



Biorisk Assessment

AMEXBio PreConference Course ***June 2011***

International Biological Threat Reduction
Sandia National Laboratories

www.biosecurity.sandia.gov

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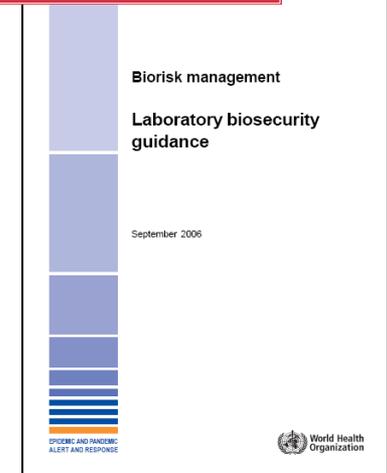
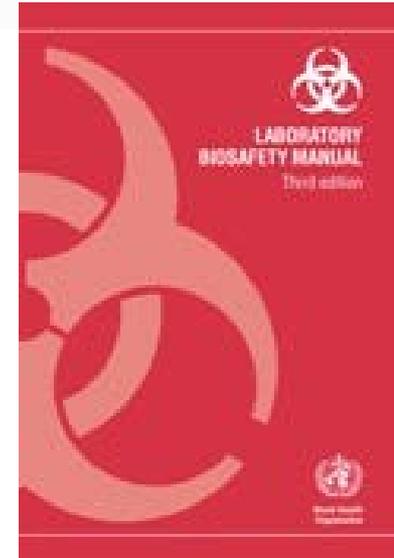
Risk Assessment

- **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**



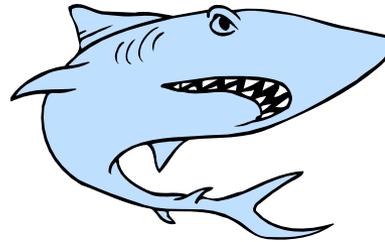


What is a hazard?



Key Terms

Hazard is a source that has a potential for causing harm



A **hazard** is not a risk without a specific environment or situation





What is a threat?



Key Terms

- **A hazard is a source that has a potential for causing harm**
- **A threat is a person who has intent and/or ability to cause harm**
- **A risk can be based on either a hazard and/or a threat**



Tiger Assessment (page 6)

- What is the risk of being attacked by a Tiger?

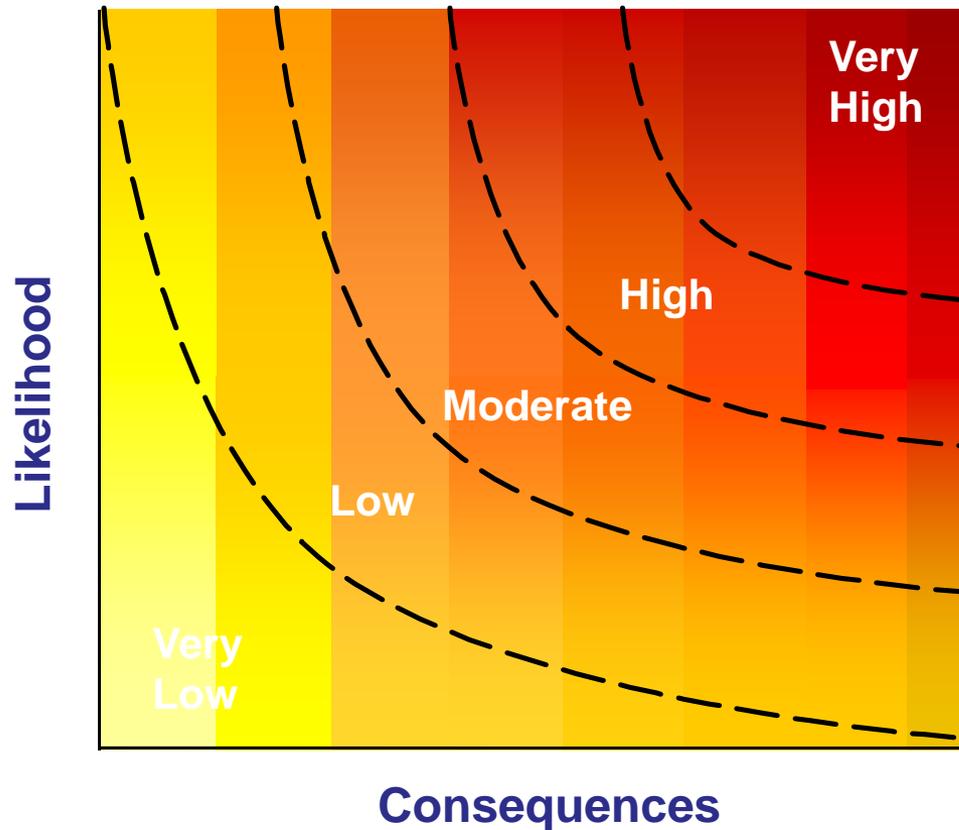




What is risk?



Risk is a function of likelihood and consequences

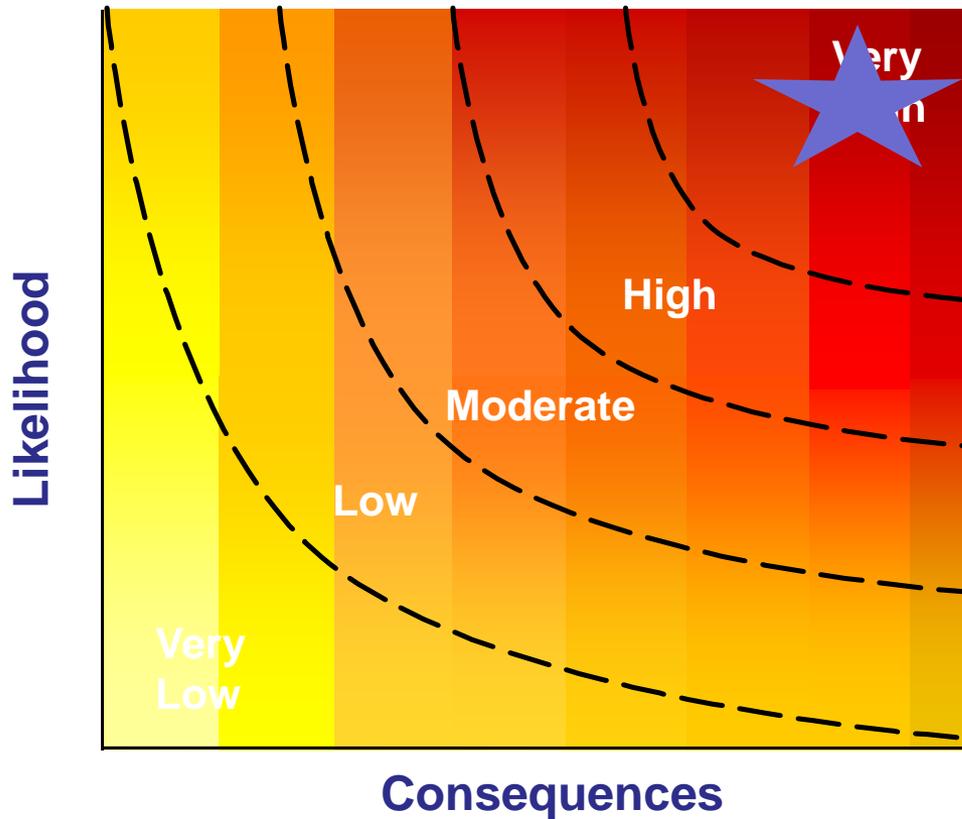


$$R = f(L, C)$$



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

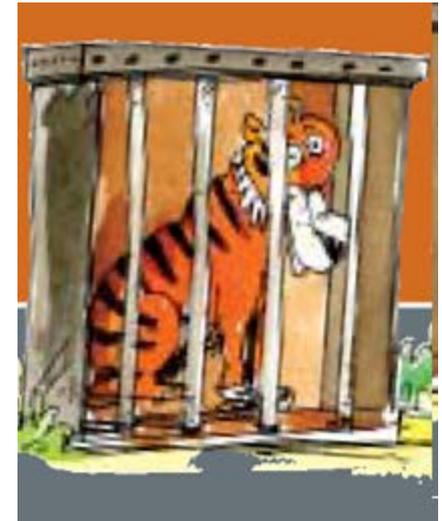
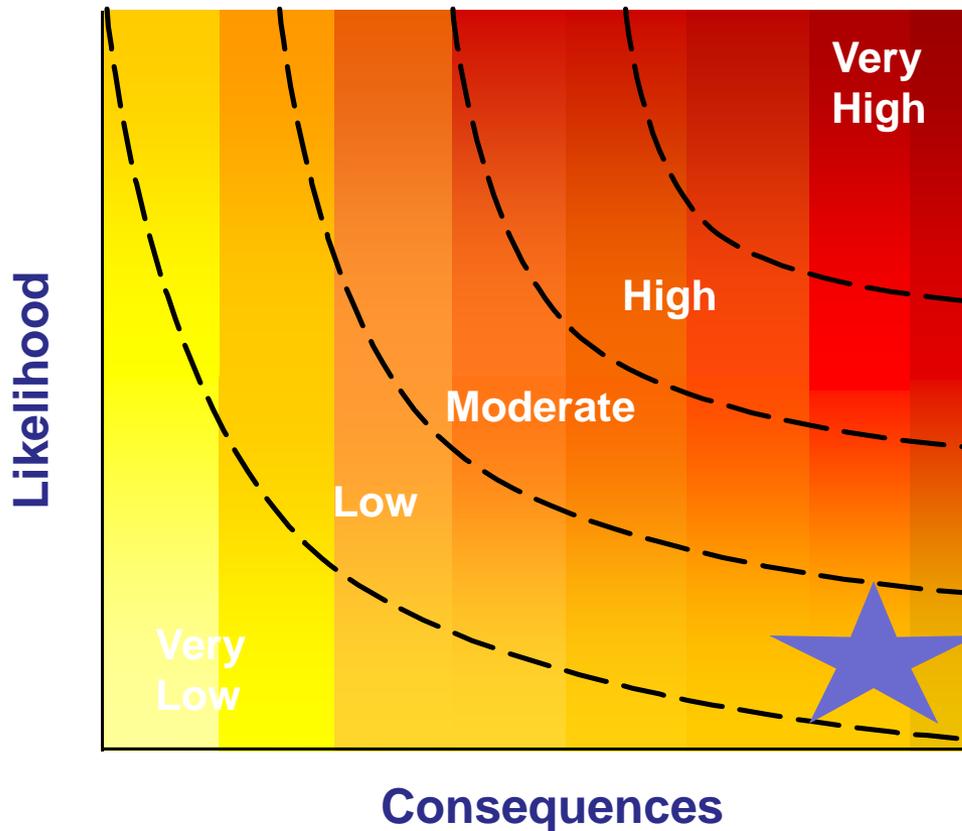
You are in an open field next to a very hungry, aggressive, adult tiger that is unrestrained and sees you as food





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

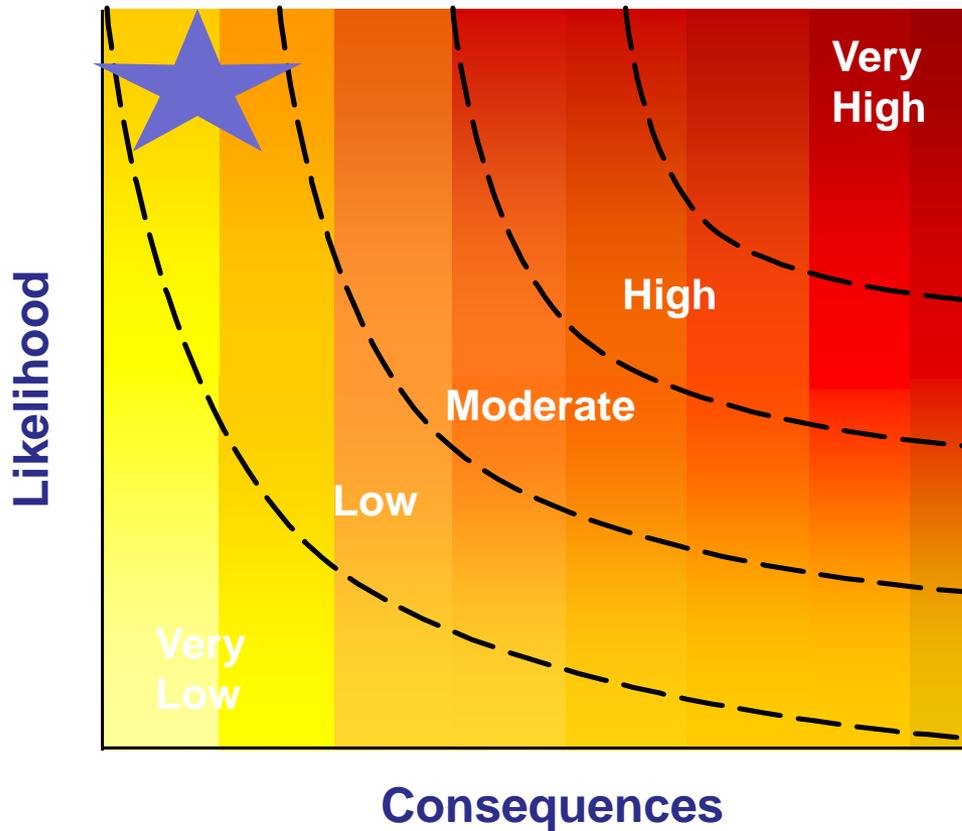
You are at the zoo, looking at an adult tiger which is well fed, had a mild temperament and in a secure enclosure





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

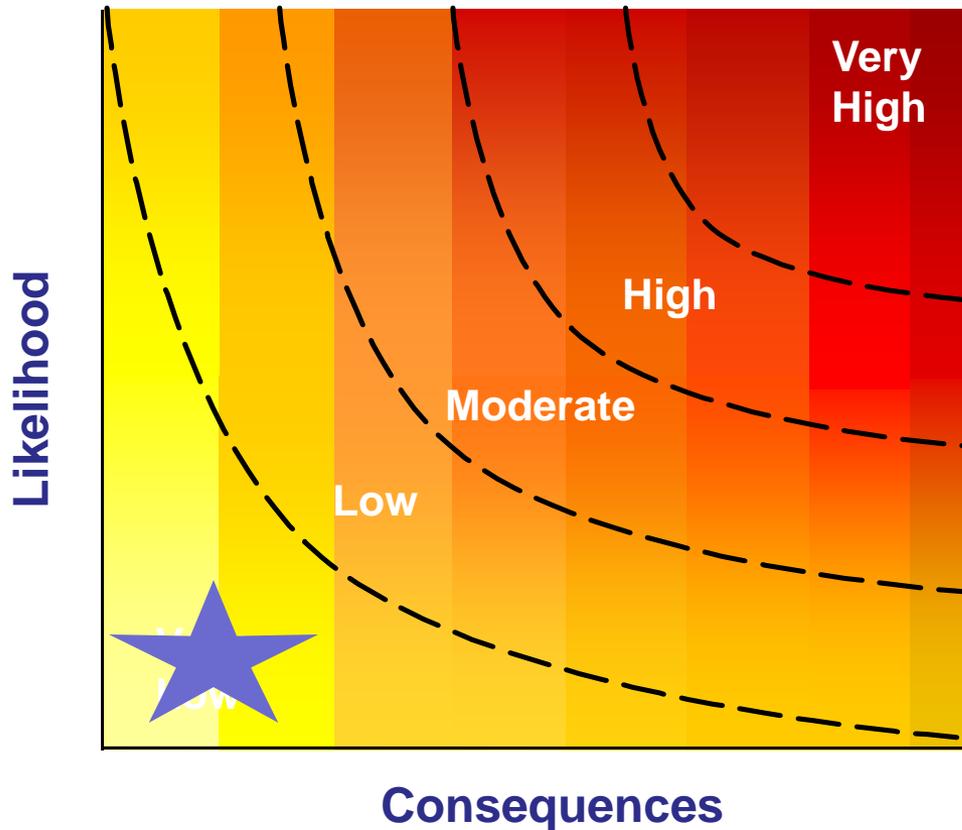
You are holding a tiger kitten with a playful temperament





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

You are at the zoo and looking at mellow tiger kitten, which is located behind a glass window.

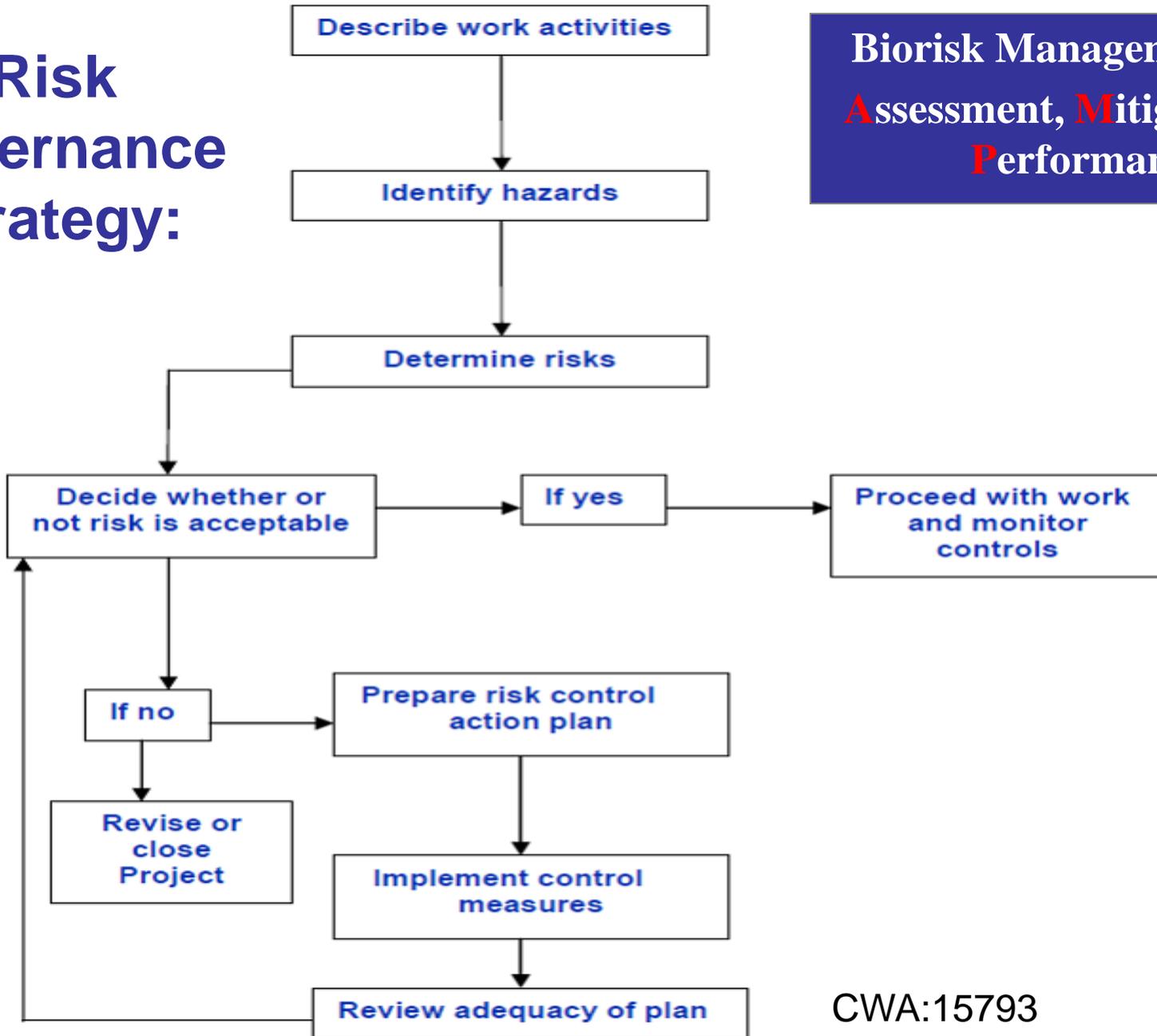




Risk Assessment Principles

- **Define the problem**
 - Think about how the factors would change if you were assessing the risk of someone stealing a tiger vs. being attacked by 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**

Risk Governance Strategy:

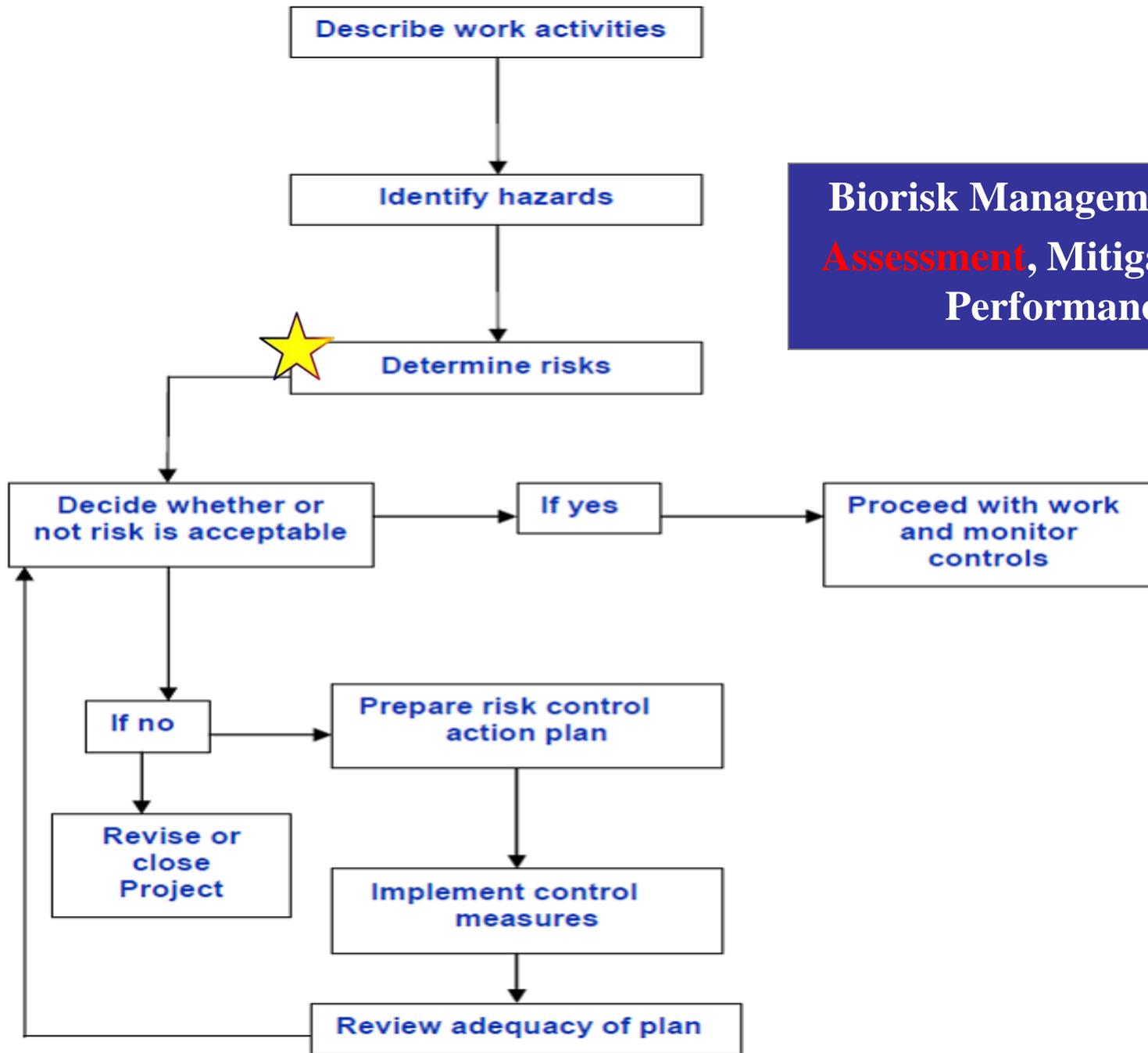


**Biorisk Management =
Assessment, Mitigation,
Performance**



Laboratory Biorisk Assessment (page 11)

- **You are planning to conduct diagnostic testing on a patient with an acute respiratory illness, suspect anthrax. A nasal swab will be collected and sent to you in your lab. You will be conducting the diagnosis by culturing the swab and looking for bacteria and viewing the colony growth to determine if it looks like anthrax.**
- **Work in your group to determine:**
 - What is the hazard? What are the threats?
 - What are the safety and security risks?
 - What are the key factors needed to conduct a risk assessment?
 - Based on the factors, possible agent(s) and procedures, characterize the risk.



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



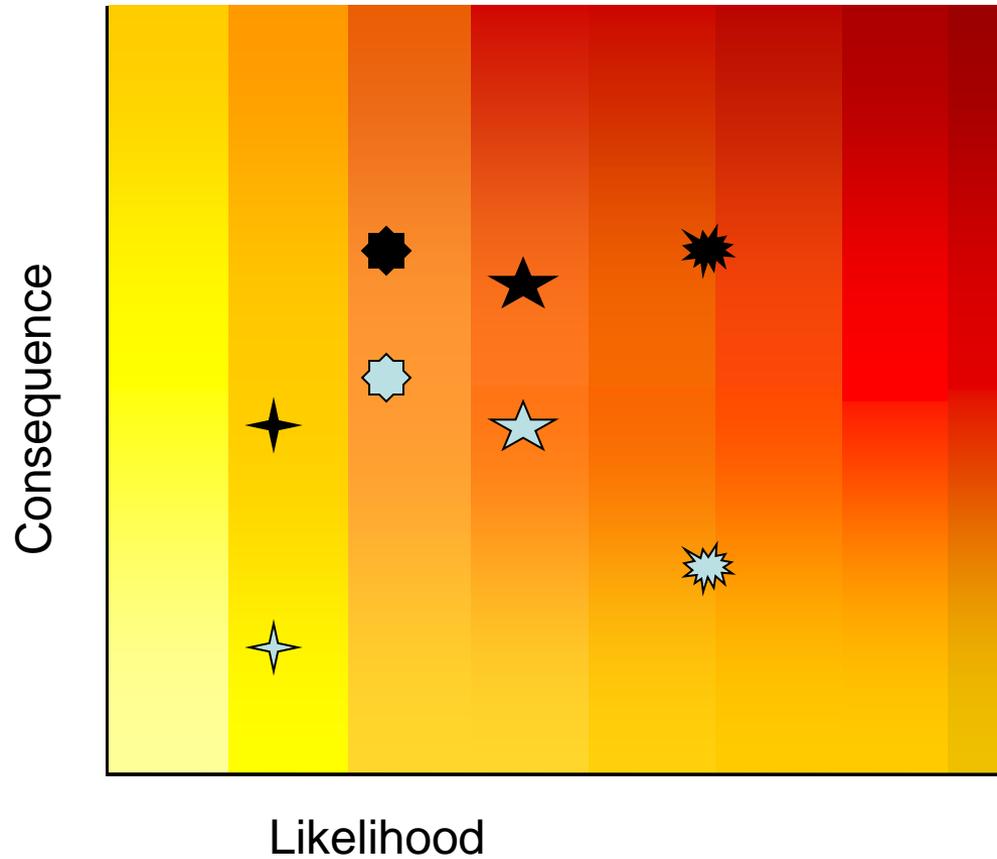
Determine Risk

- **Define the risk based upon the defined hazard (and threat)**
 - Define the likelihood for that risk
 - Define the consequences for that risk
- **Characterize the risk**

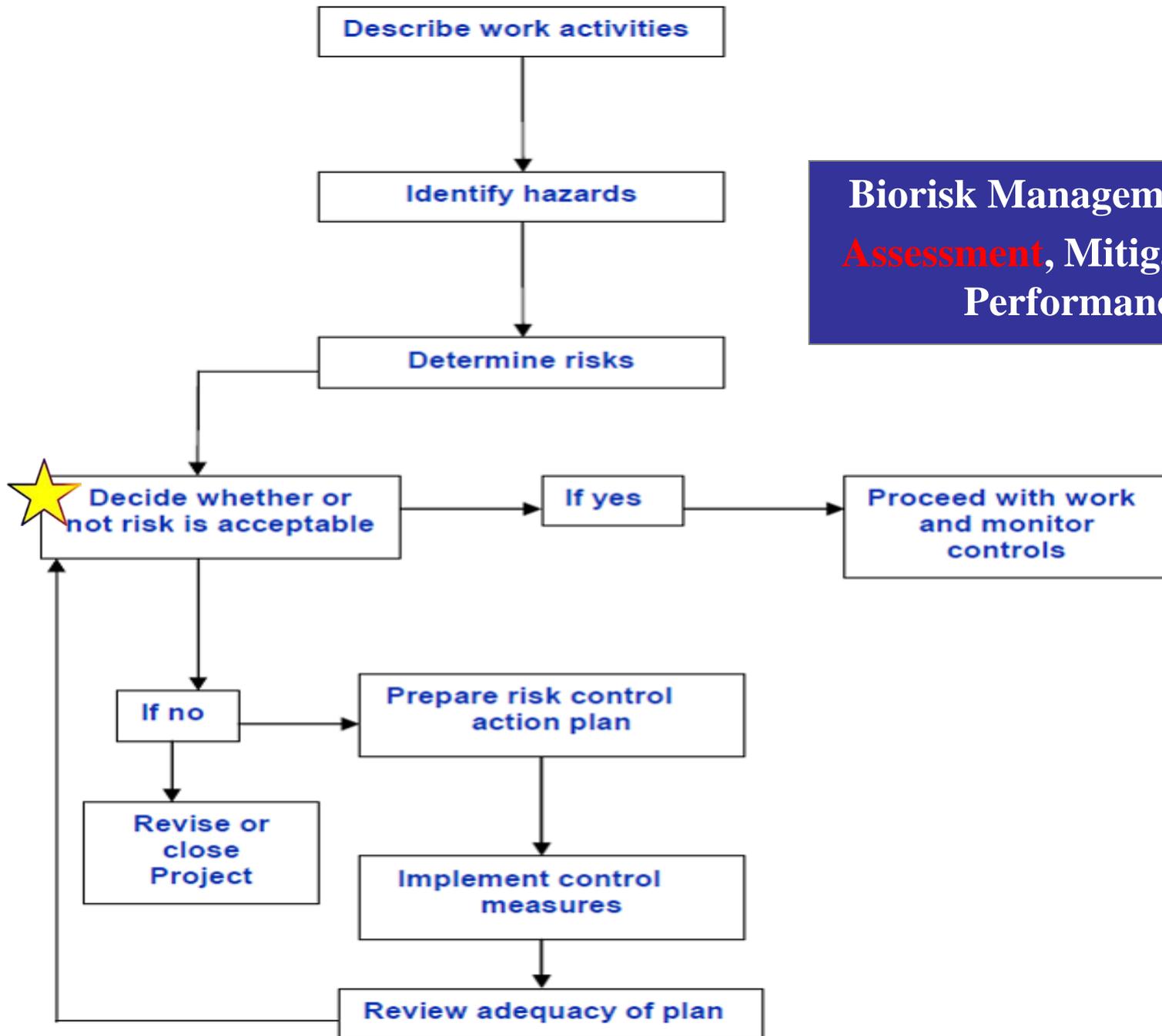


Risk Characterization

- Evidence-based



**Biorisk Management =
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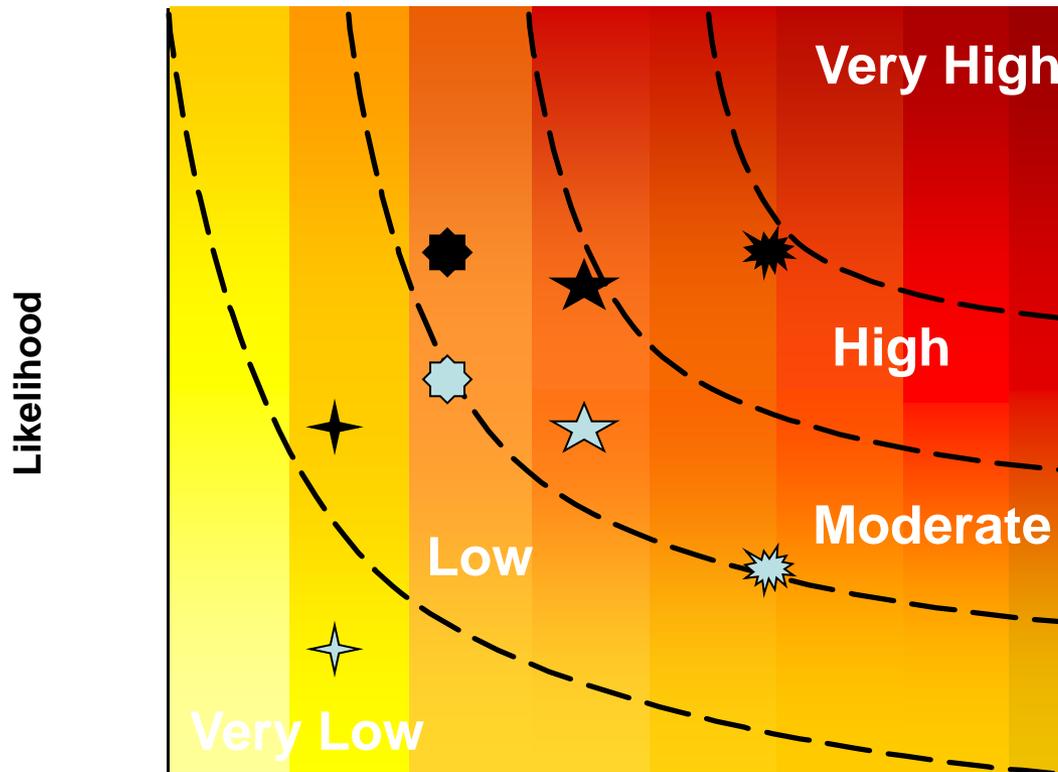
What are some considerations when determining if a risk is acceptable?



Risk Evaluation

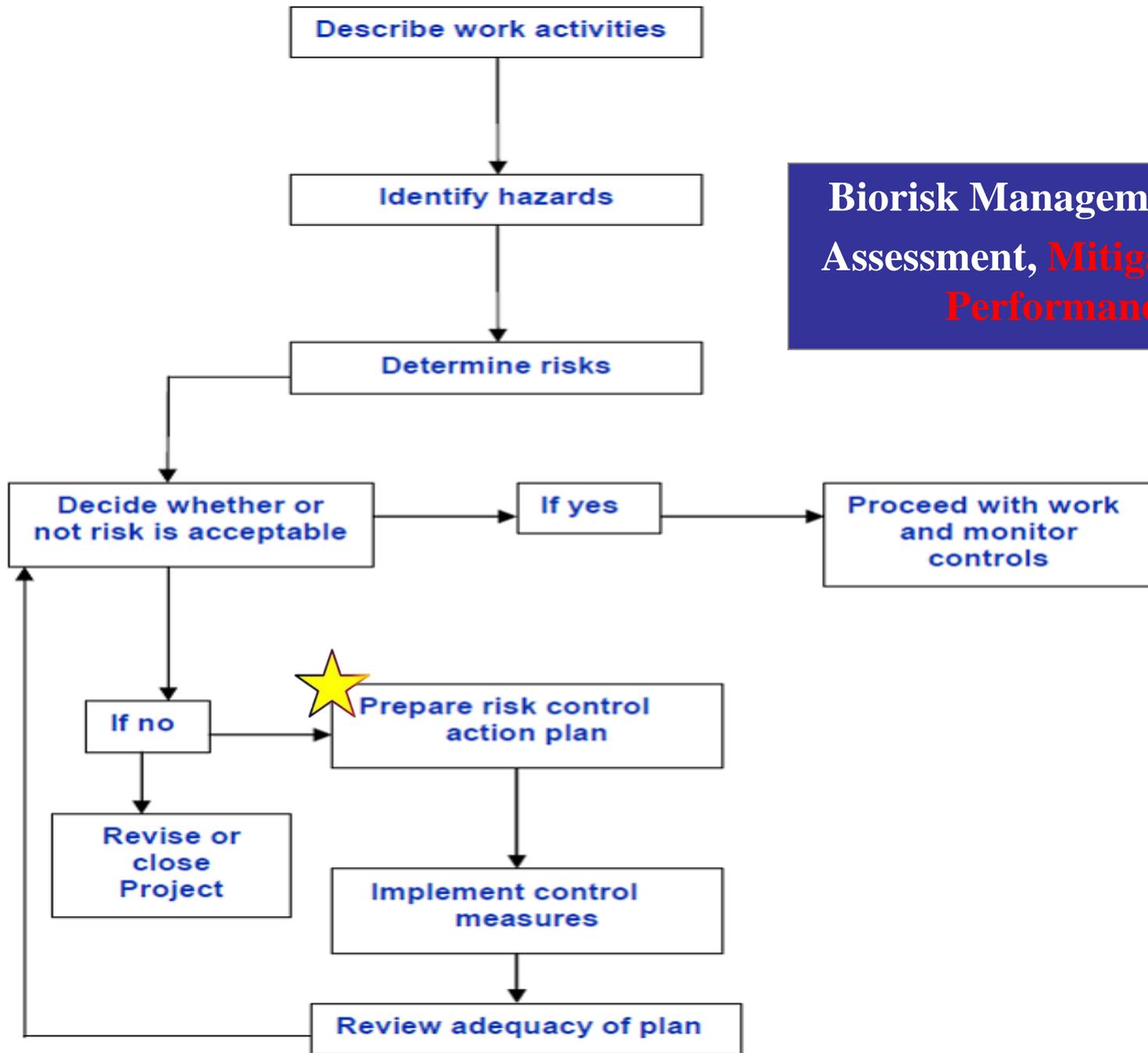
- **Value-based**

- What is acceptable, tolerable, and intolerable?



- Protect against unacceptable risk scenarios

- Develop incident response plans for acceptable risk scenarios



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



Review the provided scenario



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



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



BioRAM



BioRAM

vision & mission



- **Vision**

- A standardized approach to risk assessment
- Create understanding
 - A tool for prioritization
 - A tool for communication

- **Mission**

- Get consensus
 - **What risks do we see in bio-labs**
 - Get stakeholders from all over the world to help
- Create tool
 - **Make it available**



Strategy

- **Brainstorming**
- **Workshops**
- **Software design**
- **Workshops**
- **Software modification**
- **Workshops**
- **Software adjustment**
- **α , β testing**
- **Software finalizing**
- **Workshops – report generators**





BioRAM: Idea to Product: 3 years



2007

Feb-07

2nd Biorisk workshop in Winnipeg

2008

Oct-07

Internal Sandia funding received. Outline methodology

Mar-08

3rd Biorisk workshop in Winnipeg

2009

Oct-08

Review in Reno

Mar-09

4th Biorisk workshop in Winnipeg

Jul-09

Review by subject matter experts

Nov-09

Software release of α -version -version to limited peer review group

2010

May-10

Software release of α -version to large peer review group

Oct-10

Software release of β -version



Safety Risks based on routes of exposure

- Inhalation
- Ingestion
- Contact
- Percutaneous

Security Risk based on Adversary's level of access

- Insider
- Outsider

Agent Properties

Laboratory Procedures

Risk Assessment Model Beta

File Edit Assessment

Likelihood of Infection

Transmissibility

Humans

Inhalation

Is this agent known to cause infection via inhalation in humans (i.e. cause infection via deep-lung or alveolar route) that have entered the upper or lower respiratory tract) in a laboratory setting?

2

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1,000 as unknown in humans?

3

4 = Yes
2 = No
1 = Unknown
0 = If this is not an infectious route

Percutaneous

Is this agent known to cause infection via percutaneous exposure in humans (i.e. infection through compromised skin or direct injection into the blood stream) in a laboratory setting?

1

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

Is the infectious dose (ID50) of this agent for this route less than 1,000 in humans?

2

4 = Yes
2 = No
1 = Unknown
0 = If this is not an infectious route

Direct Contact

Is this agent known to cause infection via direct contact in humans (i.e. contact through the mucosal membranes) in a laboratory setting?

3

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

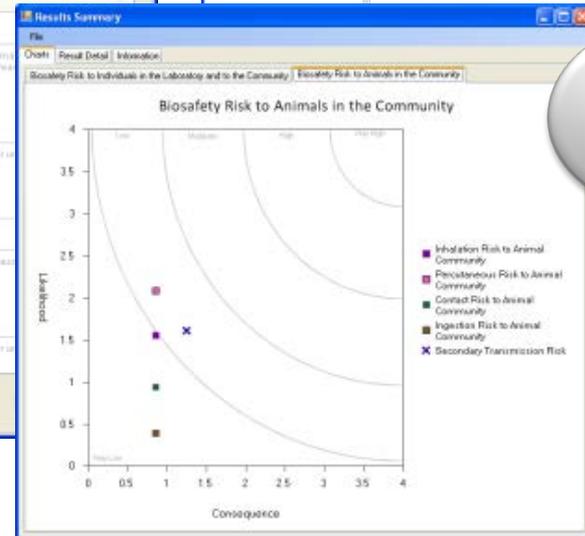
Is the infectious dose (ID50) of this agent for this route less than 1,000 in humans?

4

Response:

Flag response as an unknown answer

File	Default Charts	Result Summary	Question Impact
1.25526	Likelihood Ingestion Individual	0.246	Is the agent known to cause infection via ingestion in humans?
1.24473	Likelihood Percutaneous Individual	0.214	What is the potential for aerosols to be generated as a byproduct to the infectious dose (ID50) of the agent for the route less than 1,000?
1.02070	Likelihood Percutaneous Community	0.2	Is respiratory protection used in this procedure? (judged masks in use)
1.48339	Likelihood Contact Individual	0.1475	What is the potential and extent of a splash or spill in this procedure?
0.20739	Likelihood Ingestion Community	0.135	Does the laboratory have procedures in place for agent handling in Biosafety cabinets used in this procedure?
1.275875	Likelihood Percutaneous Community	0.102	Is all the equipment used in this procedure with a potential to generate aerosols?
1.471025	Likelihood Contact Community	0.102	Are there other forms of Primary Containment used in this procedure?
0.288443	Likelihood Ingestion Animal	0.09004	What is the implemented process for the decontamination of equipment?
1.953651	Likelihood Inhalation Animal	0.07425	What type of material will be used in this procedure? (if the procedure involves animal handling)
2.083456	Likelihood Percutaneous Animal	0.07425	Are animals housed in a manner that isolated or sealed to prevent escape?
0.936265	Likelihood Contact Animal	0.07425	Are animals transported in a manner that prevents aerosol escape?
0.283975	Consequence of Disease to Humans	0.045	Does the laboratory have animal handling procedures in place to prevent escape?
1.283775	Secondary Consequence of Disease to Humans	0.045	Are any animals are in use in this procedure?
0.95176	Consequence of Disease to Animals	0.00996	What is the special size of these animals?
1.24215	Secondary Consequence of Disease to Animals	0.03	What is the greatest volume of material existing at one time in the laboratory?
0.36683	Consequence of Disease to the Community	0.03	Are there more than one species of animal in use in the laboratory?
1.782753	Likelihood of Secondary Transmission	0.03	Are there any animals which have the potential to shed infectious particles?
1.02070	Likelihood of Secondary Transmission	0.03	How do you ensure do the laboratory animals used in this procedure have defined roles and responsibilities to be followed?
		0.00996	Has the laboratory made a commitment to safety?
		0.00996	Does the laboratory periodically review the laboratory program?
		0.00336	Are there any procedures in place for preventative equipment maintenance?
		0.00264	Does the laboratory have comprehensive facility documentation?
		0.00264	Does the laboratory conduct biosafety drills or exercises?
		0.00264	Are there standard operating procedures in place for unexpected events?
		0.00264	Does the laboratory have standard good laboratory practices?
		0.00132	Is there a formalized spill response procedure in place?
		0.00132	Is there a formalized decontamination program in place at the laboratory?
		0.00132	Are all biological waste disposal procedures followed?
		0.00066	Are all biological waste disposal procedures followed?



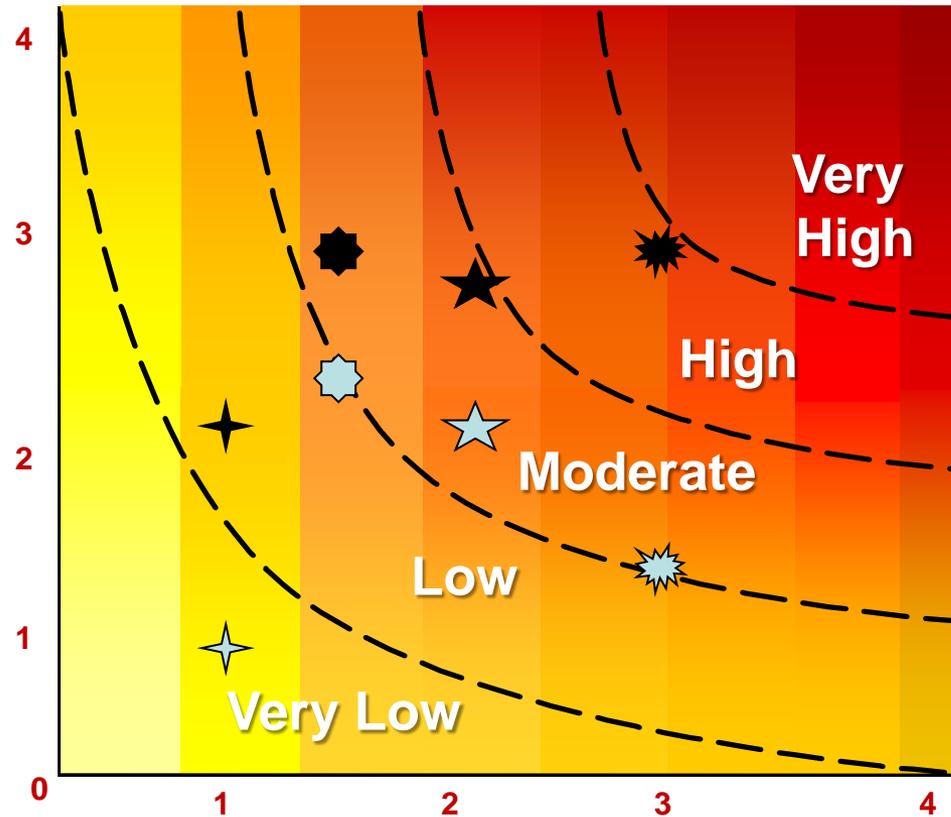


Likelihood – Consequence

Biosafety

Biosecurity

Both need to be addressed

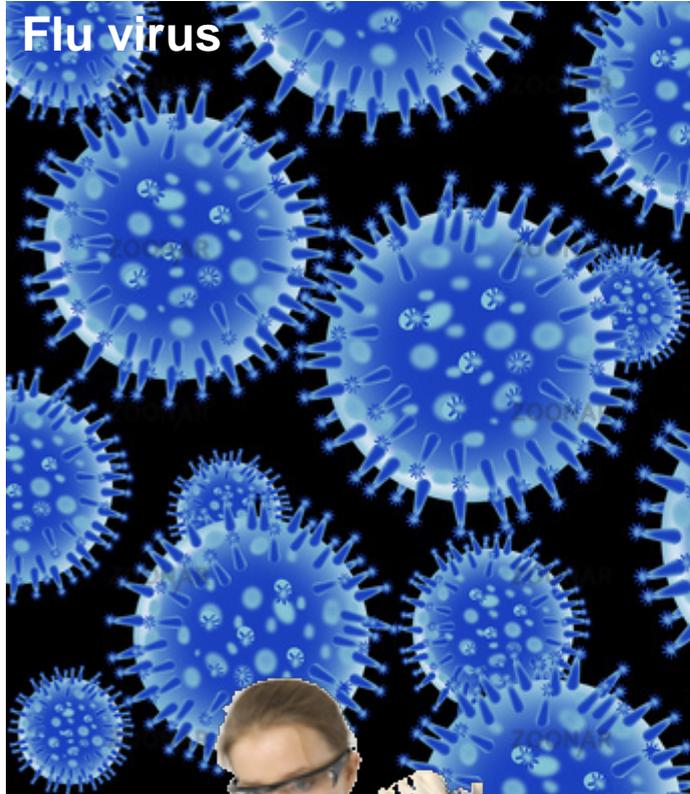




Biosafety RAM

Agents (Hazard)

Procedures



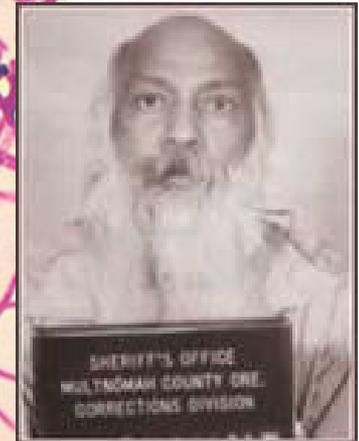
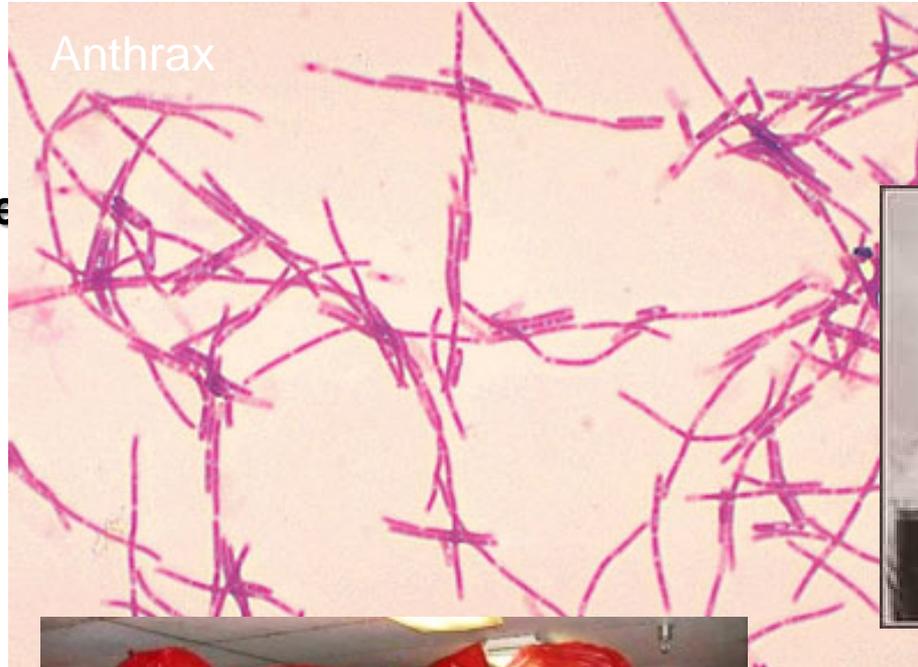


Biosecurity RAM

Agents (Hazard)

Laboratory Vulnerabilities

Adversary (Threats)



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BioRAM: Visual Impact

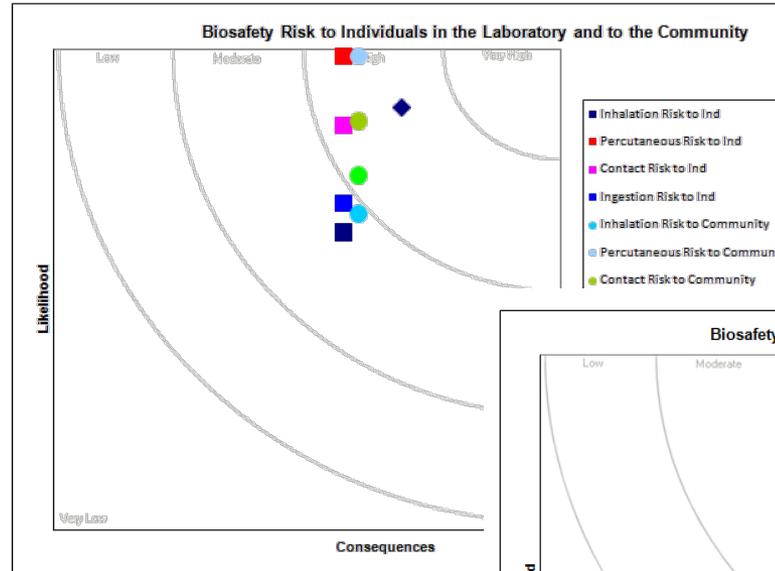
Example

Spietz Laboratory

Switzerland

Nipah Virus

Data from Spietz Laboratory Review of Biosafety RAM model (Daniel Kumin)



Before mitigation

Figure 1: Risks posed by Nipah Virus prior to any implementation of Mitigation

After mitigation

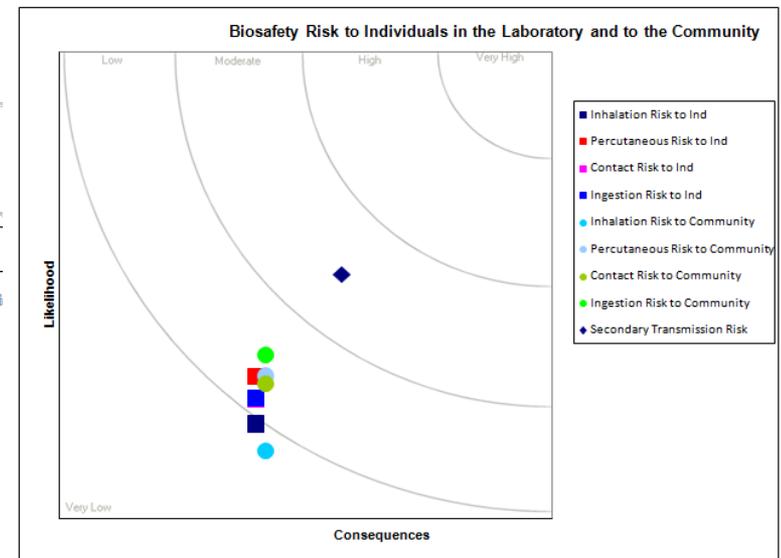


Figure 2 Risks posed by Nipah virus post implementation of procedural, engineering, and ppe control measures



- **In your group, conduct a biorisk assessment based upon the example(s) provided.**
 - Define the Hazard(s)
 - Define the Threat(s)
- **Using BioRAM characterize the risks associated with your example(s)**



- **Is this risk acceptable?**
 - Why or why not?



Risk Communication

- **Whom should you communicate these risks?**
- **What about these risks should you communicate**



- **If your risk was unacceptable, define one or two mitigation measures you would like to implement.**
- **Input the scores into BioRAM to reflect the implementation**
- **How does this change your risks? Are they now acceptable?**



- **How do you see this type of risk assessment aid in risk communication?**



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



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)

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

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