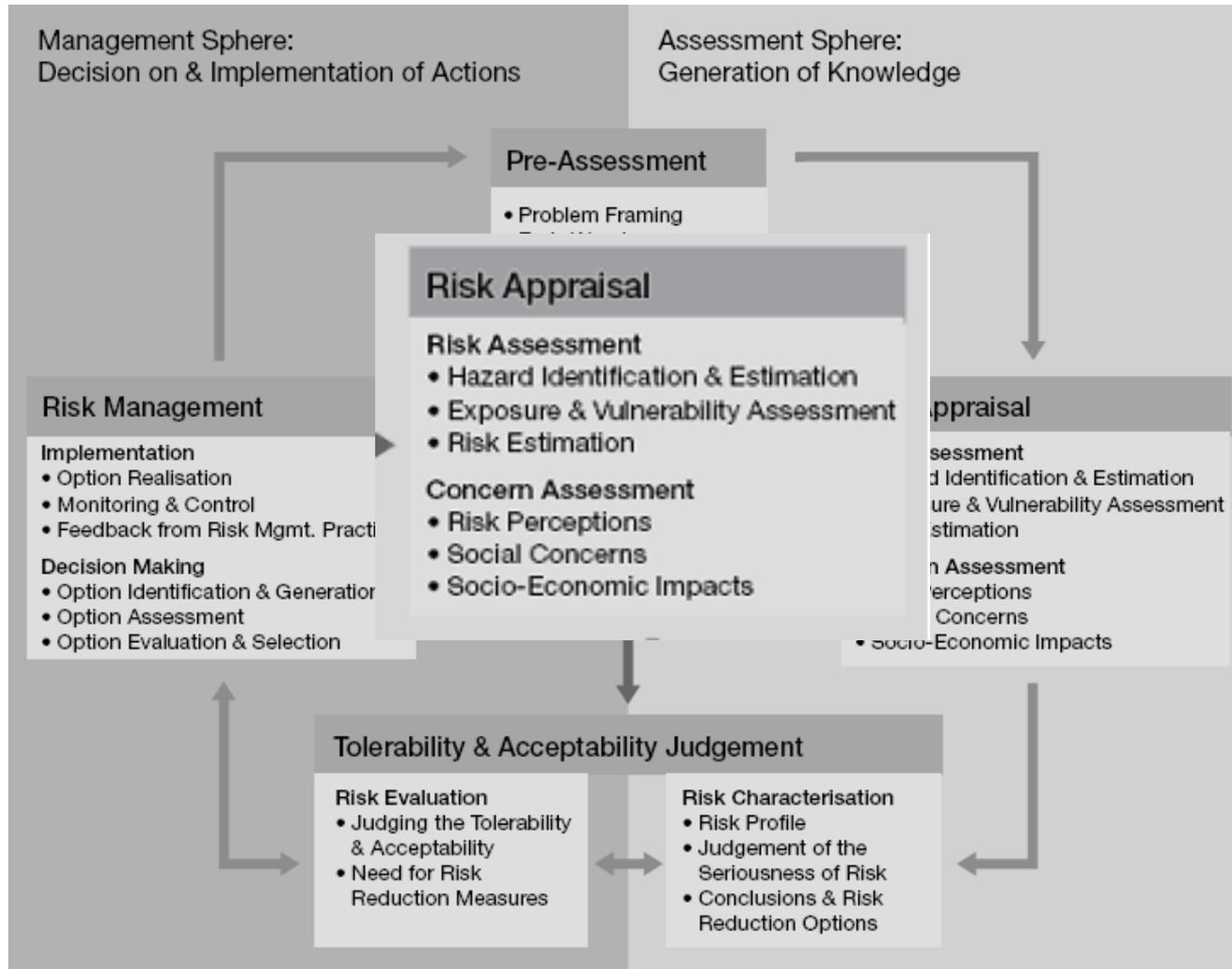
- **Identify “specific adversaries”**
 - Operational Means
 - Opportunity
- **Identify “specific assets”**
 - Uniqueness of asset at facility
 - Location of asset
 - State of asset (e.g. in long-term storage, in active research, type of research, quantity, ...)
- **Facility vulnerabilities**
 - Physical,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

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?**

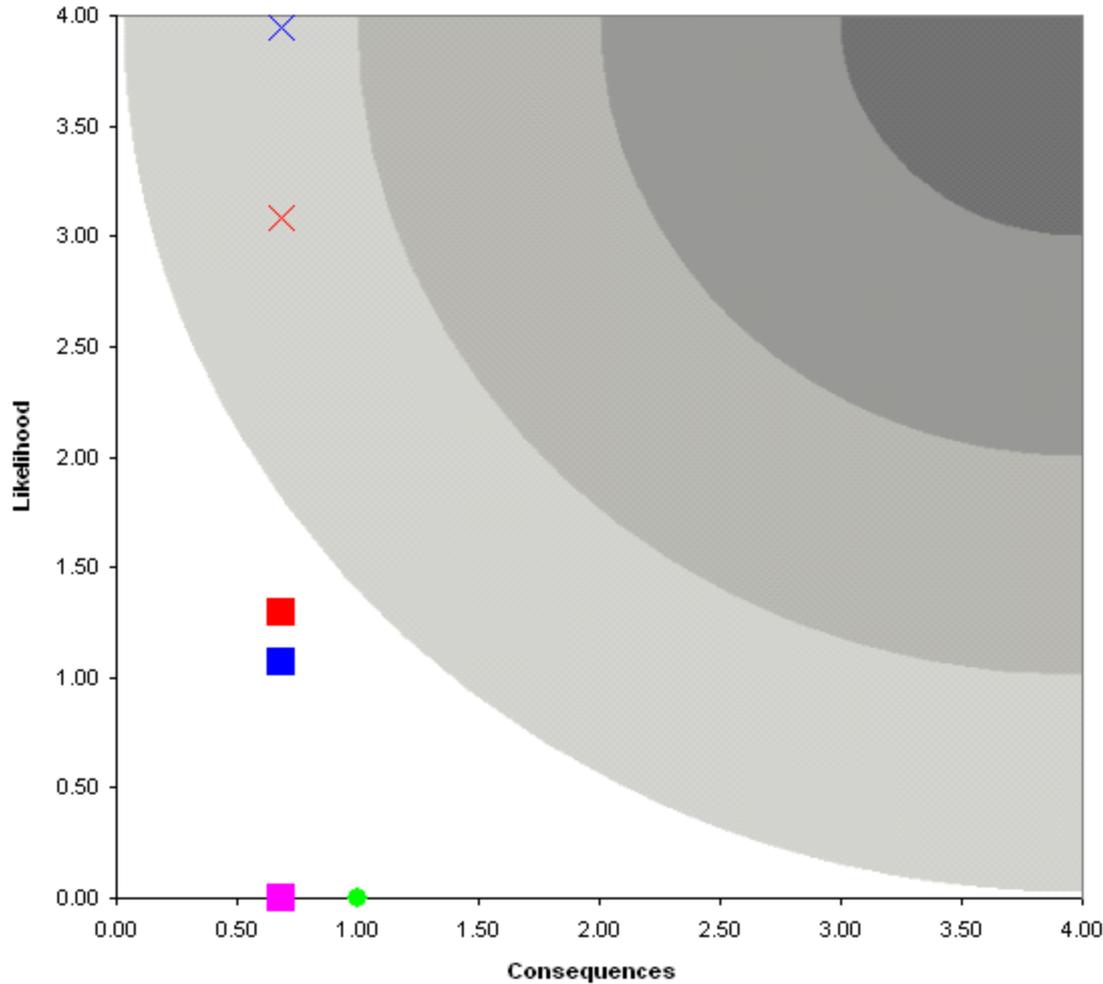


Risk Acceptance

- **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?**

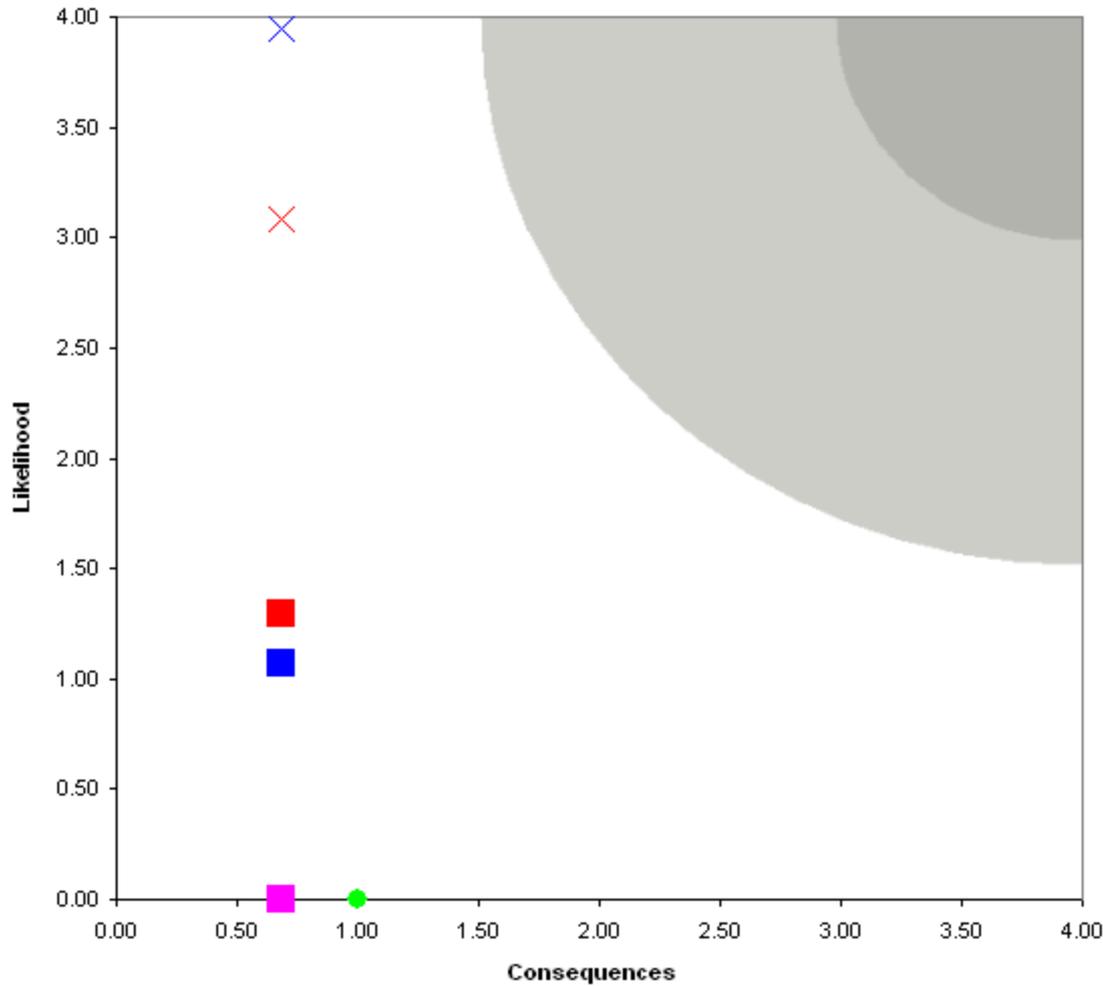


Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community Equal Risk Distribution

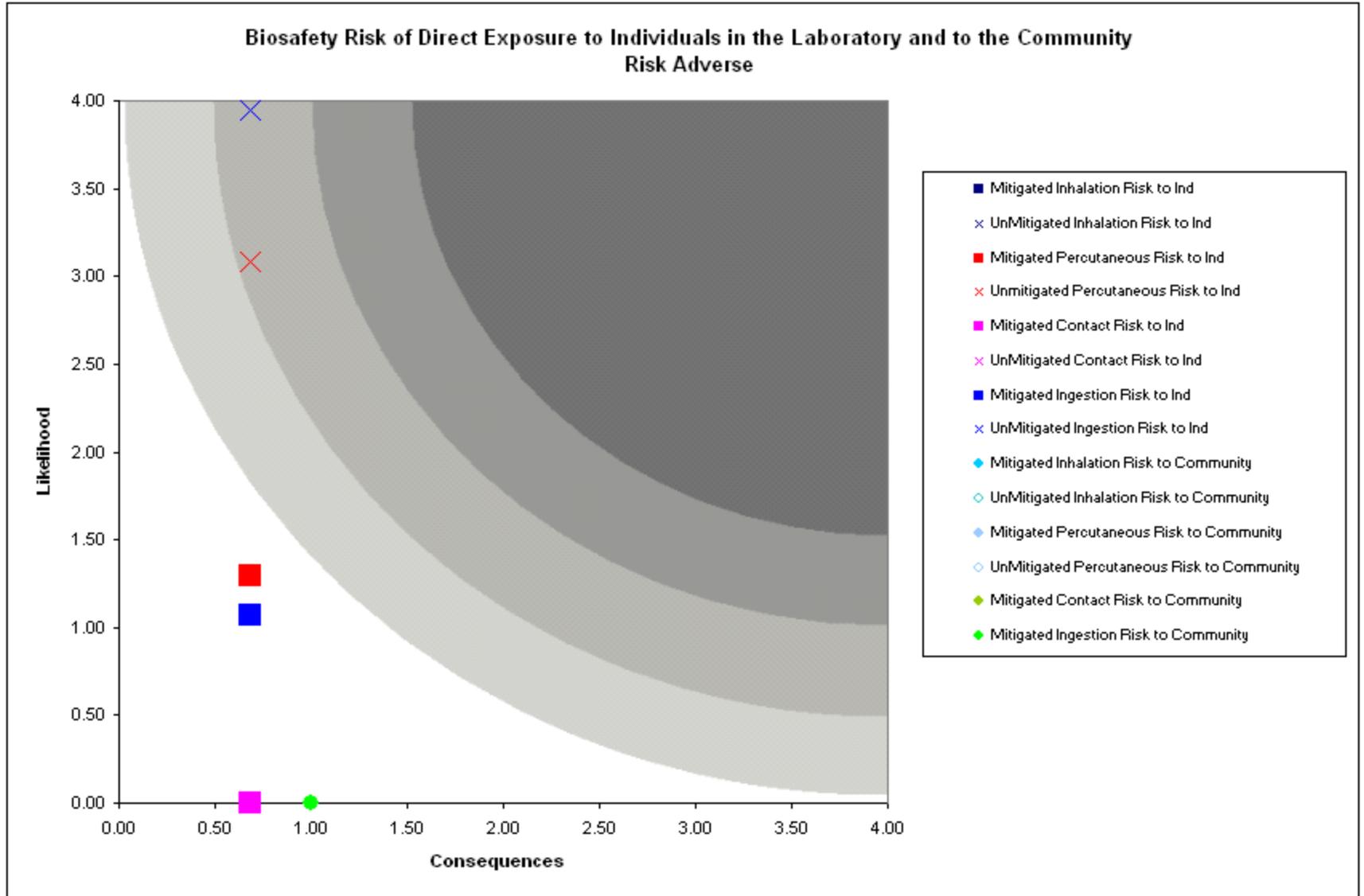


- Mitigated Inhalation Risk to Ind
- × UnMitigated Inhalation Risk to Ind
- Mitigated Percutaneous Risk to Ind
- × UnMitigated Percutaneous Risk to Ind
- Mitigated Contact Risk to Ind
- × UnMitigated Contact Risk to Ind
- Mitigated Ingestion Risk to Ind
- × UnMitigated Ingestion Risk to Ind
- ◆ Mitigated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

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

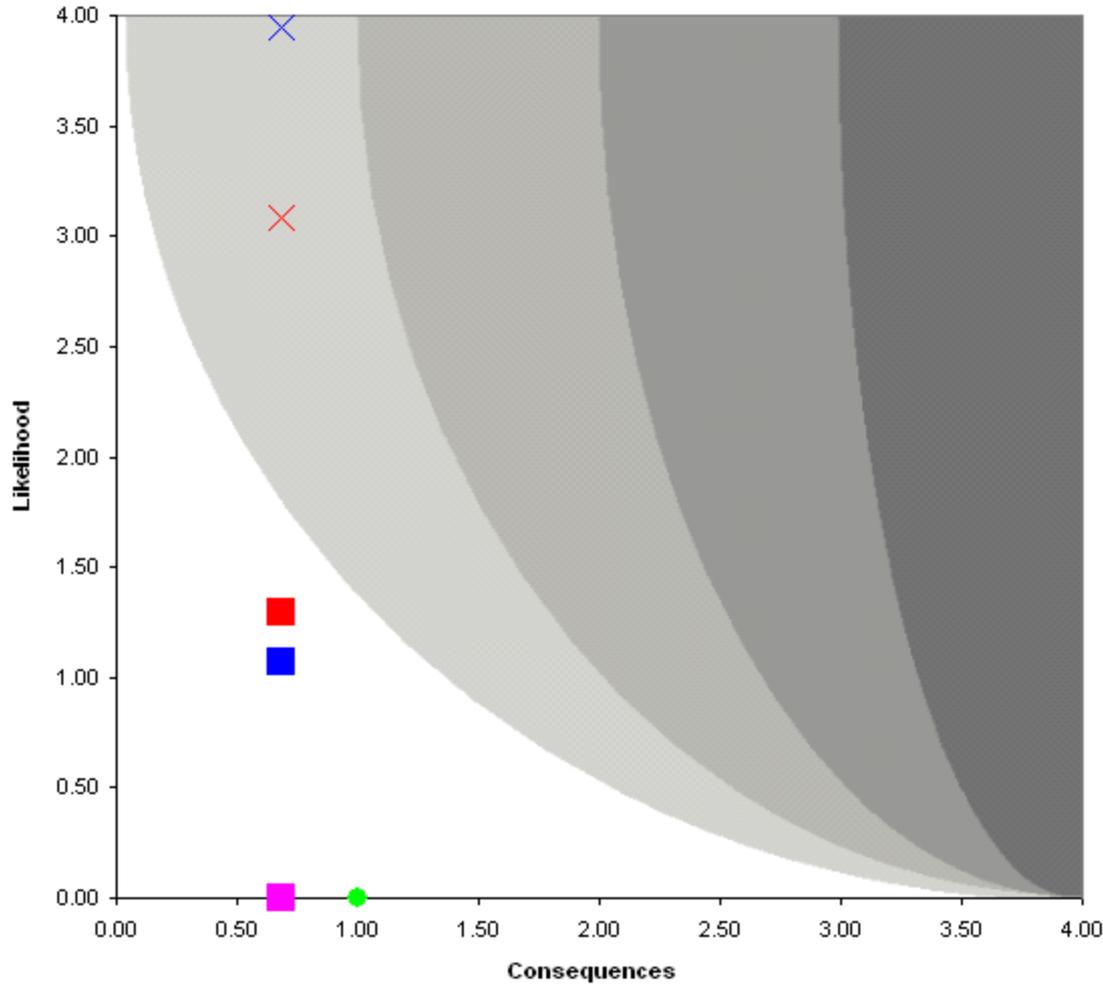


- Mitigated Inhalation Risk to Ind
- × UnMitigated Inhalation Risk to Ind
- Mitigated Percutaneous Risk to Ind
- × Unmitigated Percutaneous Risk to Ind
- Mitigated Contact Risk to Ind
- × UnMitigated Contact Risk to Ind
- Mitigated Ingestion Risk to Ind
- × UnMitigated Ingestion Risk to Ind
- ◆ Mitigated 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 Consequence Driven



- 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



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?**