

# Biorisk Assessment

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*International Biological Threat Reduction Program*

*Sandia National Laboratories*

*American Biosafety Association Preconference Course*

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## Instructor Bios

### Jennifer Gaudioso, PhD

**Jennifer Gaudioso** is a Principal Member of the Technical Staff in the International Biological Threat Reduction Program at Sandia National Laboratories (SNL). Her work focuses on the responsible use of biological agents, equipment, and expertise at bioscience facilities, with an emphasis on risk assessment. Jennifer has worked extensively on laboratory biorisk management issues internationally. She has consulted on these topics for basic and high containment bioscience laboratories in over thirty countries. In recent years, she has organized many international conferences, trainings, and workshops. Jennifer led the design of SNL's training laboratory and associated course, Controlling Laboratory Biorisks. She has also participated in assessments at US government bioscience facilities, and contributed to the development of international biosecurity guidelines. She is author of numerous journal articles and has presented her research at national and international meetings. She also co-authored the Laboratory Biosecurity Handbook, published by CRC Press. Jennifer serves on SNL's Institutional Biosafety Committee, and is an active member of the American Biological Safety Association. She earned her Ph.D. at Cornell University.

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### Susan Caskey

**Susan Caskey** is a Senior Member of the Technical Staff in the International Biological Threat Reduction Program at Sandia National Laboratories (SNL). Currently, she is the project lead for biosafety and biosecurity work in South Asia along with leading efforts on developing formal risk assessment tools for biosafety and biosecurity. Susan has degrees in Biology and Computer Science specializing in information management and security. She is also certified in network security architecture and has designed and implemented secure information management systems worldwide. Susan designs methodologies for performing biological risk assessments and conducts assessments of biological agents and bioscience facilities. She provides a wide range of training in both information security and biological threat reduction; focused on biosafety and biosecurity. In addition, Susan has designed and implemented network based disease surveillance systems for humans and animals; including the backend database as well as the communication components. She performs statistics based risk assessments of biological agents and, audits and secures biological databases, and has conducted physical security assessments of bioscience facilities. Susan has contributed to the development of international biosecurity guidelines focusing on information management. Recently, she has been developing laboratory based biosecurity and biosafety standards, procedures, and risk assessment tools for laboratories working on high risk agents.

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## Learning Objectives

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By the end of the course, participants should be able to meet the following objectives:

1. Understand the principle of AMP and specifically the value of assessment
2. Define risk
3. Develop a risk model for biosafety and/or biosecurity
4. Compare the differences between technical assessments and concern assessments

## Biorisks

**What are the risks of working with biological material?**

Work in your group to identify some of these risks

**1.**

**2.**

**3.**

Use these risks to develop a definition for biorisk:

*CWA 15790 Laboratory Biorisk Management Standard, Feb 2008* defined biorisk as:

**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

In your group, answer the following questions

**How do you identify risks?**

**How do you manage risks?**

**How do you know your management strategy is working?**



## Biorisk Assessment

Why is doing a risk assessment important?

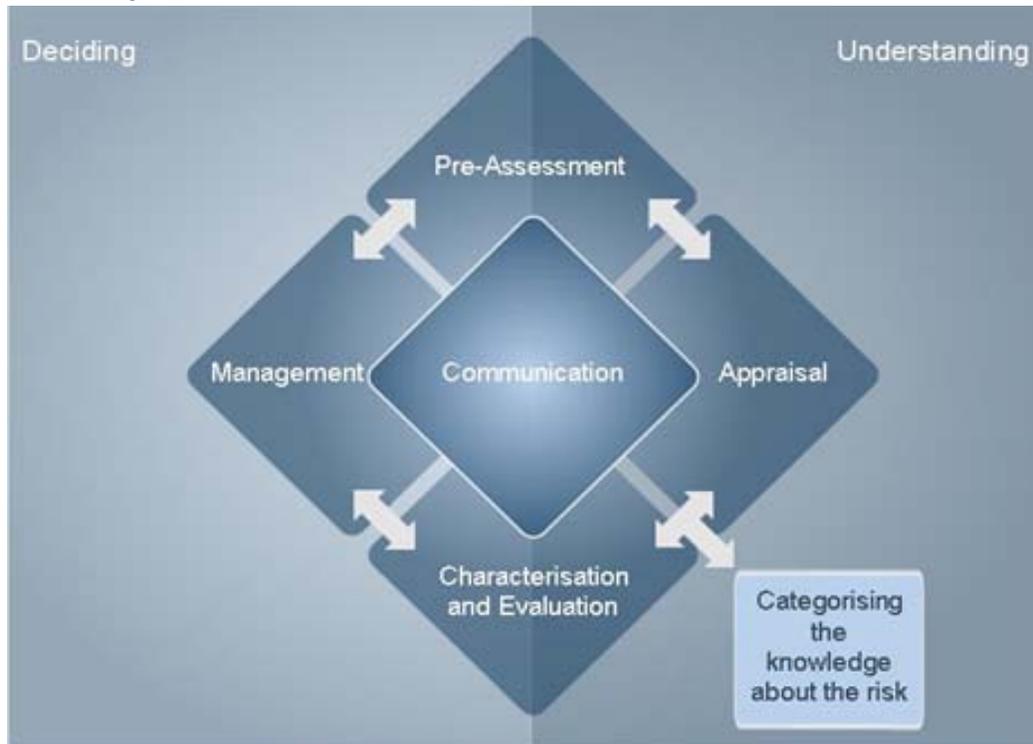
### Laboratory Biosafety

- 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**

## Risk Analysis Process



The Pre-assessment identifies the risks to be assessed, determines the mode of assessment (creates the model) and collects needed data for the assessment.

The Appraisal is the conducting of both a technical assessment and also evaluating risk perceptions.

Information which is unknown or uncertain should be documented and communicated.

Risk Characterization is the process of presenting the risk results without judgment.

Risk Evaluation is the process of making judgments based upon the risk characterization

Management must make the final determination of the acceptability of the risk. This process also includes reviewing risk perceptions and regulations to make the determination of risk mitigation strategies.

- Work in your group to explain why we handle the following agents differently in the laboratory:

Ecoli K-12

HIV

MDR-TB

*Shigella*

*B. Anthracis*

Ebola

1.

2.

3.

4.

5.

6.

7.

8.

Can you place your reasons into one of these two categories?

**How the agents get into a host**

**What that agent does to the host**

Based on these characterizations, how would you define risk?



## Risk

Is a function of Likelihood and Consequence



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## Risk Assessment Principles

- **Define the problem**
  - What is the question you are trying to answer with your risk assessment?
- **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**

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Activity: A researcher is working to create a new animal model for HIV studies. Using mice, he plans on injecting HIV. A technician will hold the animals for the researcher during inoculation. The researcher has been distracted lately and keeping all the laboratory information to himself.

*HIV causes the disease Aids and is transmitted in a laboratory through percutaneous exposure and mucosal membranes (typically the eyes). In the natural environment HIV is transmitted from person to person through exchange of body fluids.*

What are the risks associated with this work?

For one of the identified risks, define the questions you need to answer to you need to conduct a risk assessment? E.g. route of infection, mortality rate of agent, etc...

Likelihood:

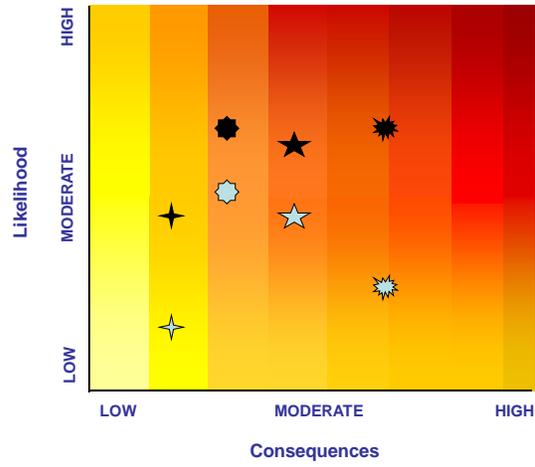
<b>FACTOR</b>	<b>Define good</b>	<b>Define Bad</b>
1. Use of sharps	No sharps in use	Sharps used without training, controls, or appropriate PPE...
2.		
3.		
4.		
5.		
6.		
7.		
8.		

## Consequences

<b>FACTOR</b>	<b>Define good</b>	<b>Define Bad</b>
2. Mortality Rate of Agent	No mortality	High rate of mortality (over 90%)
2.		
3.		
4.		
5.		
6.		
7.		
8.		



## Risk Characterization

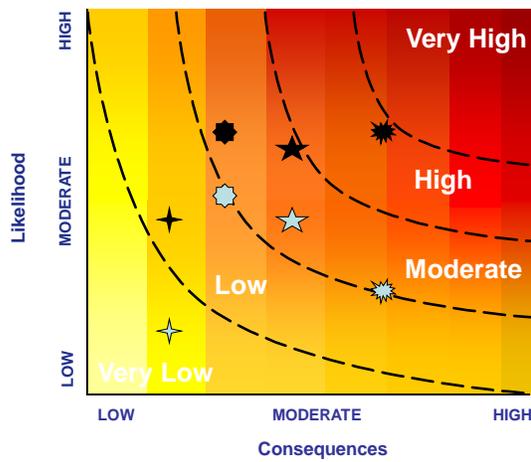


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## Risk Evaluation

What is acceptable, tolerable, and intolerable?



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### Case Studies

1. Medical technologists are using blood cultures to diagnosis *Brucella melitensis* using commercial blood culturing systems.
2. Medical technologists are using clinical stool samples to look for diarrheal diseases with a focused look for MDR strains of *Shigella sonnei*. The technologists are culturing the bacteria and upon identification of *Shigella* strains are conducting sensitivity tests looking for MDR strains.
3. A bovine has been exhibiting signs of FMD, a veterinarian collected nasal swabs which have been sent to the laboratory for testing. Testing will be done using RT-PCR.
4. A researcher is conducting drug sensitivity studies of TB positive human samples to determine if strains are MDR or XDR. Studies are done in culture tubes.

## Laboratory Biosafety Risk Assessment Methodology (Biosafety RAM)

$$\text{Risk} = F(\text{Likelihood}, \text{Consequence})$$

- **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

**For your case study, be prepared to answer the following questions:**

What are the routes of infection? What are the possible routes of exposure?

What are the consequences of disease and to whom?

Is this risk high, moderate, or low? Acceptable? Why?

## Laboratory Biosecurity Risk Assessment Methodology (Biosecurity RAM)

$$\text{Risk} = F(\text{Likelihood}, \text{Consequence})$$

### 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

**In your group, conduct a biosecurity risk assessment based upon the example(s) provided.**

What is the potential for misuse of the agent? What are the possible areas an adversary could acquire the agent?

What are the consequences of misuse and to whom?

Is this risk high, moderate, or low? Acceptable? Why?

What are some of the benefits of a structured risk assessment?