Biorisk Assessment

High Containment Workshop

May 2011

Susan Caskey
International Biological Threat Reduction
sacaske@sandia.gov

www.biosecurity.sandia.gov

SAND No. 2010-2121P
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.

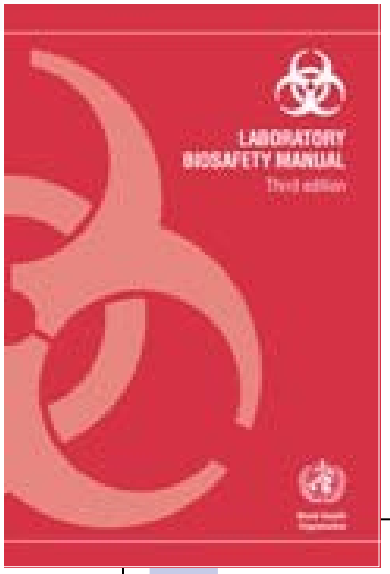
International
BIOLOGICAL THREAT REDUCTION

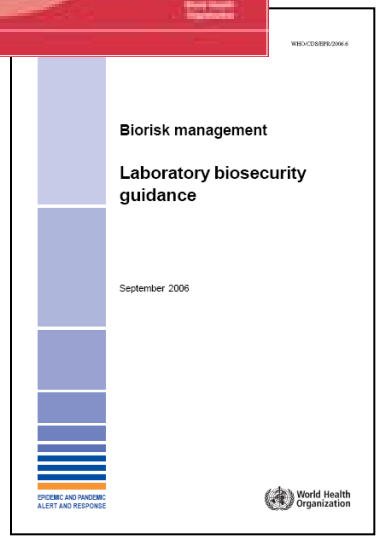
Risk Assessment

- **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**



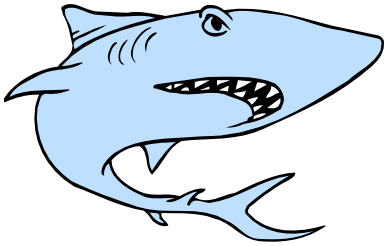


International
BIOLOGICAL THREAT REDUCTION

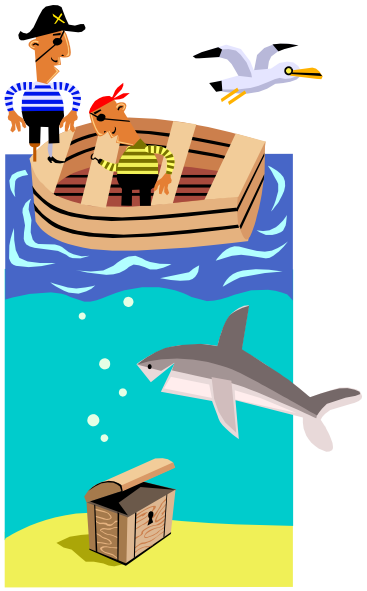
What is a hazard?

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

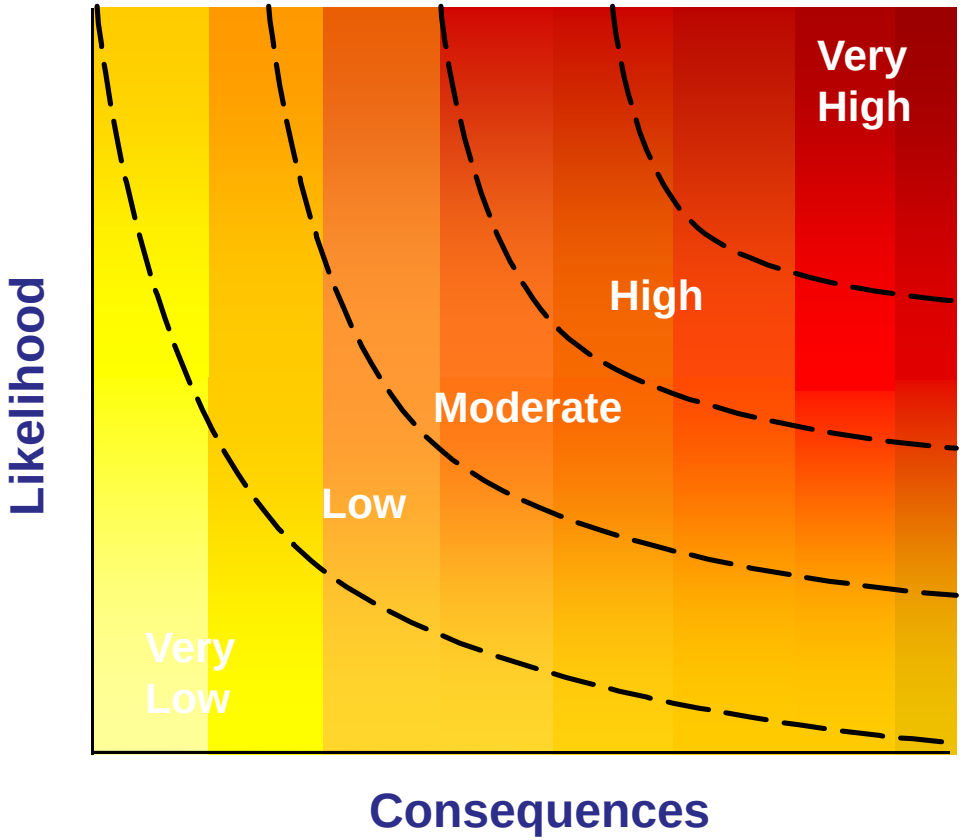
Tiger Assessment (page 6)

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

International
BIOLOGICAL THREAT REDUCTION

What is risk?

Risk is a function of likelihood and consequences

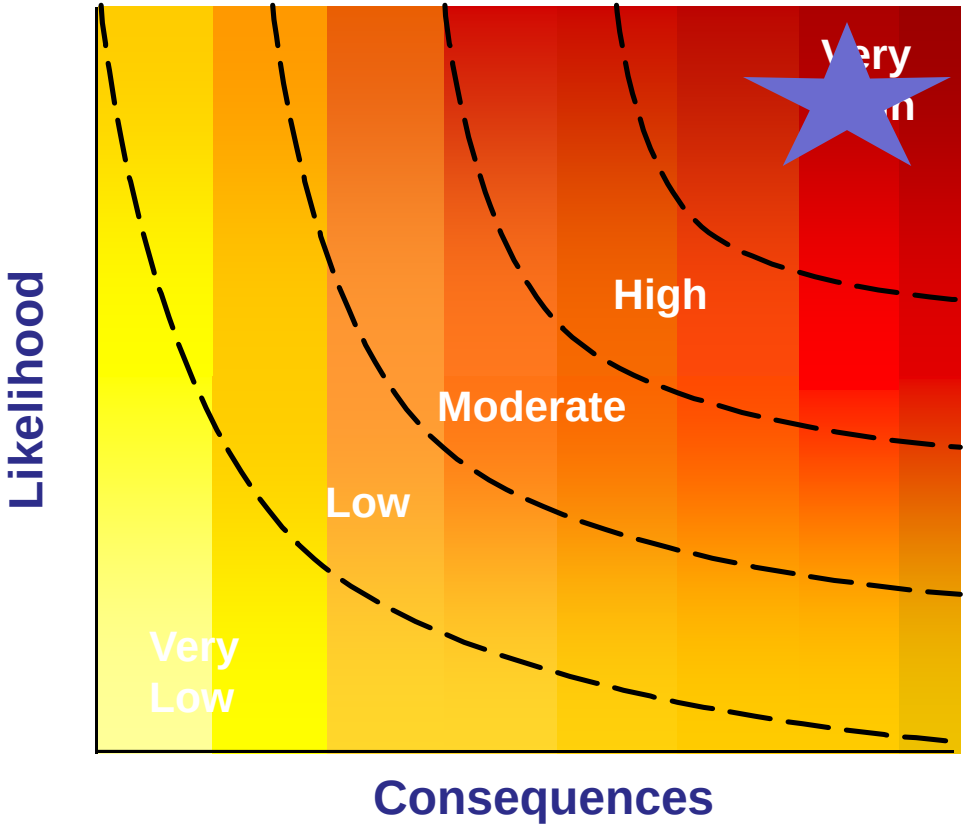


$$R = f(L, C)$$

International
BIOLOGICAL THREAT REDUCTION

R = f (L, C)

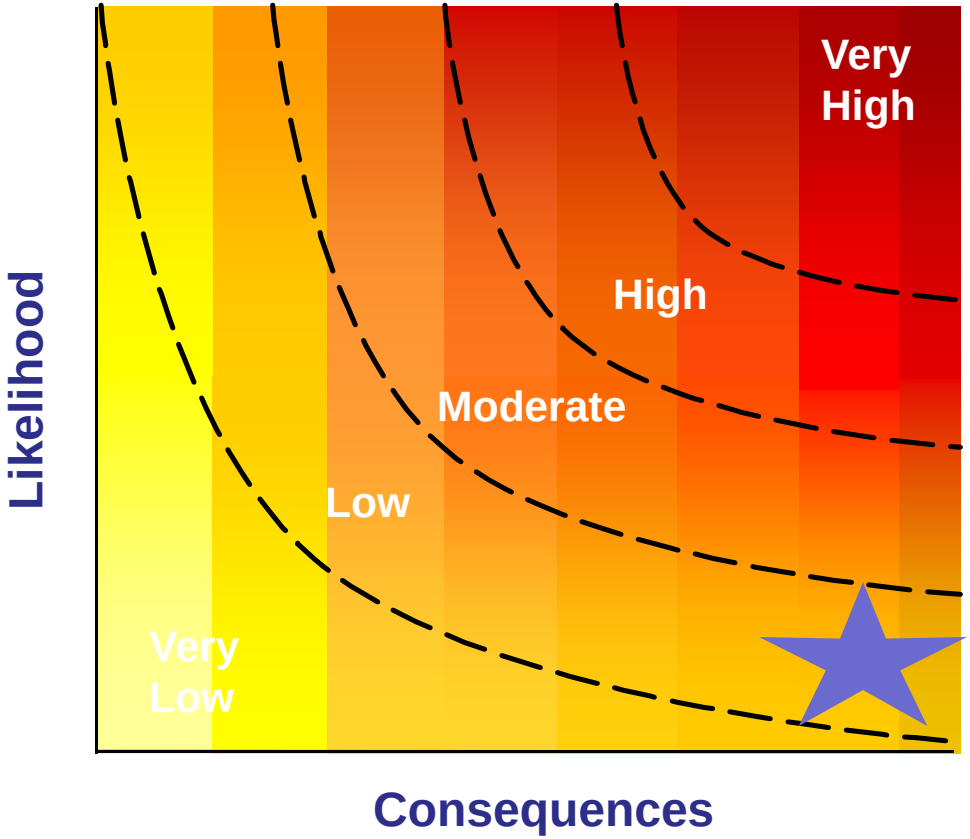
You are in an open field next to a very hungry, aggressive, adult tiger that is unrestrained and sees you as food

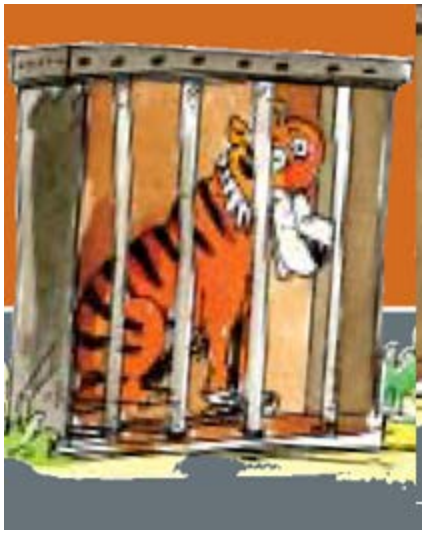


International
BIOLOGICAL THREAT REDUCTION

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

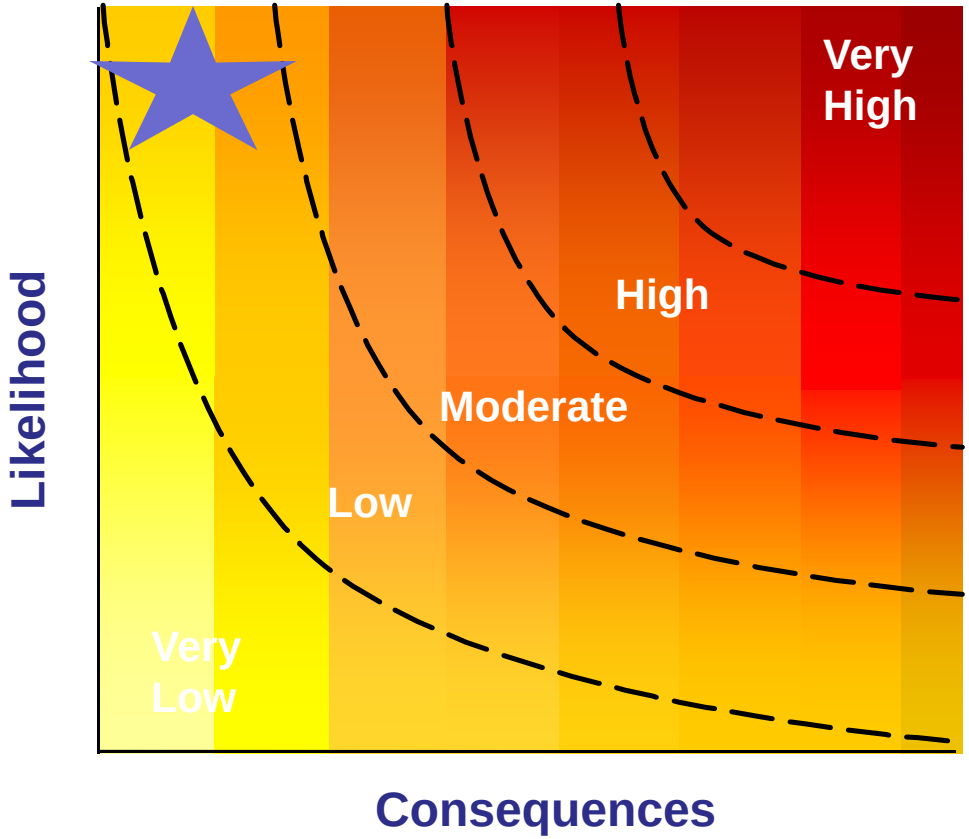




International
BIOLOGICAL THREAT REDUCTION

R = f (L, C)

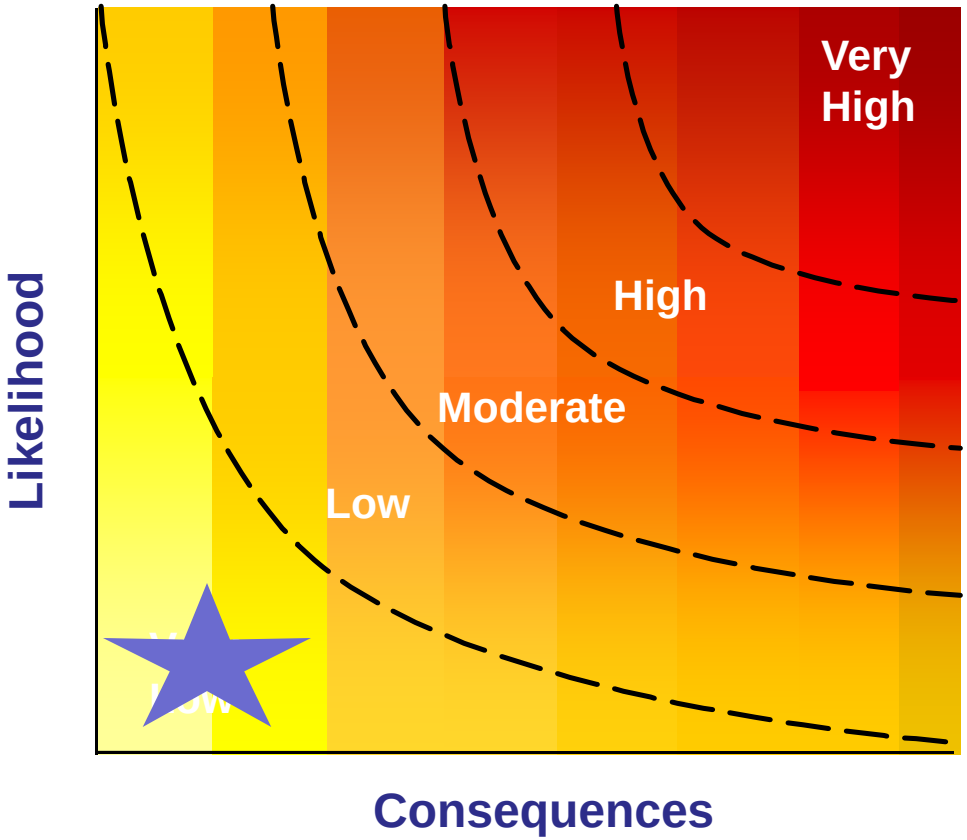
You are holding a tiger kitten with a playful temperament



International
BIOLOGICAL THREAT REDUCTION

R = f (L, C)

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



International
BIOLOGICAL THREAT REDUCTION

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**

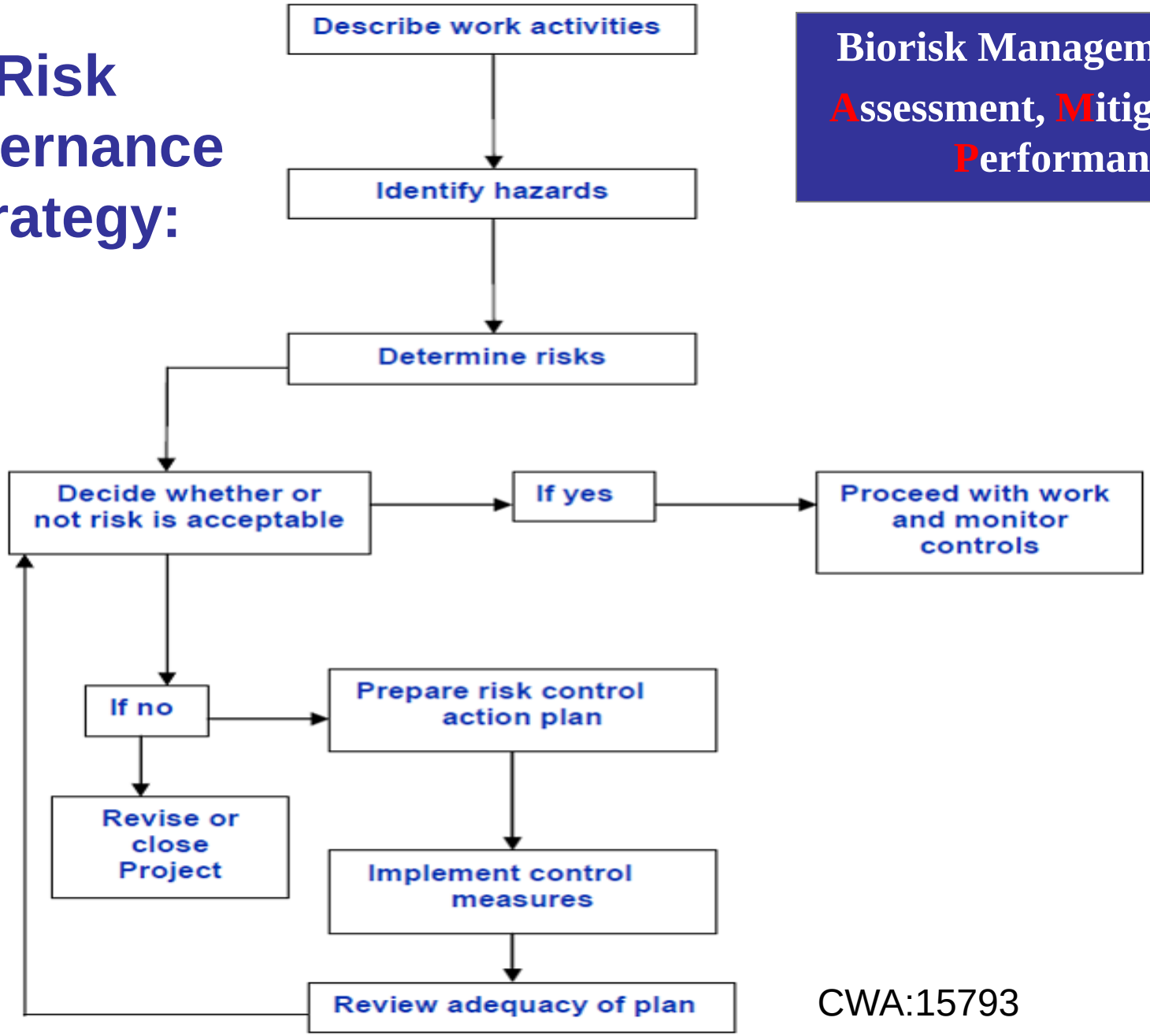
Laboratory Biorisk Assessment (page 11)

- **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.

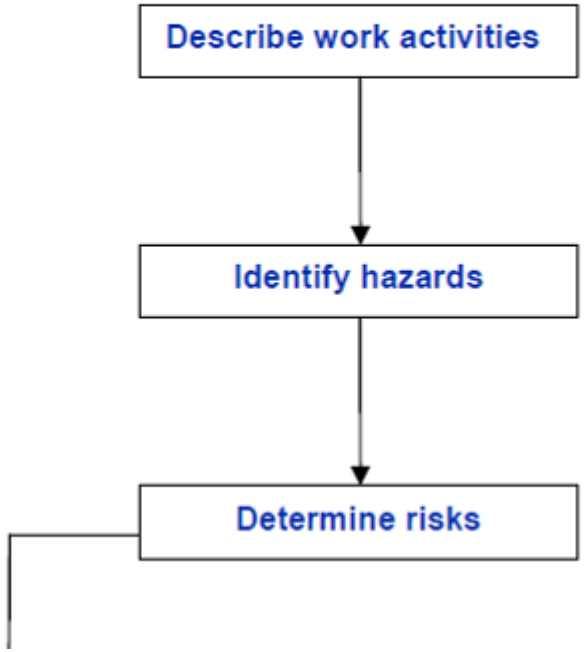
Risk Governance Strategy:



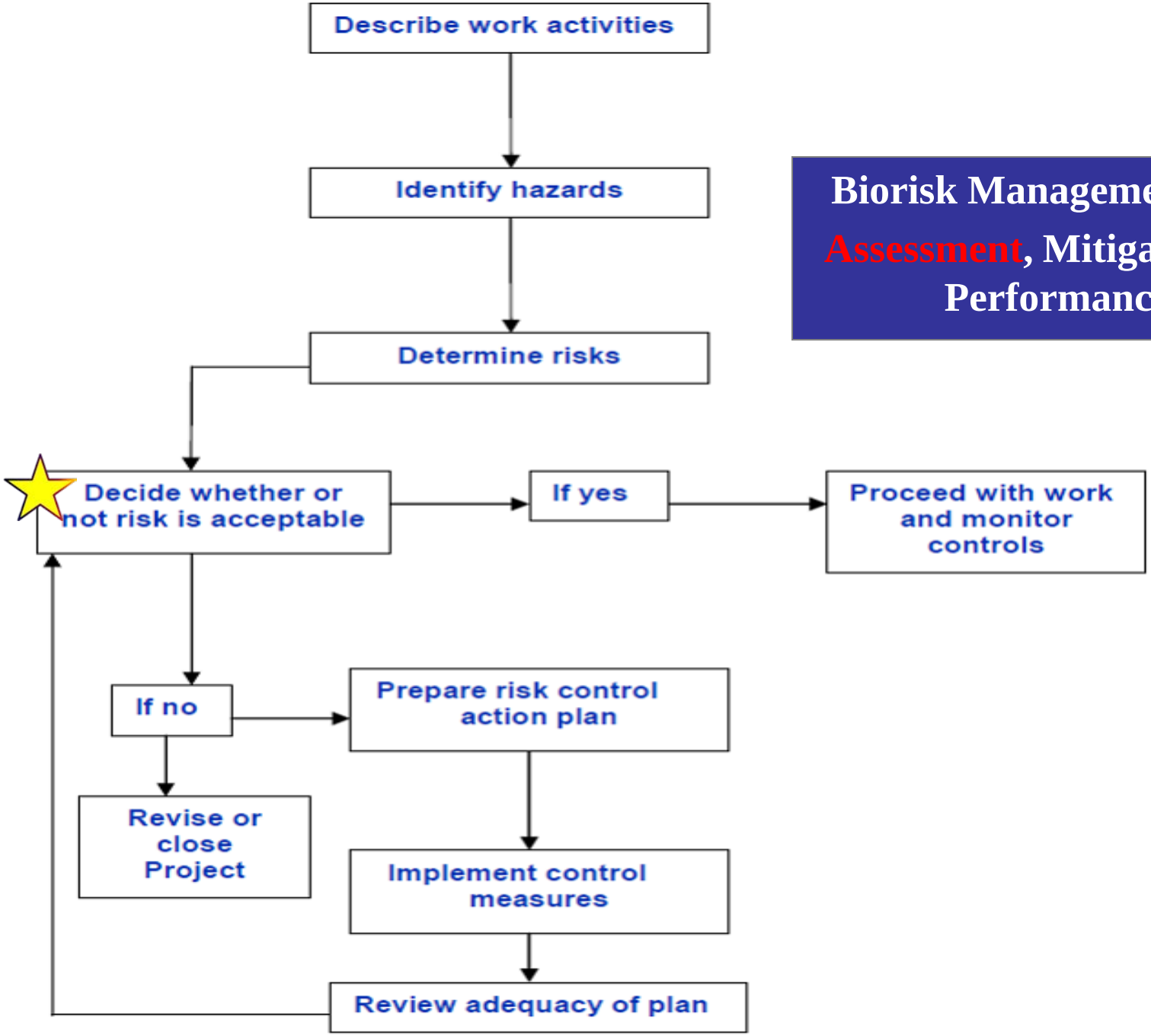
Biorisk Management = Assessment, Mitigation, Performance

CWA:15793

Biorisk Management = Assessment, Mitigation, Performance



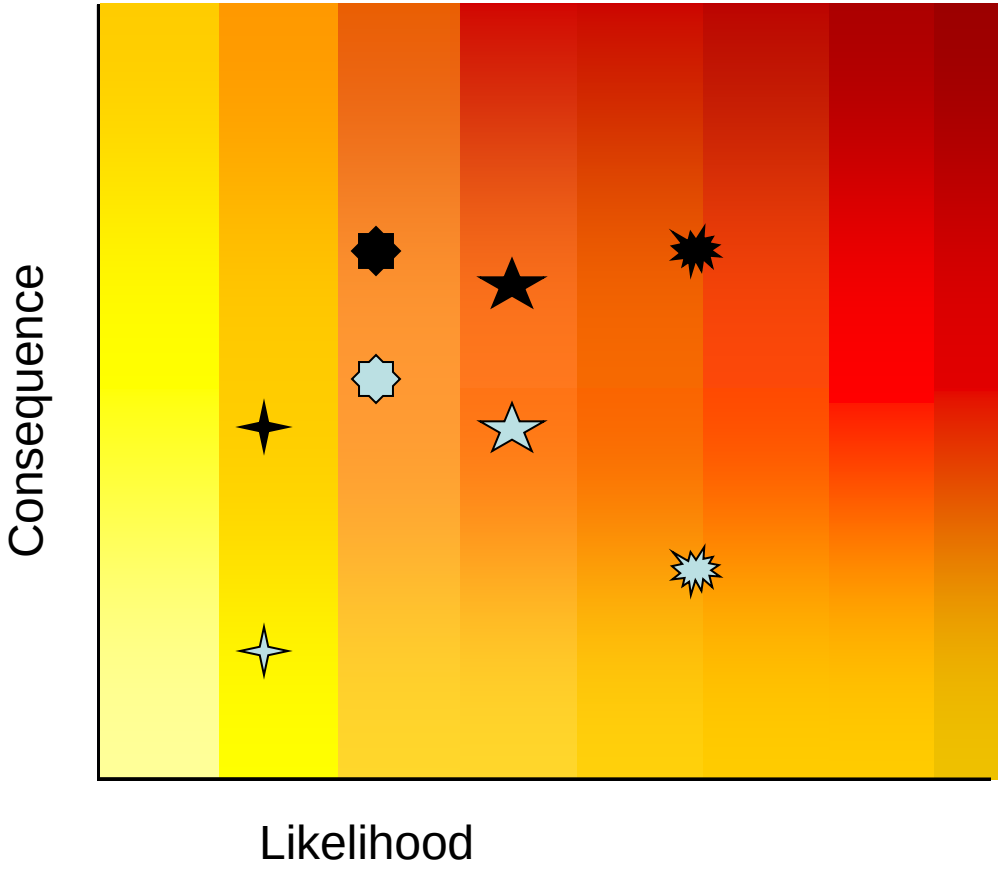
International BIOLOGICAL THREAT REDUCTION



Biorisk Management = Assessment, Mitigation, Performance

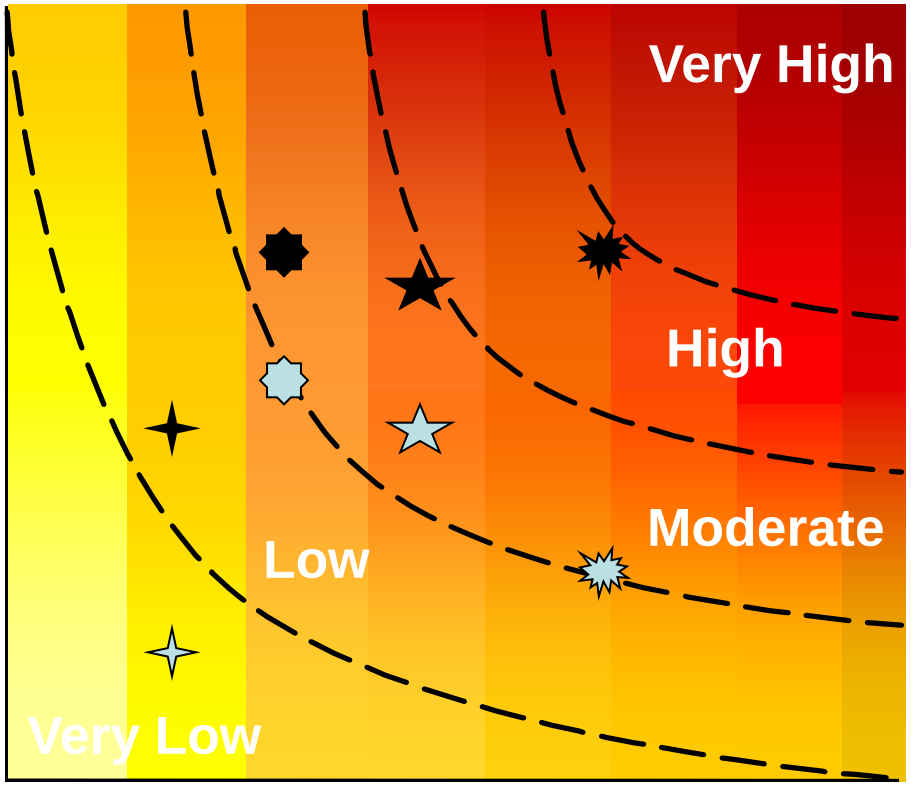
Risk Characterization

- **Evidence-based**



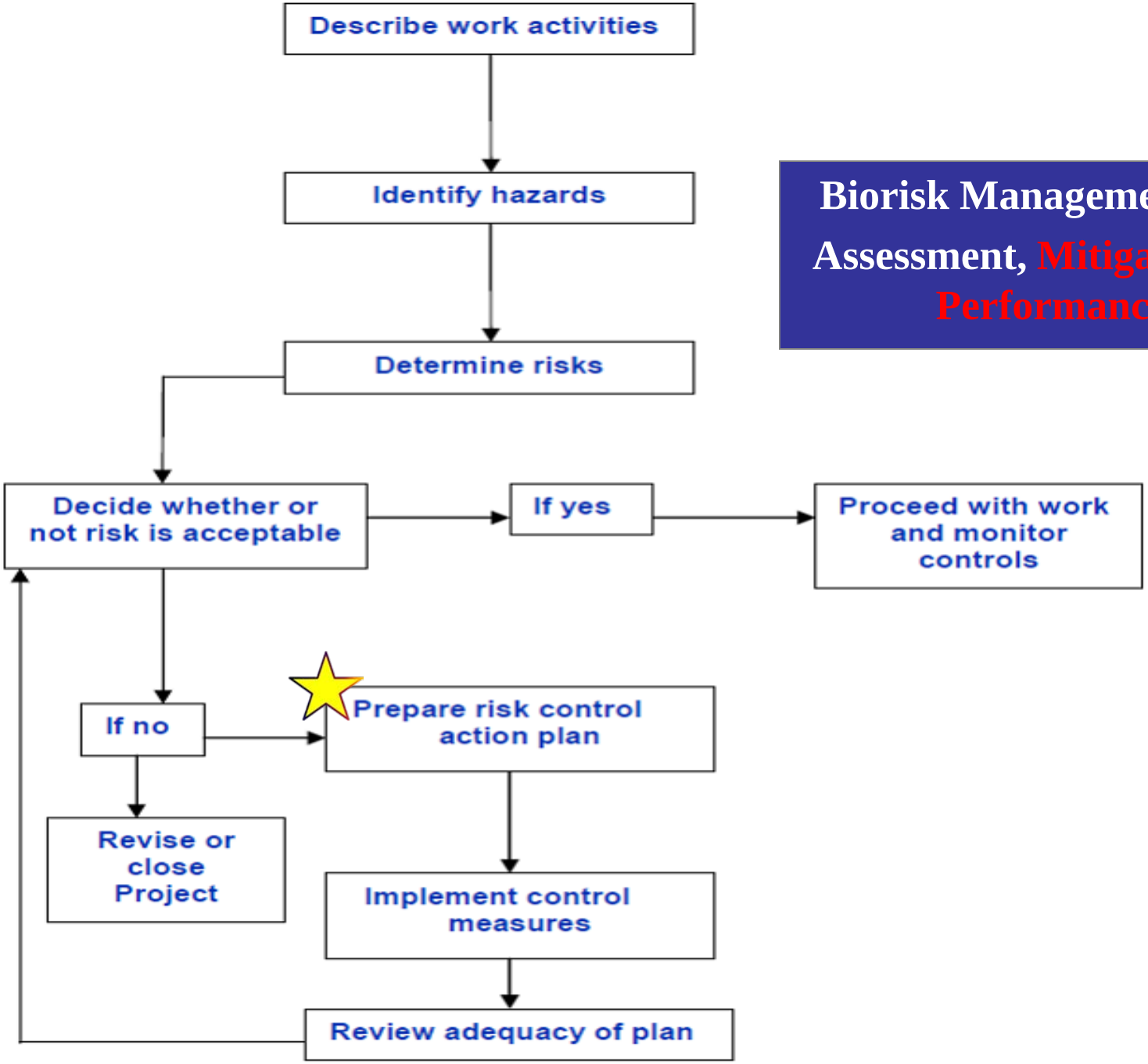
Risk Evaluation

- **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

Laboratory Biosafety Risk Assessment Methodology (Biosafety RAM)

Risk = *f* (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)

Risk = *f* (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

LDRD LABORATORY DIRECTED RESEARCH & DEVELOPMENT

International BIOLOGICAL THREAT REDUCTION

- **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 you 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)
  - **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