



Biorisk Assessment – Session 2



**Biorisk Management =
Assessment, Mitigation, Performance**



Learning Objectives

- Understand what is risk
- Understand the components of a suitable risk assessment methodology, and the critical resources required
- Become familiar with a biorisk assessment model that addresses safety and security
- Be able to execute a risk assessment with the model
- Identify/justify/quantify key risk drivers



Group Exercise 1, Step 1

Consider this scenario:

A two-year-old child is left alone in a kitchen while there is boiling water on the stove

- ④ What could go wrong? List all the possibilities
- ④ Choose the single most important risk for this scenario
- ④ Identify the hazard for that risk
- ④ Report out to the class



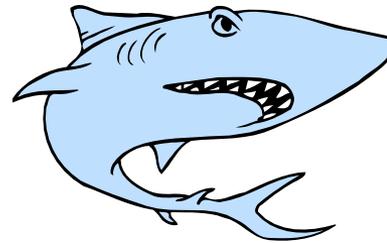
What is a hazard?





Hazard

☠ **Hazard** is a source that has a potential for causing harm



☠ **Hazard** is not a risk without a specific environment or situation





What affects whether or not
there is an incident with the shark?

How likely is an incident?





An incident with the shark would be how severe?

What are the consequences of the incident?





What is risk?





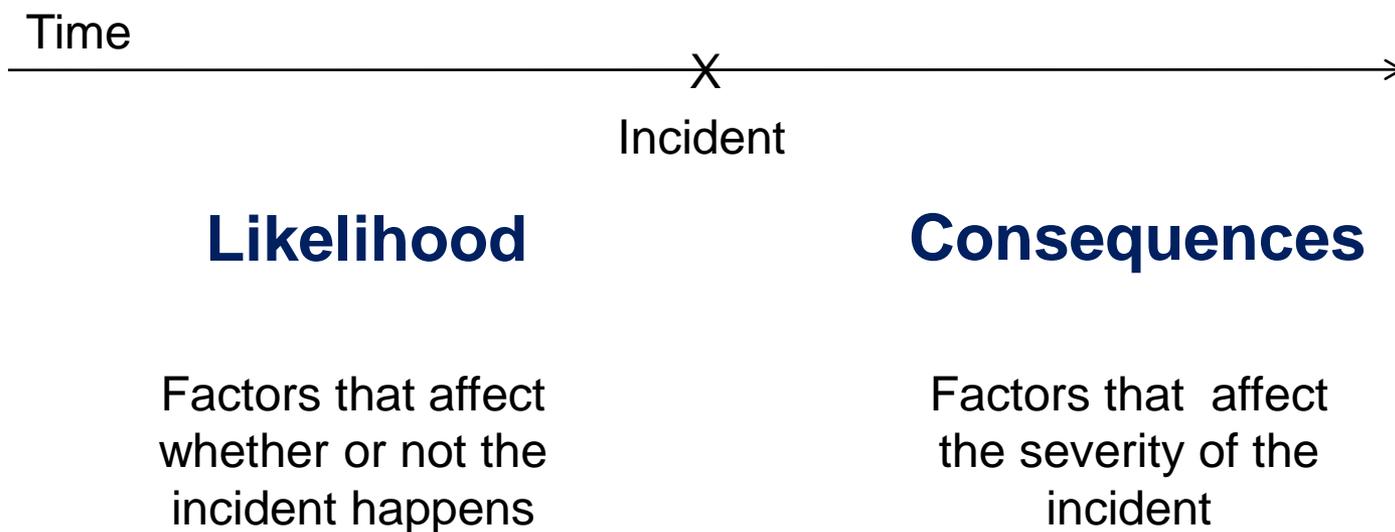
Risk

⚠ Risk is the likelihood of an event with a hazard that has consequences





Risk





Small Group Exercise 1, Step 2

Consider again the two-year-old in the kitchen scenario:

Risk: child being burned by the boiling water

Hazard: pot of boiling water on the stove

- ④ Identify the factors that influence the likelihood and consequences of the risk; use post-it notes for each factor
- ④ Evaluate the risk (low, moderate, high)
- ④ Report your results to the class



What would be different if the risk were the child being injured by an older brother, whose toy had just been broken by the two-year-old?

What is the hazard (threat) now?



What is the difference between
a hazard and a threat?





Hazard, Threat, and Risk

- ⚠ A **hazard** is an object that can cause harm
- ⚠ A **threat** is a person who has intent and/or ability to cause harm to other people, animals, or the institution
- ⚠ A **risk** can be based on either a hazard and/or a threat



How can we define risk, likelihood,
and consequences?





Risk, Likelihood, and Consequences

- ⚠ **Risk** is the likelihood of an event with a hazard that has consequences
- ⚠ **Likelihood** is the probability an event occurring
- ⚠ **Consequences** is the severity of an event



How can we define risk as an equation?



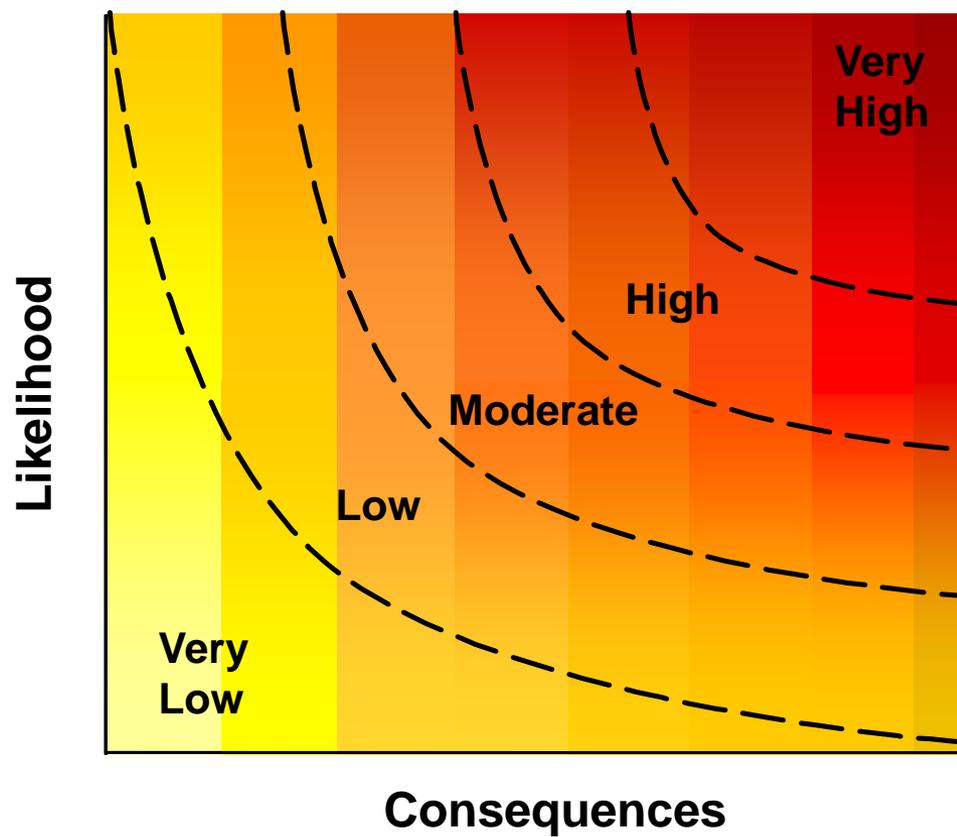


The Risk Equation

$$R = f(L, C)$$



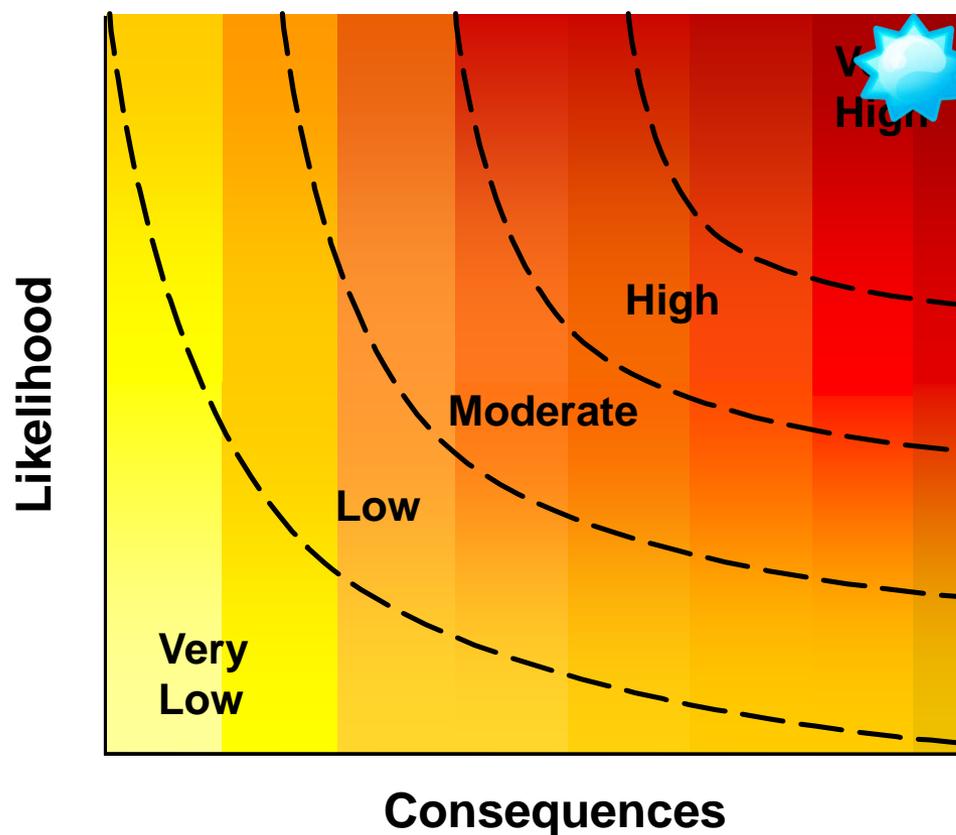
Risk Graph I





Risk Graph II

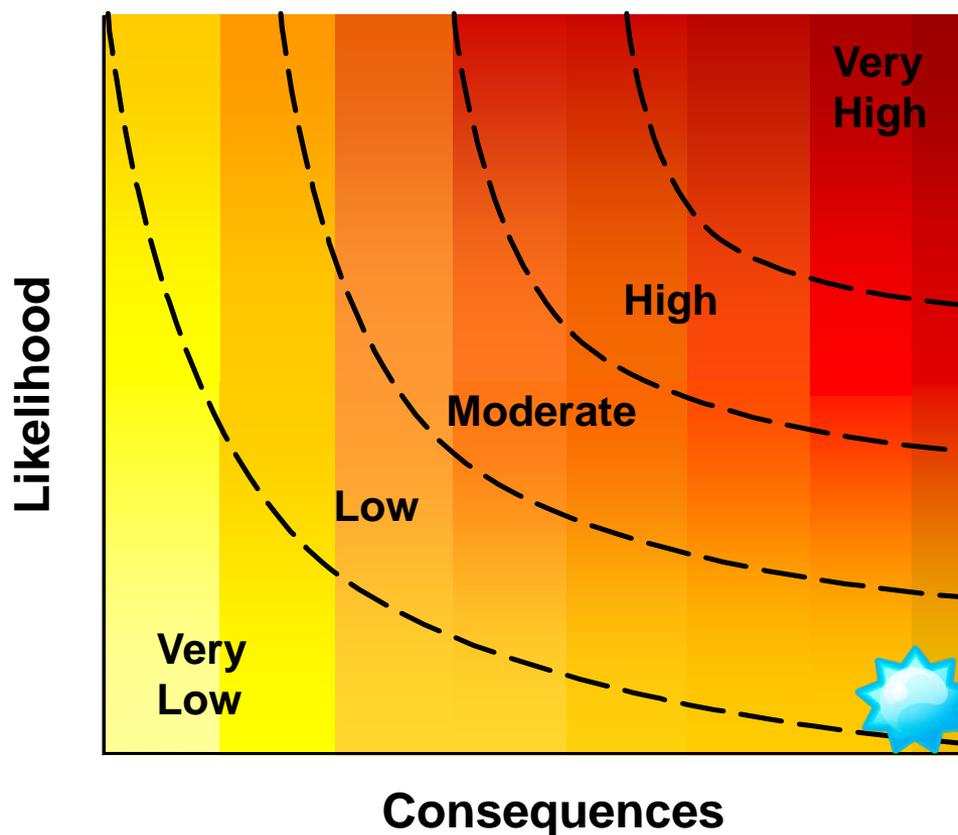
Large amount of boiling water on front of stove, step stool next to stove, child not restrained





Risk Graph III

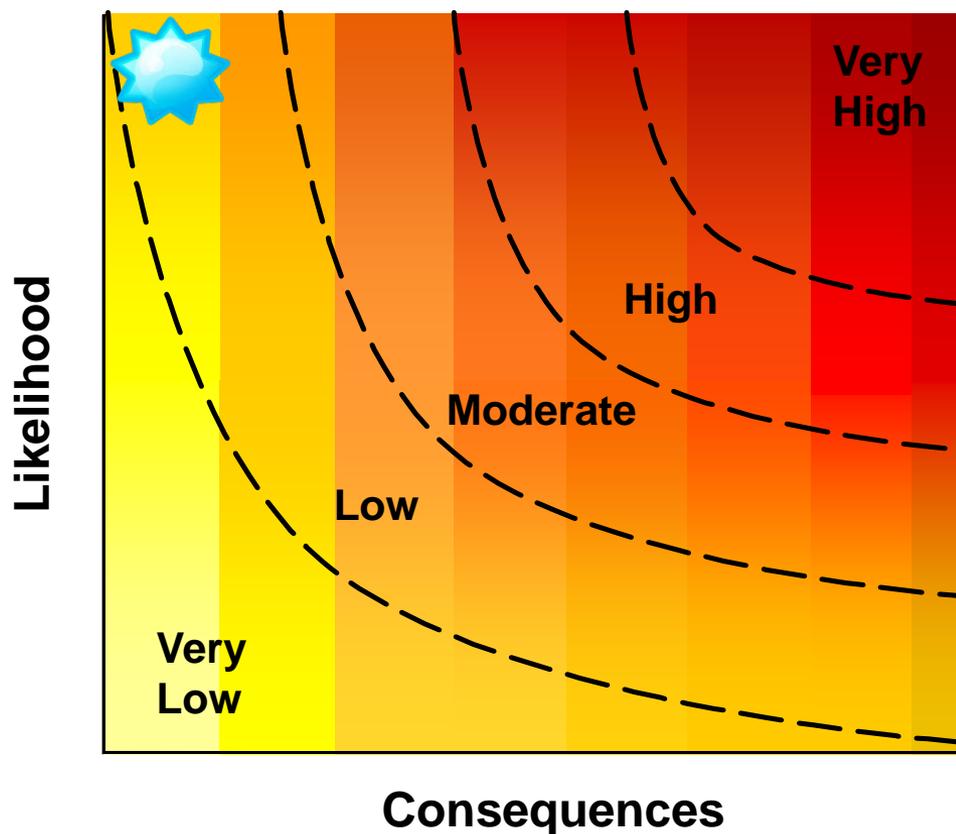
Large amount of boiling water, no step stool, child strapped in a high chair





Risk Graph IV

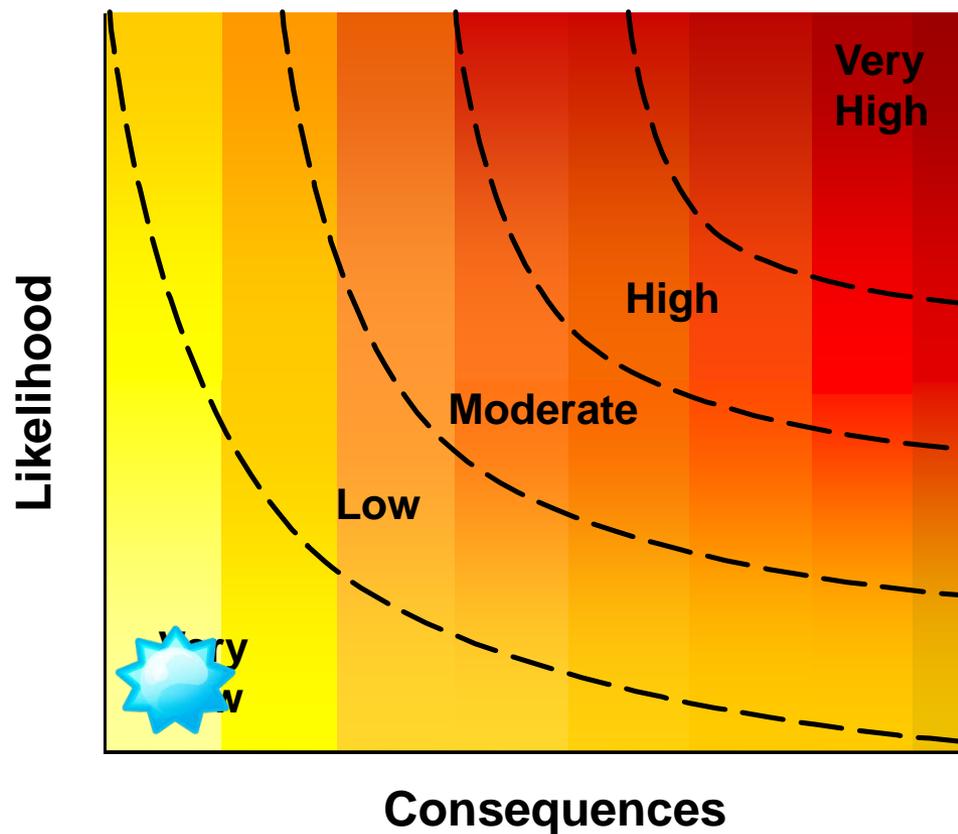
Small amount of cold water in the pan over a hot stove, step stool next to stove, child not restrained





Risk Graph V

Small amount of cold water over a hot stove, no step stool, child strapped in a high chair



Individual reflection

- ☣ How do you assess risk in your own labs?
- ☣ Write down your own answers, and then share with others at your table

If you wish, share with the class

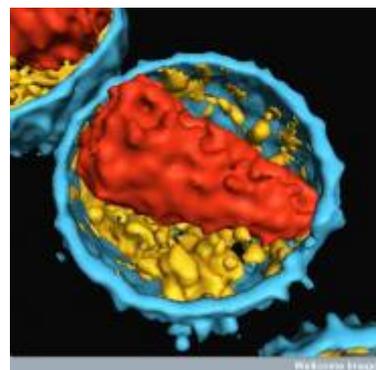


Group Exercise 2, Step 1

Consider the first biological scenario (HIV):

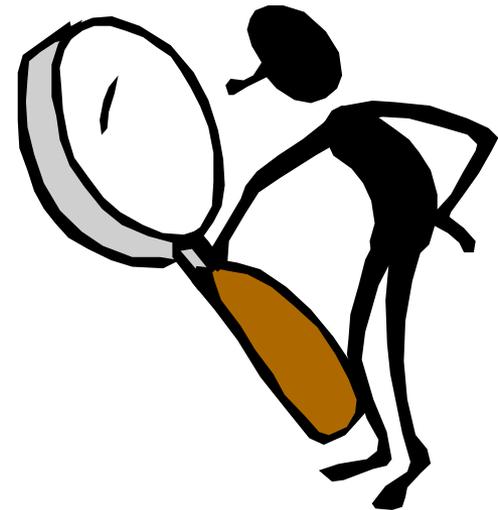
☠ Define the risks in this scenario

☠ Report out to the class



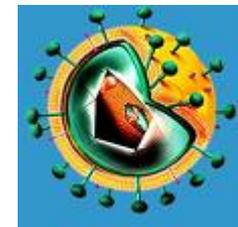


On what aspect of biorisk did you focus?



Group Exercise 2, Step 2

Using the HIV scenario:

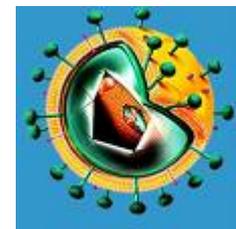


- ☣ Choose one risk to assess
- ☣ Define the hazard and/or threat
- ☣ Can you evaluate the risk of this scenario? If so, what is it (low/moderate/high)?
- ☣ Capture answers on a flip chart, and report to the class

Group Exercise 2, Step 3

Using the HIV scenario:

- ⚠️ What different type of information do you need to do a risk assessment? List all questions that you think need to be asked.
- ⚠️ Use small post-it notes, one per question, and place your post-it notes on a flip chart.





Group Exercise 2, Step 4

Categorize the criteria:

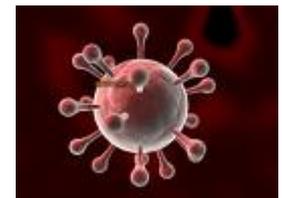
- ⚠ Put the questions, or criteria, into four or five general categories.
- ⚠ Place the small post-it notes on top of larger post-it notes that represent the four or five general categories.

Group Exercise 2, Step 5

Using the HIV scenario:

- ⚠️ Categorize the questions, or criteria, according to
 - ⚠️ Likelihood
 - ⚠️ Consequences

- ⚠️ Which of these criteria are relatively more important than the others?





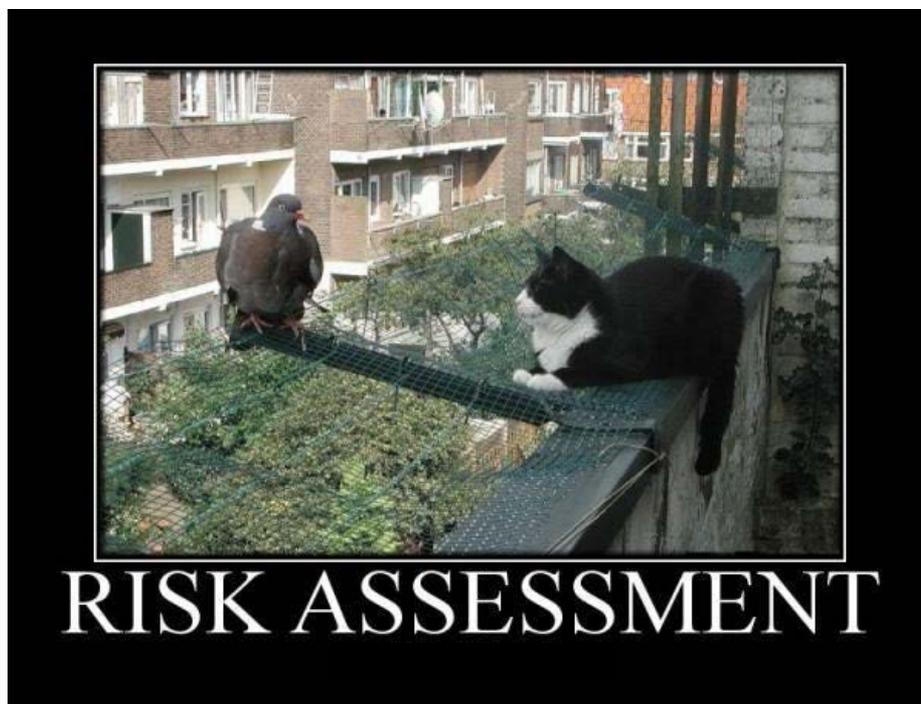
- ④ How might the result of your risk assessment change using this process (compared to your earlier method)?

- ④ How has your risk assessment improved? Think about how you assessed the risk of the two-year-old in the kitchen and how you assessed the HIV scenario the first time.





What are the benefits of a robust risk assessment?

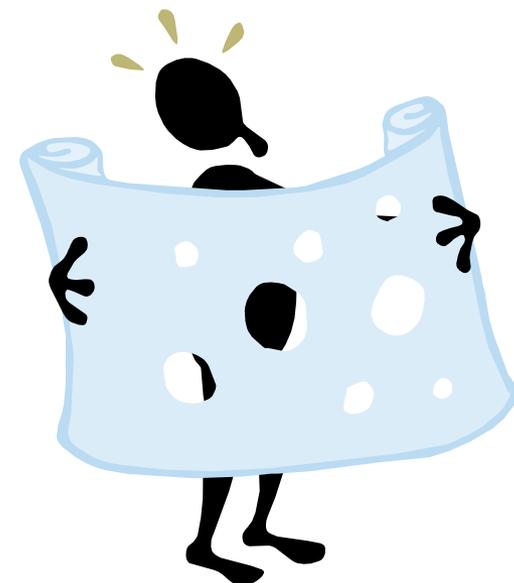




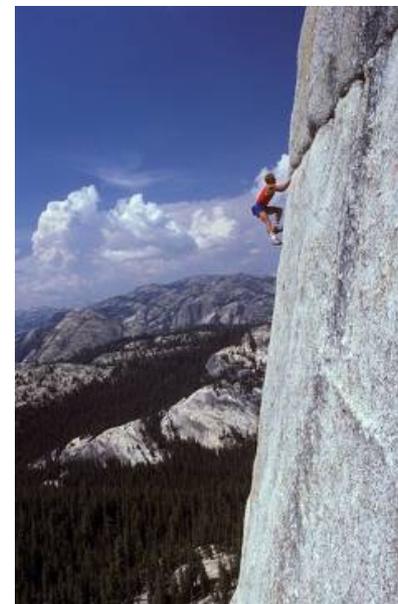
Benefits of a Robust Risk Assessment

- ⚠️ Facilitate a risk assessment process;
repeatable/reproducible
- ⚠️ Facilitate risk mitigation decisions
- ⚠️ Provide quality control documentation

What might be missing from this technical risk assessment?



What is 'acceptable risk'?



BioRAM

- ❖ BioRAMs were designed for use by biorisk officers at laboratories and provide visualization of the relative risks, and help to identify risk mitigation measures.
- ❖ BioRAM asks a series of questions
 - ❖ If the question contributes to risk, the score is 0-4
 - ❖ If the question mitigates risk, the score is 4-0
- ❖ BioRAM has embedded weights for the questions, and the categories of the questions





BioRAM

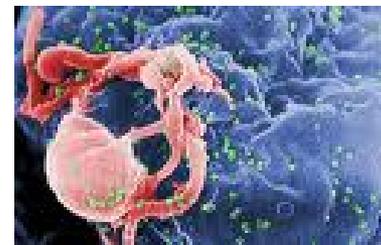
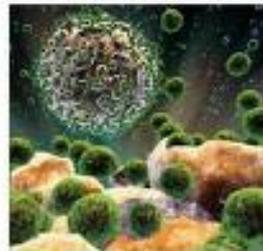
- ⊗ Biosafety risk assessment model
- ⊗ Biosecurity risk assessment model
- ⊗ Both have relied extensively on external experts from the international community
- ⊗ The full BioRAM models are available



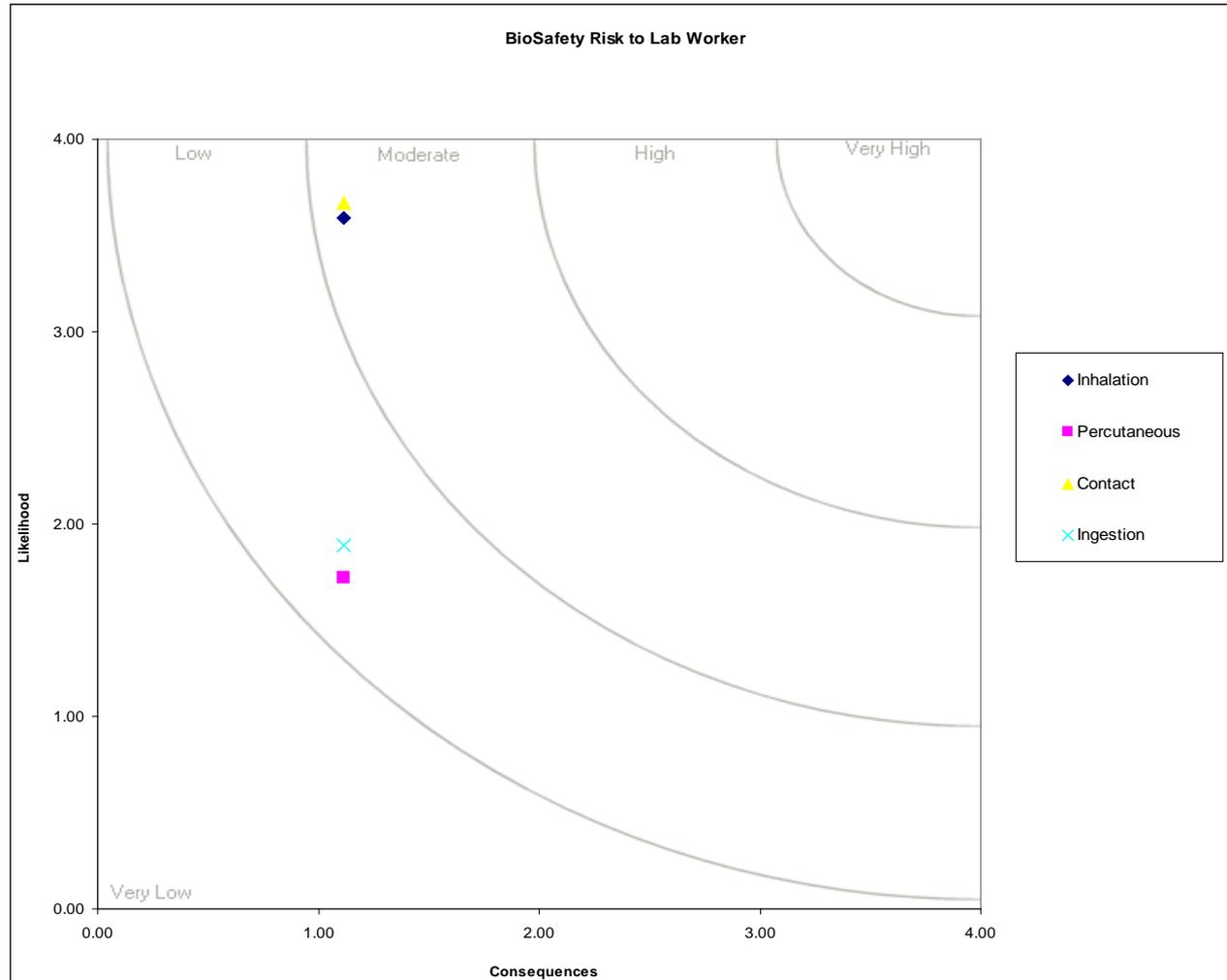


Class Exercise 2, Step 4

- ⚠ In your group, use the BioRAM software to conduct the safety risk assessment and the security risk assessment for the HIV scenario
- ⚠ Scores can be 1.5, 2.5, or 3.5 – not only 1, 2, 3, or 4
- ⚠ Share your scores with the class

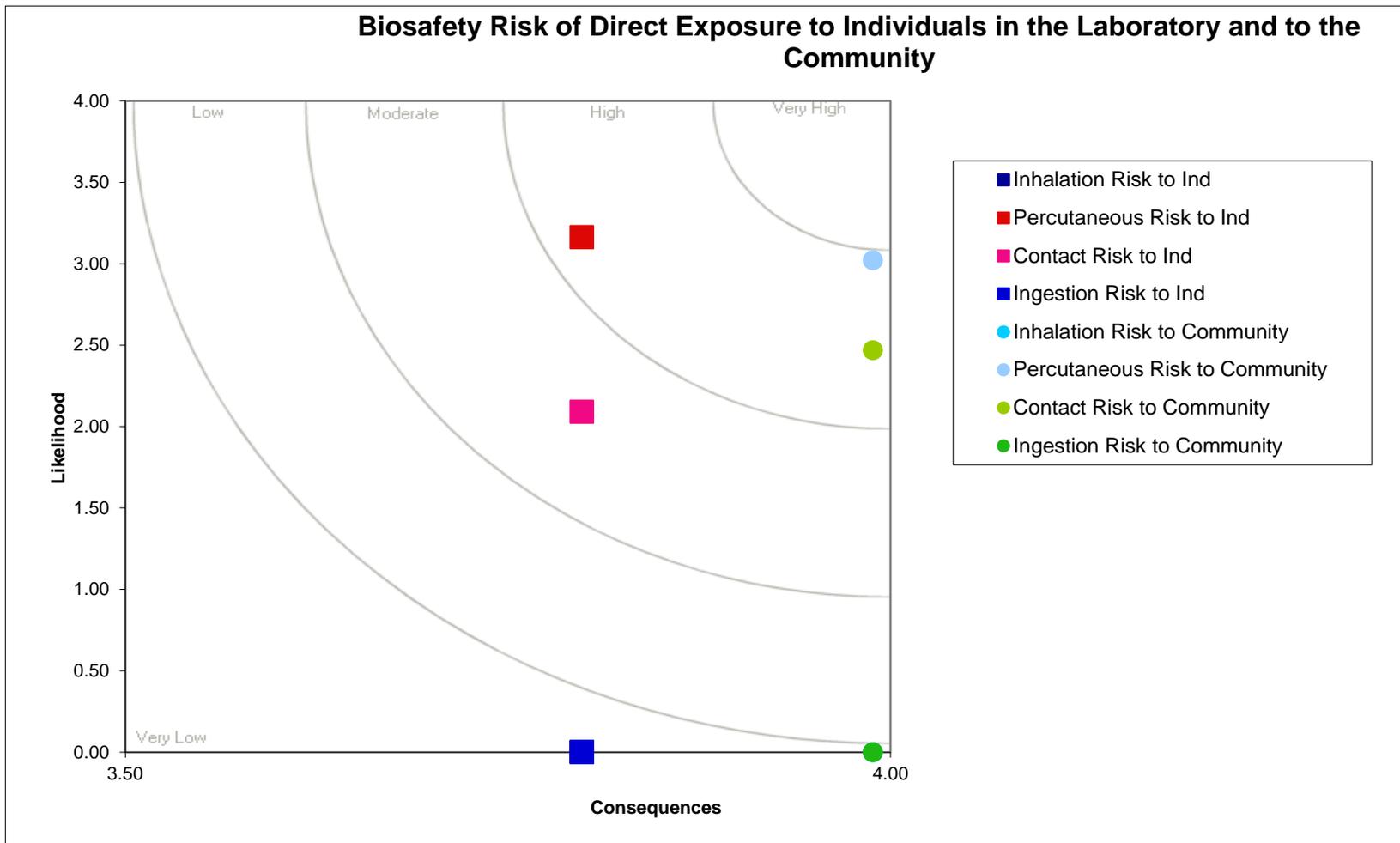


Examples of Risk Graph: Lab Worker Biosafety Risk

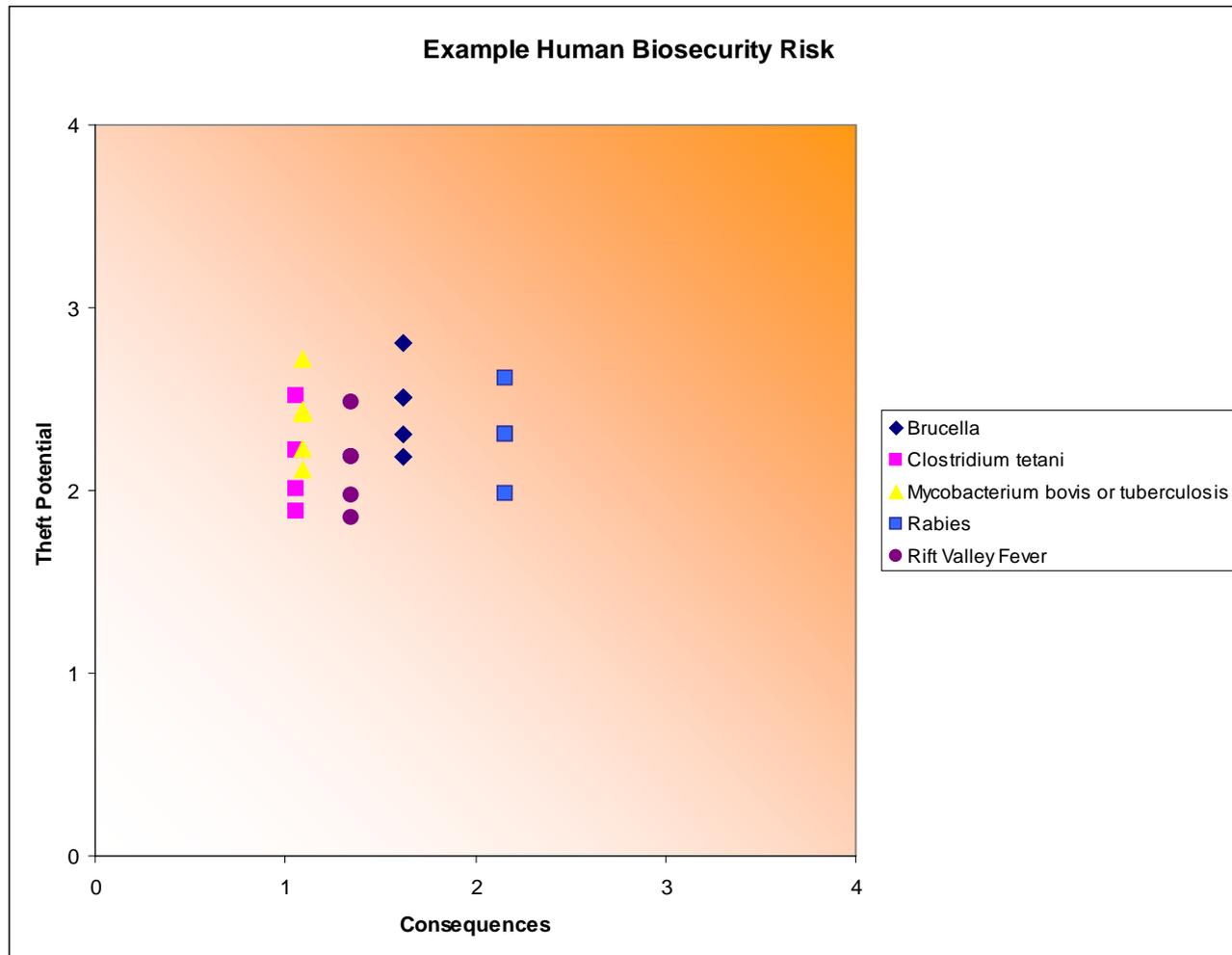




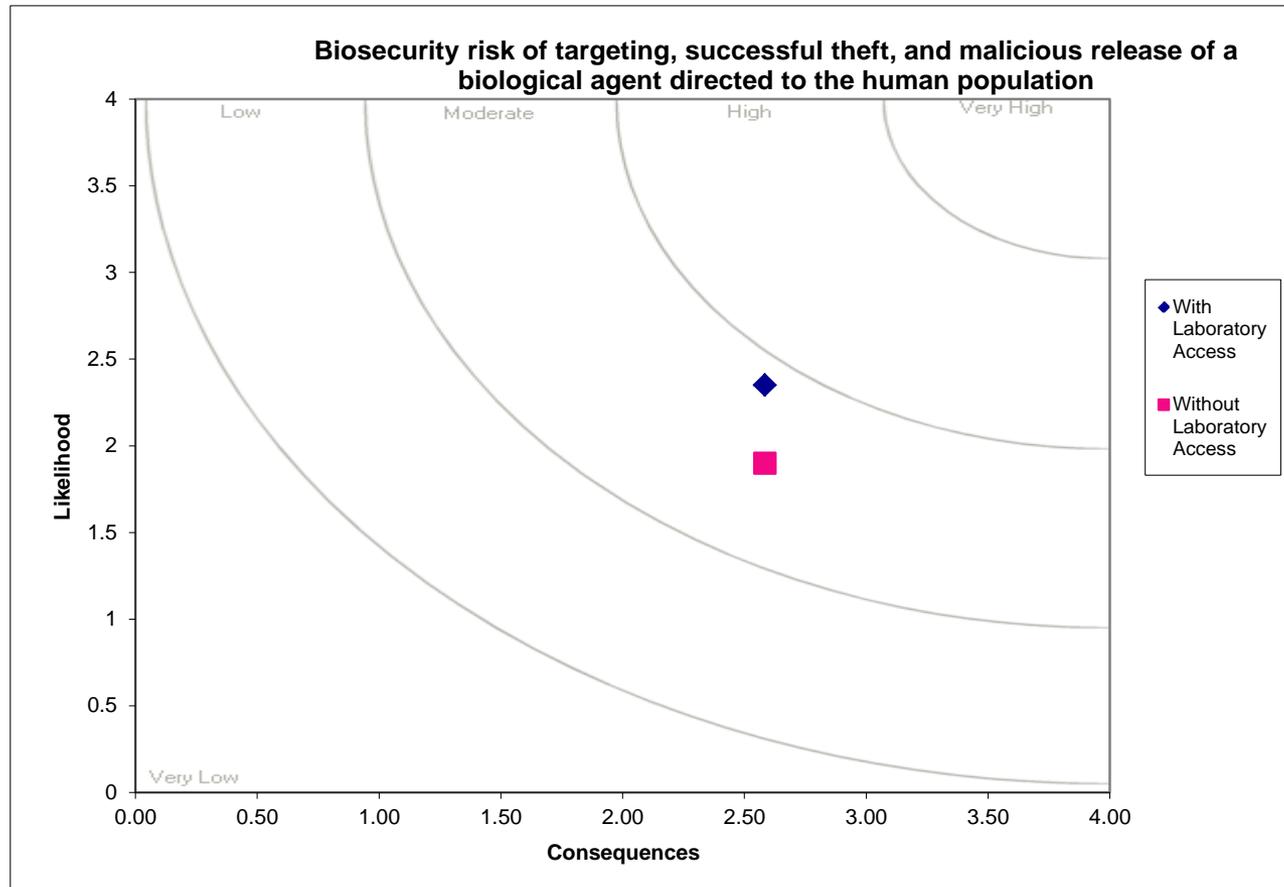
Example Biosafety Results



Examples of Risk Graph: Human Biosecurity Risk



Example Biosecurity Results



Individual reflection

- ④ What was new?
- ④ What insights have you had? What implications are there for you?
- ④ What will you change when you return to your home institute?

If you wish, share your thoughts with the class





Summary I

- ⚠ **Hazard** (threat) is a source that can cause harm

- ⚠ **Risk** is the combination of the likelihood and consequences of an undesirable event related to a specific hazard (or threat)
 - ➡ $R = f(L, C)$

- ⚠ **Likelihood** is the probability of an event occurring

- ⚠ **Consequences** is the severity of an event



Summary II

Benefits of a robust risk assessment

- ⚠️ Facilitates risk assessment process; repeatable/reproducible
- ⚠️ Facilitates risk mitigation decisions
- ⚠️ Provides quality control documentation



Summary III

- ⚠ **Technical risk assessments** generally do not include perceived social, cultural, political concerns
- ⚠ **Risk acceptance** will depend on the ‘owner’ of the risk: risk averse or risk tolerant



Intersession Assignment

☣ Exercise 1

- ☣ Select one of the provided scenarios
- ☣ Conduct a risk assessment using the BioRAM model

☣ Exercise 2

- ☣ Select an actual scenario from your laboratory
- ☣ Conduct a risk assessment using the BioRAM model



Inter-session Assignment Guidelines

For each scenario

- ⚠️ Conduct a *safety* risk assessment
- ⚠️ If there is not adequate information to answer the question, assume the risk mitigation is NOT in place
- ⚠️ Determine risk; plot those risks on the graphs
- ⚠️ Identify four key risk drivers and the most important risk driver



Inter-session Assignment Guidelines

For each scenario

- ⚠️ Conduct a *security* risk assessment
- ⚠️ If there is not adequate information to answer the question, assume the risk mitigation is NOT in place
- ⚠️ Determine risk; plot those risks on the graphs
- ⚠️ Identify four key risk drivers and the most important risk driver



Inter-session Assignment Guidelines

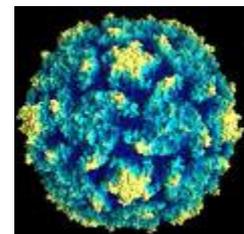
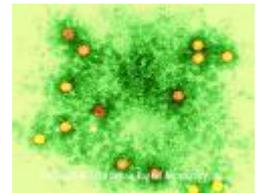
For each scenario

- ⚠️ Institute risk mitigation measures, then recalculate the *biosafety* and *biosecurity* risk
- ⚠️ Email your risk assessment results to Cecelia Williams (cvwilli@sandia.com)



Scenario A

- ❖ A basic research project uses wild type pablo virus for immune response studies using an animal model. Less than 1 liter volume of material is handled at any time. Researchers conduct necropsies on mice post euthanasia.
- ❖ Personnel wear lab coats over their own clothes. Gloves are worn sporadically. No face shields are in use. The laboratory has a sink, which is used for hand washing, and the washing of glassware.
- ❖ Isolates are kept in a freezer in the hallway next to the laboratory. Laboratory notebooks maintain a log of isolates, and are kept on top of the freezer.





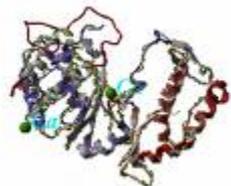
Scenario B

- ⚠️ A laboratory is culturing MDR-Titan Blue for drug susceptibility testing. MDR-TB isolates are grown and exposed to a variety of drugs to determine susceptibility.
- ⚠️ Open window ventilation, humid environment. Lab coats, surgical masks, gloves worn occasionally. No vaccination available. Lab waste is hauled away for offsite treatment.
- ⚠️ Open campus with no locks on doors. Cultures not secured or inventoried. No personnel reliability program.

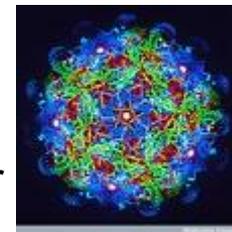




Scenario C



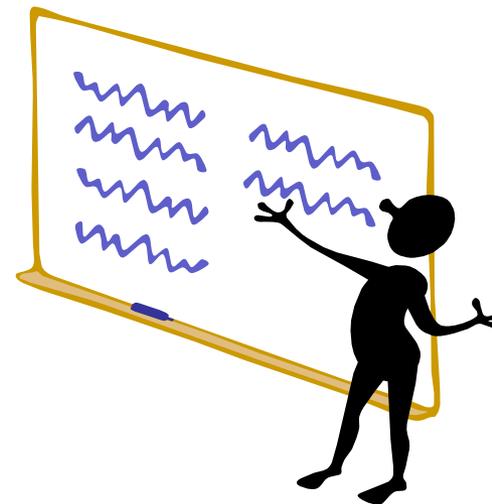
- ⚠ Researchers are conducting Funny Mutton Disease vaccine challenge studies. Bovines are used for this vaccine challenge. Animals are exposed to FMD via intranasal exposure.
- ⚠ Both control and challenge animals are housed in sealed environments, which are isolated from each other, with directional and HEPA filtered exhaust air. Liquid waste is routed through open pipes. Solid waste is sent to public trash disposal.
- ⚠ Persons are required to don coveralls and rubber boots prior to entering animal pens; upon leaving animal pens, the coveralls and rubber boots are rinsed with a decontamination solution for reuse.
- ⚠ Vaccines being tested have been imported from another country. Lyophilized FMD isolates are stored in a lock box located in the common area of the animal warehouse. Periodically, FMD isolates are grown and lyophilized; this work is done in a laboratory area located at another building.





Plenary Discussion

- ⚠️ What are critical pieces of information you need to conduct this risk assessment?
- ⚠️ Who should be responsible for conducting this type of risk assessment, and why?

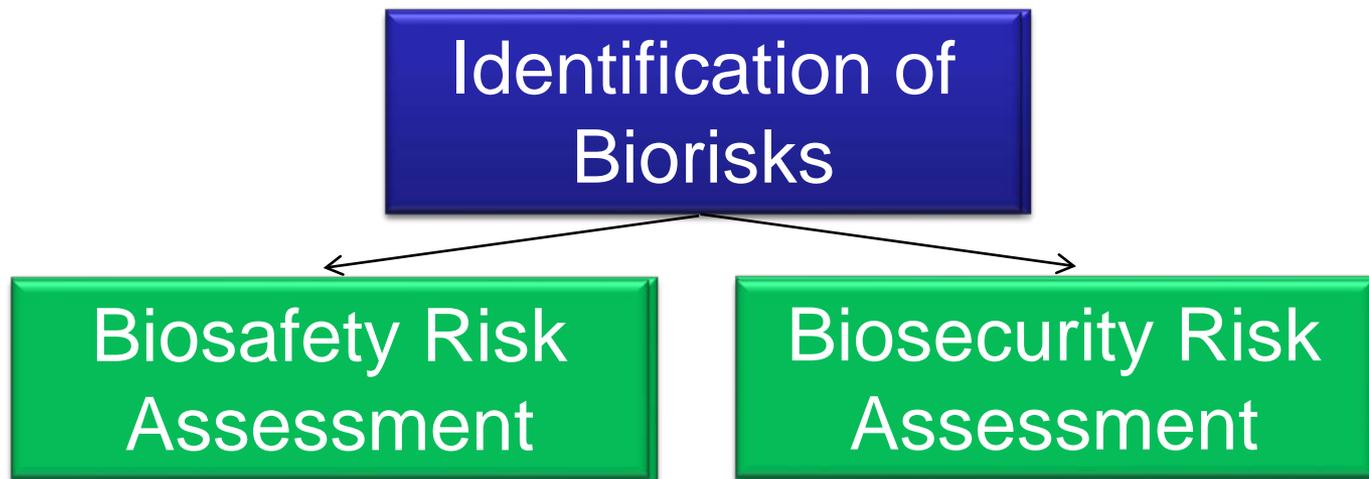




Biorisk Management = Assessment, Mitigation, Performance



Risk identification
Hazard/threat identification
Likelihood evaluation
Consequences evaluation

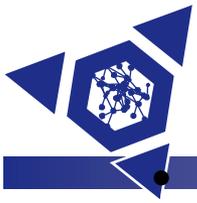




Individual Reflection

- ⚠️ Imagine you are going back to your labs and have to brief your colleagues about this workshop
- ⚠️ What are the 10 key messages you would share with them about risk assessment?

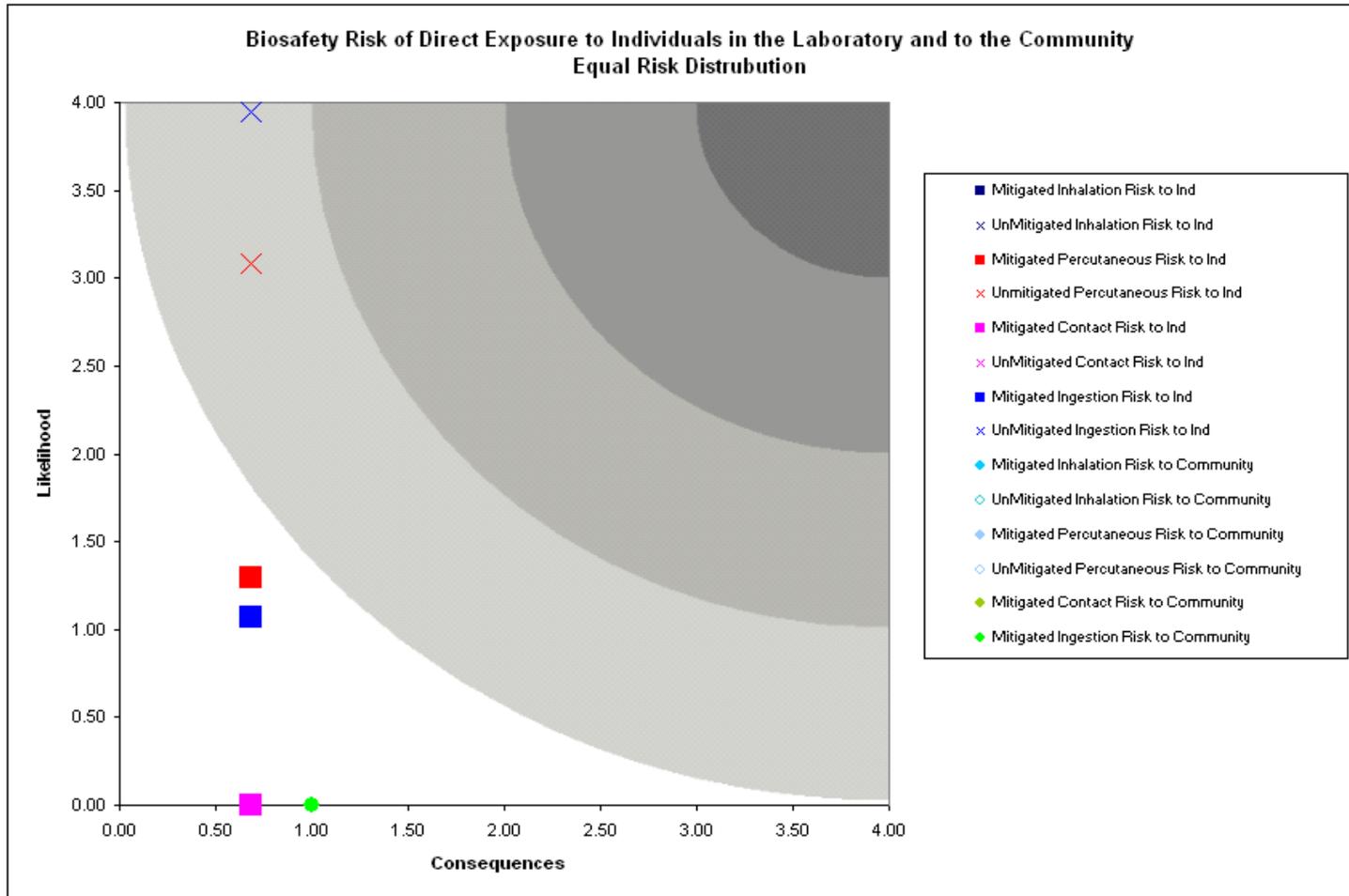




Extra Slides

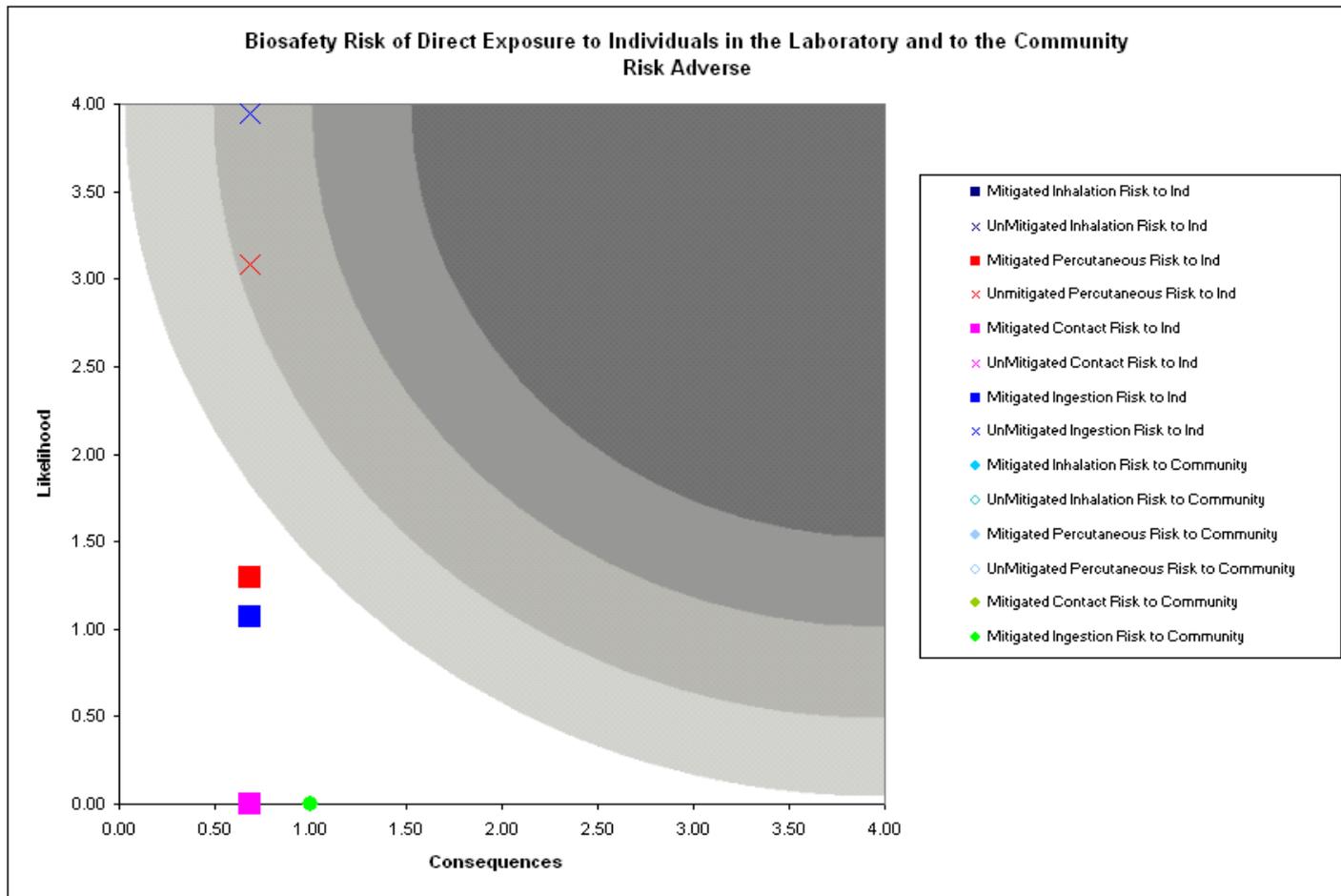
Examples of Risk Graphs





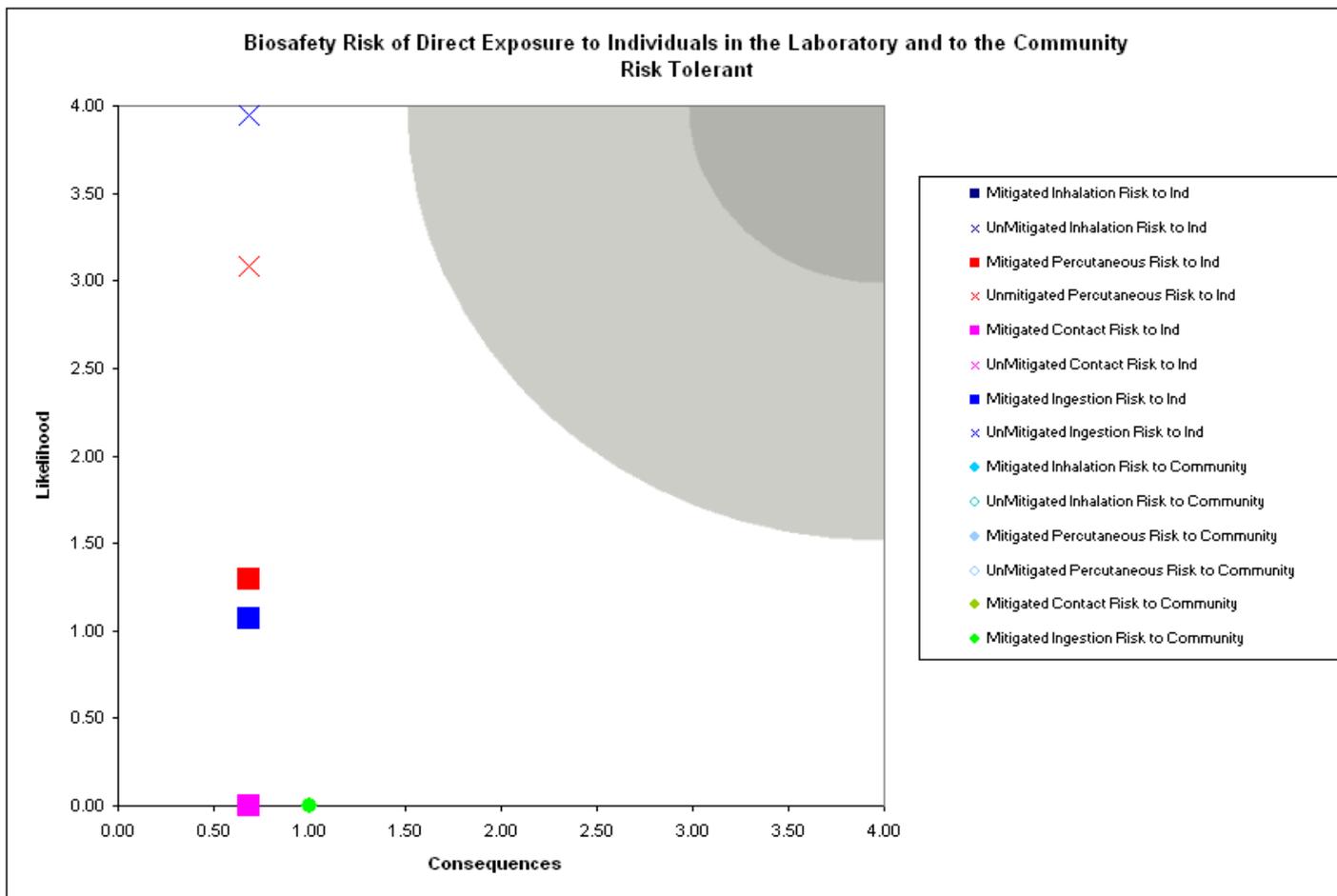


Biosafety Risk





Biosafety Risk





Biosafety Risk

