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# Biorisk Management – Orientation, Assessment and Mitigation for Biosafety and Biosecurity

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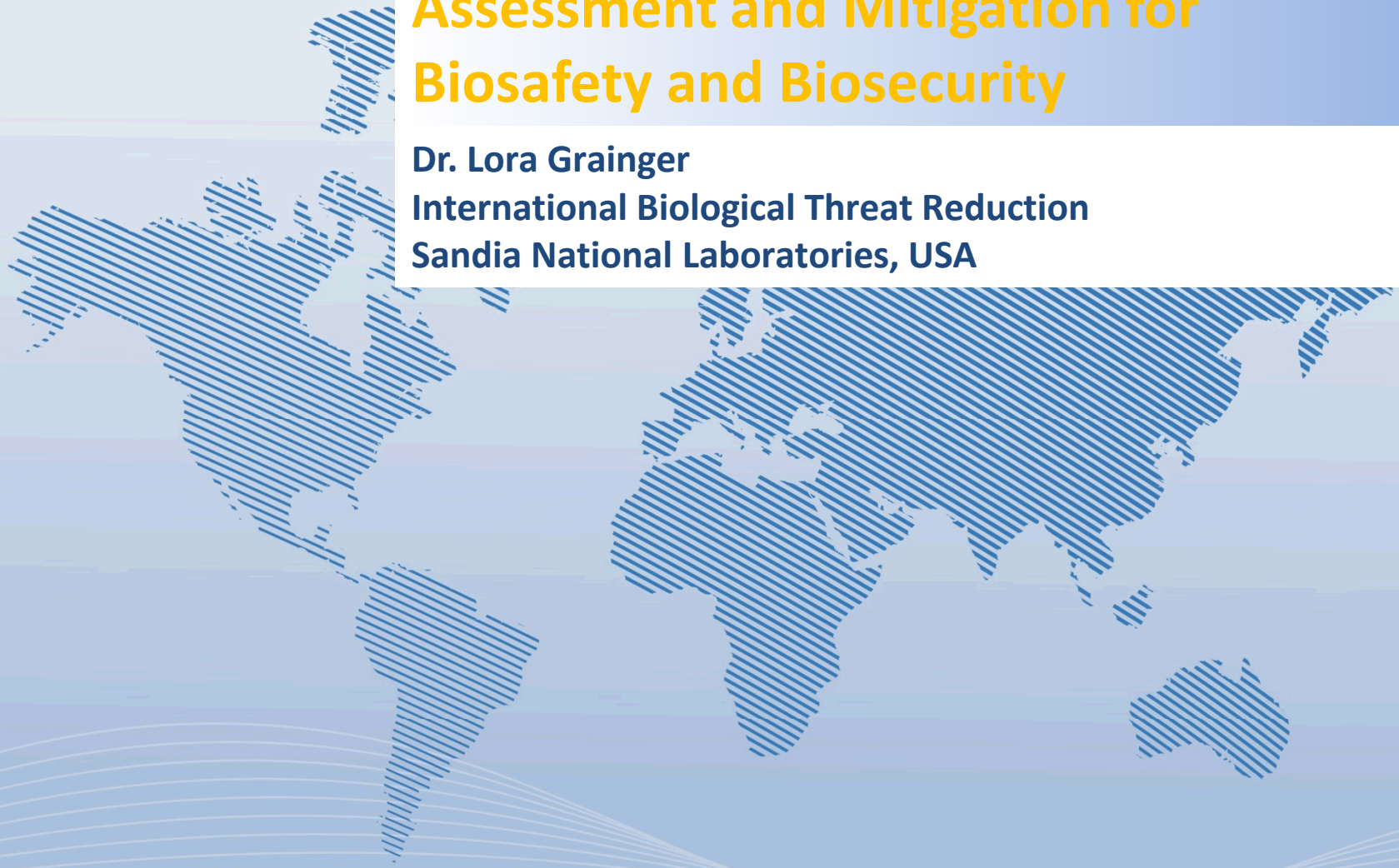
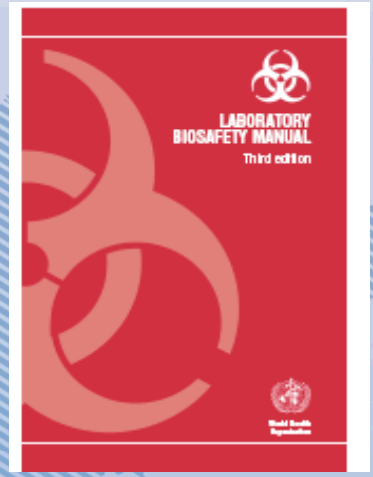
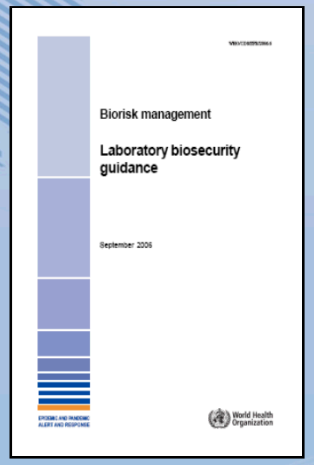


# Definitions

- **Laboratory biosafety**: containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]
- **Laboratory biosecurity**: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. [2]




[1]Laboratory biosafety manual, Third edition (World Health Organization, 2004)

[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

# Biorisk Management: the AMP Model

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

# Key Components of Biorisk Management

- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

# Key Components of Biorisk Management

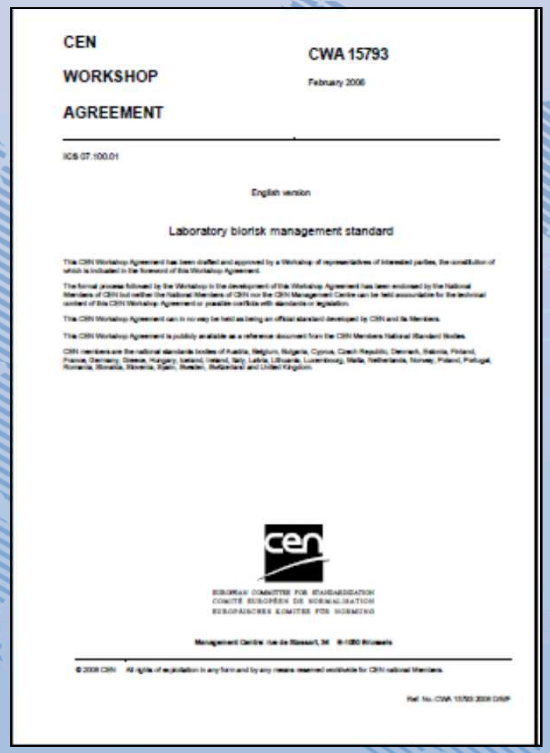
- Biorisk **Mitigation**
  - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

# Key Components of Biorisk Management

- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

# Laboratory Biorisk Management

- System or process to control **safety** and **security** risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities



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CWA 15793

February 2006

ICS 07.100.01

English version

Laboratory biorisk management standard

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. CWA 15793:2006 D/NP

# CWA 15793: Laboratory Biorisk Management

- Is a management system standard consistent with other international standards such as
  - ISO 9001 / 14001 and OSHAS18001
- The Standard is performance oriented
  - Describes what needs to be achieved
  - How to do it is up to the organization
- Does not replace national regulations
  - Compliance with local regulations is mandatory under CWA 15793
- Designed to be comprehensive framework for biosafety & biosecurity (biorisk) program
  - Risk-based; applicable to broad range of organizations, not just high containment labs

# Purpose of the CWA 15793:2011

The Standard is used for:

- Improving overall laboratory biorisk management and performance
- Increasing awareness and the adoption of performance (outcome) based approaches for biosafety and biosecurity
- Improving international laboratory collaboration and safety harmonization
- Supporting laboratory certification/accreditation, audits/inspections

# International Approach

- Extensive definition section
- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- Derived from the current WHO Biosafety and Biosecurity Guidelines

# Key Components of Biorisk Management

- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

**Question:**

*How can you identify these risks?*

# Introduction to Biosafety Risk Assessment

A **biosafety risk assessment** is an analytical procedure designed to characterize and evaluate ***safety*** risks in a laboratory.

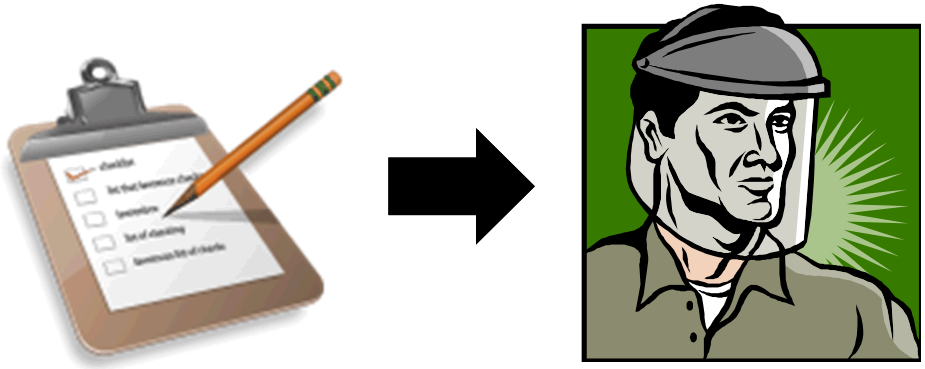
# Introduction to Biosafety Risk Assessment

To be comprehensive:

A **biosafety risk assessment** should consider **every activity and procedure** conducted in a laboratory that involves **infectious disease agents**.

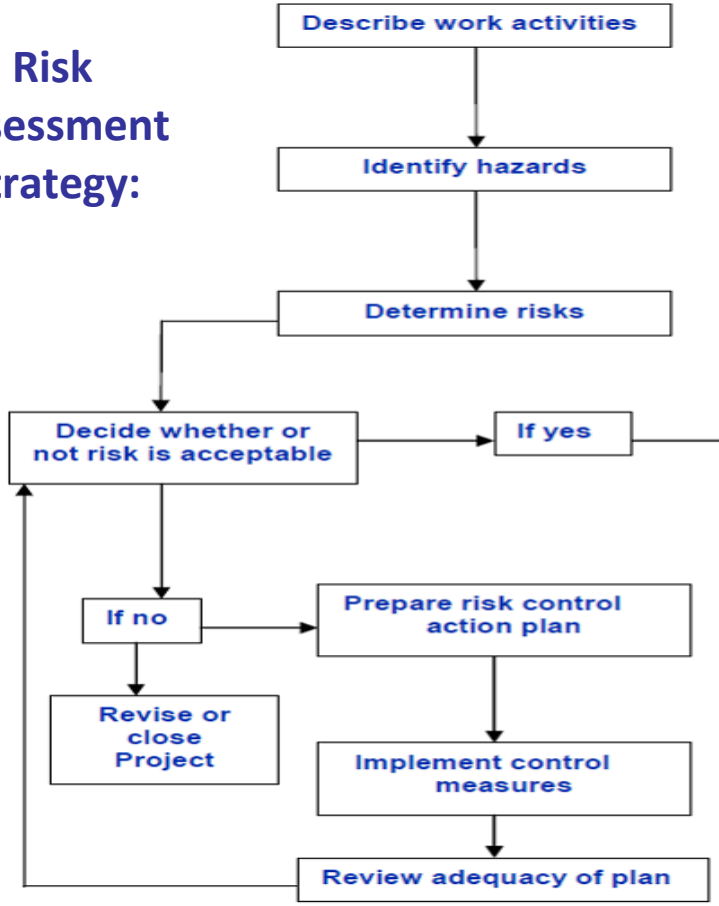
# Introduction to Biosafety Risk Assessment

A **biosafety risk assessment** allows a laboratory to determine the relative level of risk its different activities pose, and helps guide **risk mitigation decisions** so these are targeted to the most important risk.



# Risk Assessment Strategy

**Risk Assessment Strategy:**




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

Source: CWA 15793:2011

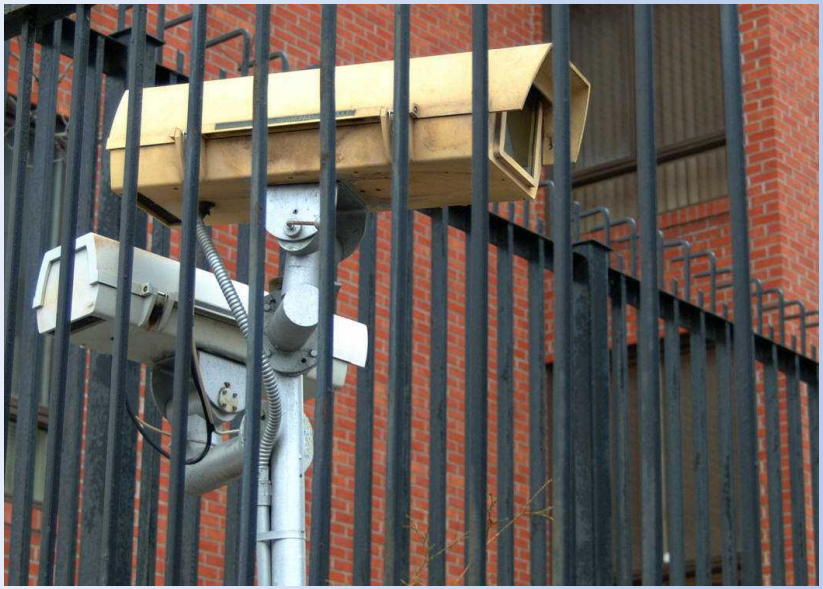
# Laboratory Biosecurity

For this course, **Laboratory Biosecurity** can be defined as:

***A set of preventive measures designed to reduce the risk of intentional removal (theft) or release of a valuable biological material in order to cause harm to others.***

# Introduction to Biosecurity Risk Assessment

A **biosecurity risk assessment** is an analytical procedure designed to characterize ***security*** risks in a laboratory.



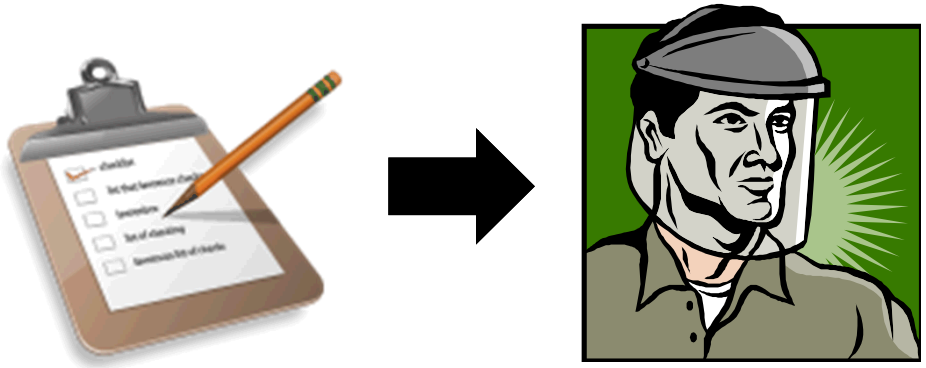
# Introduction to Biosecurity Risk Assessment

To be comprehensive:

A laboratory **biosecurity risk assessment** should consider every **asset**, **adversary** and **vulnerability** in an institution and its component laboratories and units.

# Introduction to Biosecurity Risk Assessment

A **biosecurity risk assessment** allows an institution or laboratory to determine the relative risk of security threats and/or vulnerabilities to help **guide risk mitigation decisions** so these are targeted to the most important risk.



# Risk

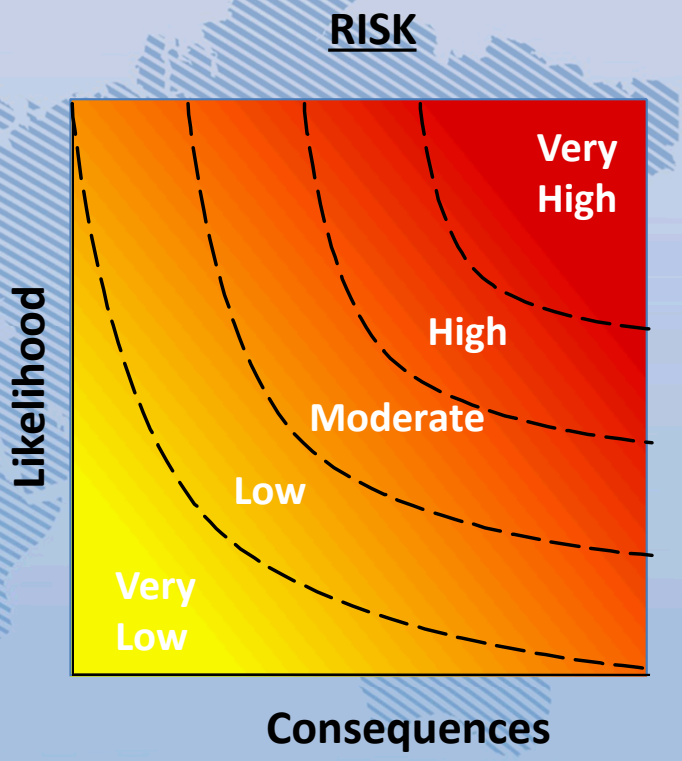
**Question:** What is Risk?

***Risk is the likelihood of an undesirable event happening, that involves a specific hazard or threat and has consequences***

**Risk = f (likelihood, consequences)**

or, more simply,

**Risk** is a function of both the **Likelihood** of something happening and **Consequences** of that occurrence



# Risk

**Question:** What is the **risk** of being attacked by a tiger?

What would you need to know to answer this question?

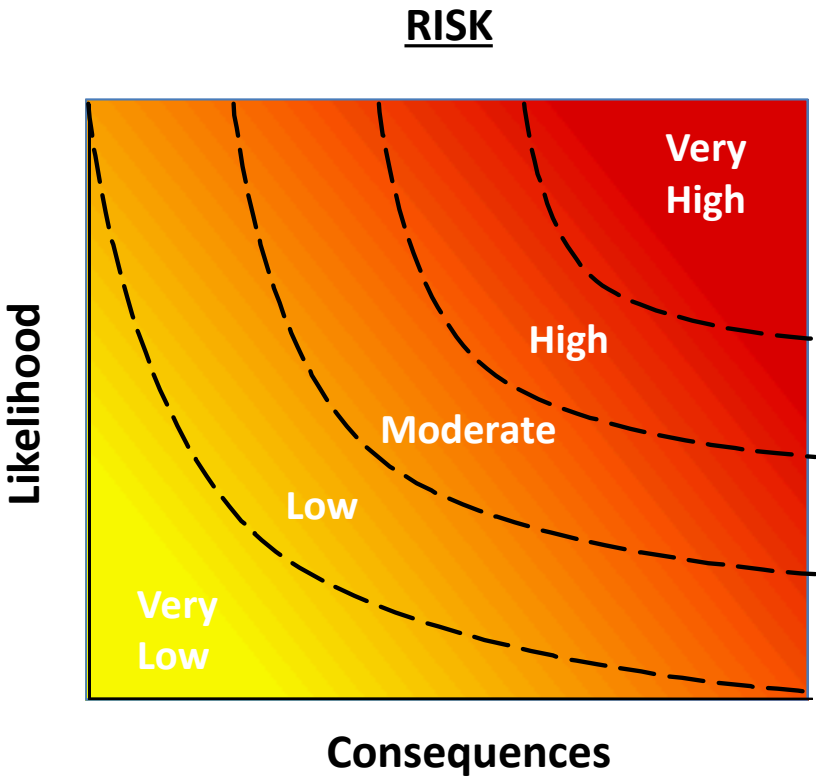
To help with this task, in your group, spend **5 minutes** listing all **examples of useful information** on sticky-notes and place them on your flip chart.

Be prepared to report your **criteria** to the class.

# Risk

Let's consider the previous question in terms of **Likelihood** and **Consequences**, and the graph on the right.

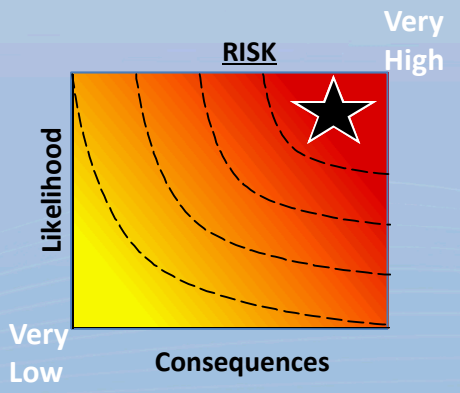
**R = f(L, C)**



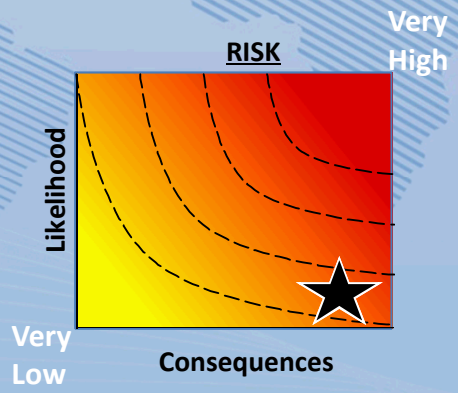
# Risk

**For the following scenarios**, draw a **STAR** where the **risk** would fall on the graph.

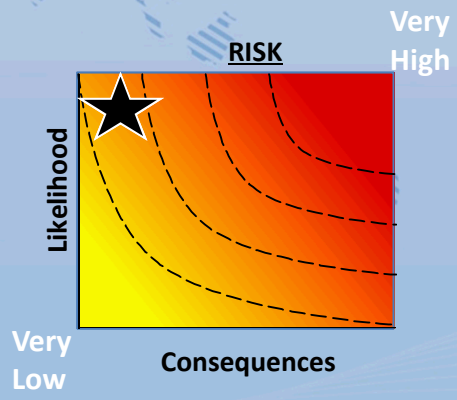
You are in an open field next to a very hungry , aggressive, adult tiger. The tiger is unrestrained and sees you as food.




You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.

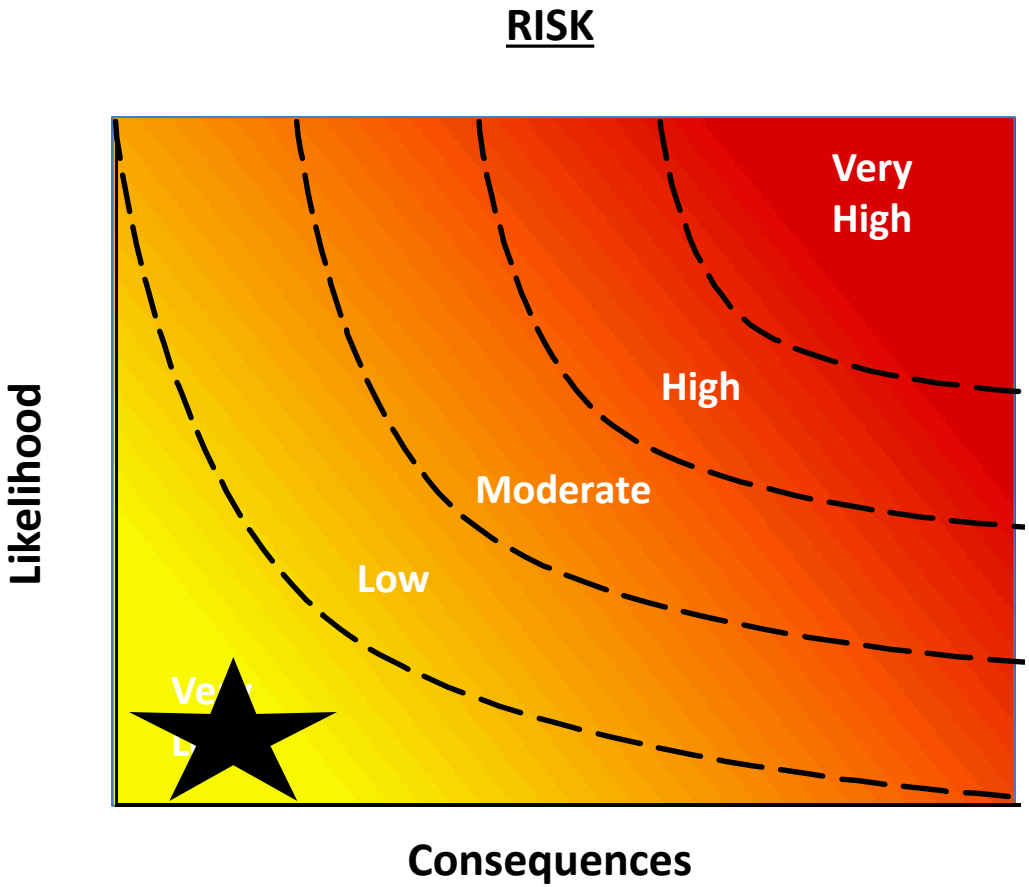



You are holding a tiger cub with a playful temperament in your arms.



# Risk

**You are at the zoo observing a mellow, tiger cub located behind a strong glass window.**



# Biosafety Risk Assessment

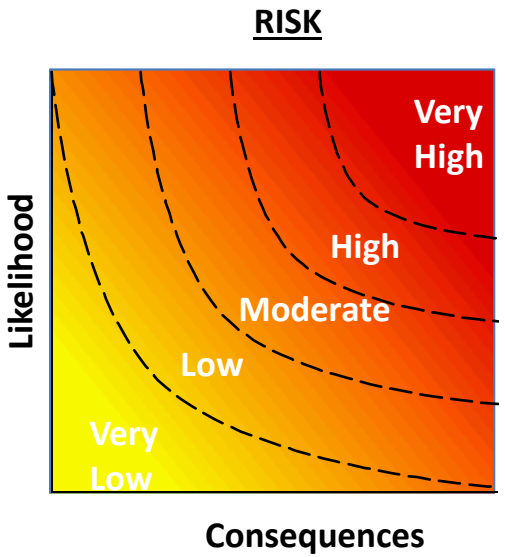
A **Risk Assessment** is a procedure that analyzes a particular process or situation in order to determine the **likelihood** and **consequences** of a certain adverse event.

In **Laboratory Biosafety**, we are concerned with preventing unintentional adverse events involving infectious disease agents.

To properly conduct a **laboratory biosafety risk assessment**, it is important first to gather certain information about the laboratory procedures involving biological agents and toxins, as well as information on the agents and toxins themselves.

# Biosecurity Risk Assessment

A **risk assessment** assigns values for **likelihood** and **consequences**, which allows us to represent the risk of a particular adverse event on a graph.




In **Biosecurity Risk Assessment**, we are concerned with **intentional adverse events** involving laboratory disease agents and/or their products.

# Biosafety Risk Assessment

## Question:

What factors should be considered in a **laboratory biosafety risk assessment**? (What are the factors that affect **Likelihood** and/or **Consequences**?)

In your group, please spend **10 minutes** to answer the above question.

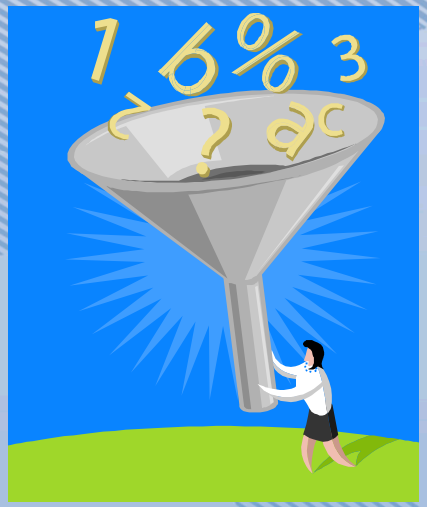
To help with this task, list all the **factors** on sticky-notes and place them on your flip chart.

Be prepared to report your answers to the class.

# Risk Characterization

As you can see many of the factors regarding laboratory biosafety risk rely on the **agent characteristics** and the laboratory **procedures**.

The **risk of exposure** to an agent is dependent on these factors.



# Risk Characterization

**Activity:**

We will work together, through a series of examples to practice determining the **risk of exposure** associated with an experiment.

# Risk Characterization

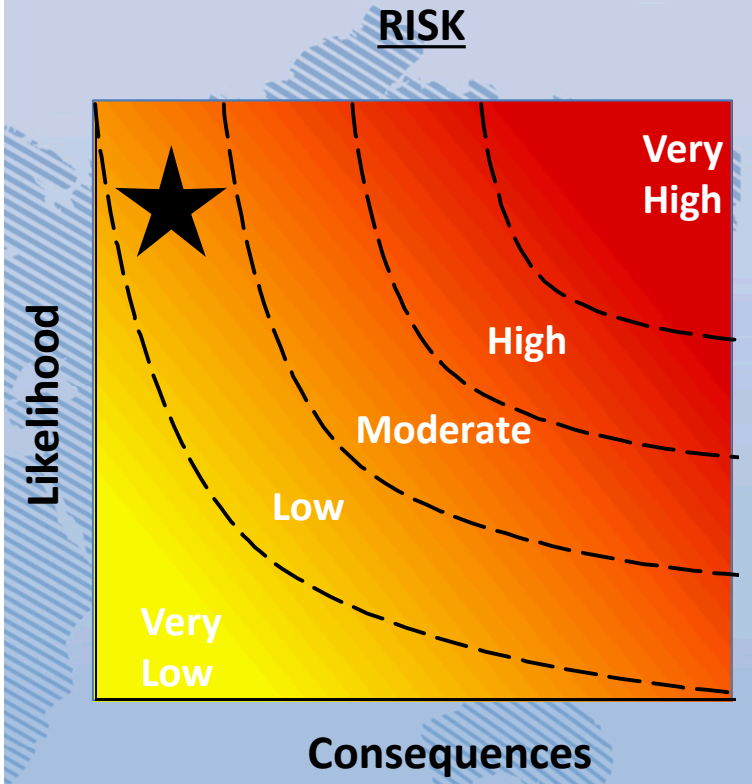
**Scenario:**

Suppose you are working with a **seasonal influenza virus**, conducting **aerosol-challenge studies** on an animal host, with little respiratory protection.

What is the **likelihood** of exposure?

What are the **consequences** of exposure?

What are some factors that should be considered?



# Biosafety Risk Assessment

This exercise could be repeated with every **organism** and every **procedure** conducted in a laboratory or facility.

Doing this in a comprehensive manner is one way to conduct a **facility-wide risk assessment**, which would then be, quite simply, the collection of the individual risk assessments for the individual procedures conducted in a laboratory or facility.

# Scenarios

**Scenario:**

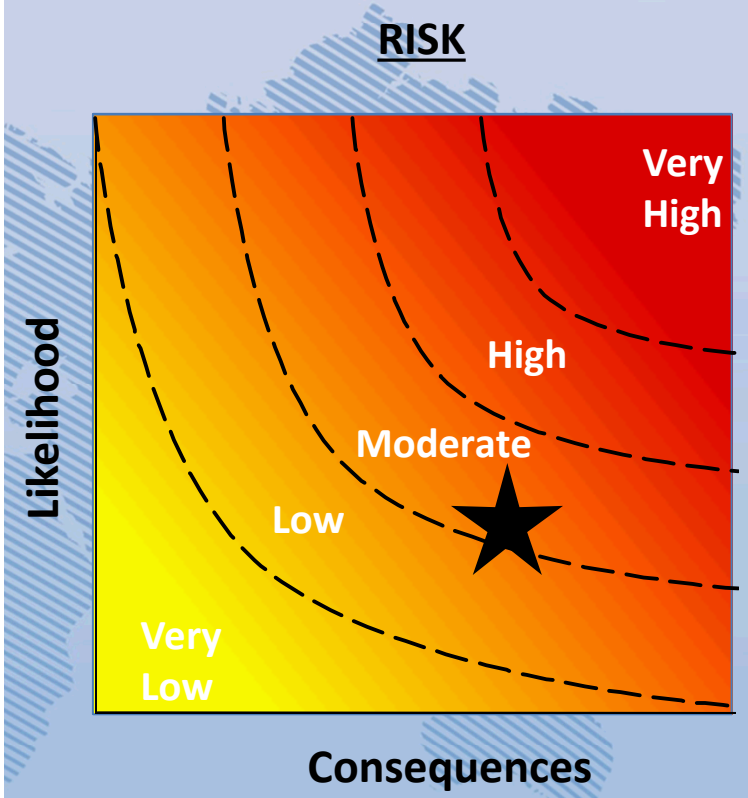
Suppose your facility stores large volumes of ***Foot and Mouth Disease Virus*** for use in animal research. Your facility's building is new and has excellent physical security.

In your groups, **take 5 minutes**, to further expand on this scenario to include a specific **adversary** as well as **a particular way** that the **adversary** will attempt to **steal and misuse** the **asset**.

What is the **likelihood** of theft?

What are the **consequences** of theft?

What are some factors that should be considered?



# Vulnerability Assessment

After generating a series of **scenarios**, the **vulnerabilities** of a facility and/or its units to the threats posed in the **scenario** should be assessed.

***How well are the facility's existing biosecurity risk mitigation measures protecting against the threats in the scenarios?***

# Vulnerability Assessment

Biosecurity vulnerabilities can be assessed based on each of the **biosecurity system's individual components**?

Physical Security
Personnel Management
Material Control and Accountability
Transport Security
Information Security

# Vulnerability Assessment

**For example**, is the **Physical Security** of a facility adequate to prevent an outsider from entering a particular laboratory and stealing several vials of an agent?

Are doors consistently locked? Are the locks reliable? If doors are locked, are there large windows in the laboratory that an outsider could enter from instead?

# Biosecurity Risk Assessment

This exercise could be repeated for every **asset and adversary in a given scenario** in a laboratory or facility.

Doing this in a comprehensive manner is one way to conduct a **facility-wide biosecurity risk assessment**, which would then be, quite simply, the collection of the individual risk assessments for the laboratory or facility.

# BioRAM

One available tool to aid in the biosafety risk assessment process is the **Biosafety RAM (BioRAM)**.

**BioRAM** is a computerized **risk assessment tool** developed by Sandia National Laboratories, in partnership with the international community, to facilitate laboratory **biosafety risk assessments** by simplifying **Risk Characterization**.

# BioRAM

**BioRAM** uses only one of several possible risk assessment methodologies.

It is based on the input of biosafety experts and validated around the world. The **BioRAM** tool helps determine *relative* risk levels in a **comparable** and **repeatable** way.

**http://biosecurity.sandia.gov/BioRAM/**

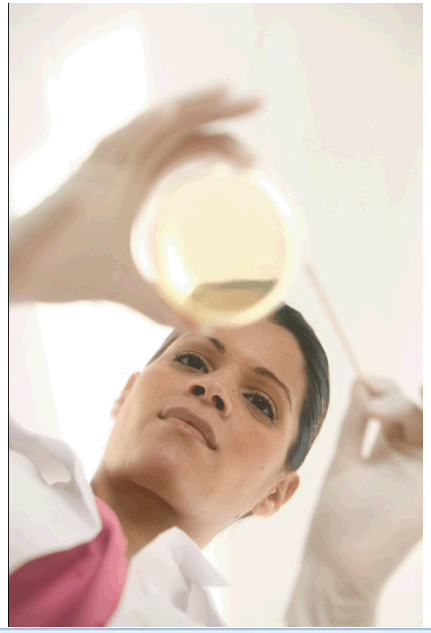
# Risk Evaluation

**Risk Evaluation** is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk.

**Risk Evaluation** is the process of determining, subjectively, whether a risk is **high** or **low**, and whether it's **acceptable** or not.

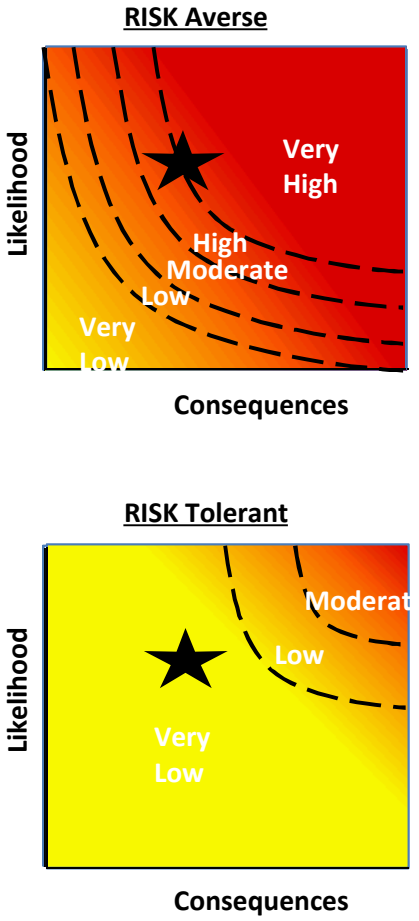
# Risk Evaluation

Unfortunately, there is **no systematic way** of evaluating risk and determining risk acceptability. This will depend on the perceptions of **individuals**, **institutions**, and the **community**.



# Risk Evaluation

Overall, two **institutions** with the **same computed risk "values"** for the risk characterization process may have **different risk evaluations** (***meanings of risk)***. For example, what is a moderate risk for one institution could be a high risk for another, depending on what each entity decides is moderate or high.



# Risk Evaluation

An **institution** that considers a certain risk **high** might be motivated to spend a **large amount of resources** mitigating that risk.

Another **institution** that considers the **same** risk to be **moderate** might decide to spend a **small amount of resources** in mitigation instead.

# Key Components of Biorisk Management

- Biorisk **Mitigation**
  - Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

**Question:**
*What are some things you can do to mitigate risk?*

# Mitigation Control Measures

There are five major categories of measures for controlling biological risks in the laboratory.

1. **Elimination or Substitution**
2. **Engineering Controls**
3. **Administrative Controls**
4. **Practices and Procedures**
5. **Personal Protective Equipment**

# Mitigation Control Measures

**Elimination or Substitution:** Removing the hazard, not working with the agent or replacing the hazard with something less dangerous

# Mitigation Control Measures

**Engineering Controls:**

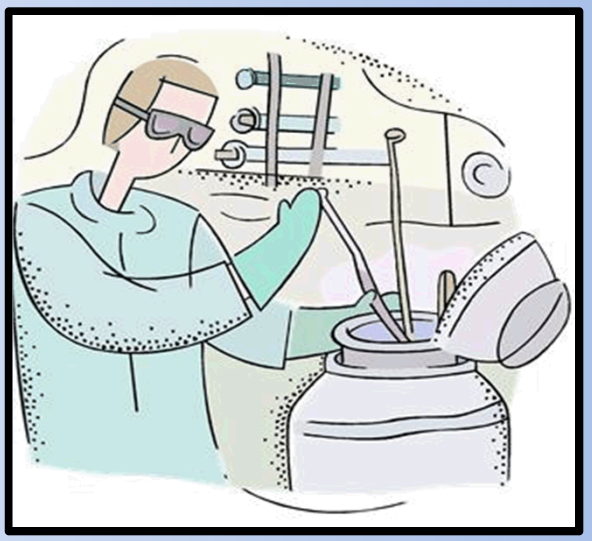
Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards

# Mitigation Control Measures

**Administrative Controls:** Policies, standards and guidelines used to control risks

# Mitigation Control Measures

**Practices and Procedures:** Processes and activities that have been shown in practice to be effective in reducing risks



# Mitigation Control Measures

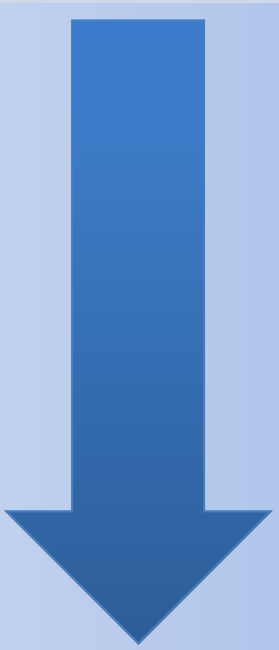
**Personal Protective Equipment:** Devices worn by the worker to protect against hazards in the laboratory

# Advantages and Disadvantages

| Control Measure | Advantages | Disadvantages |
|---|---|---|
| Elimination or Substitution | Immediate reduction of risk | Not always available or possible |
| Engineering | Efficient,<br>eliminates hazard | Cost,<br>complexity |
| Administrative | Authority approach | Indirect approach, primarily addresses the human factor |
| Practices & Procedures | SOP based (standardized approach) | Training and supervision requirements |
| PPE | Ease of use, relative cost | Does not eliminate hazard, PPE fails exposure happens, uncomfortable, limits ability,<br>only protects the user |

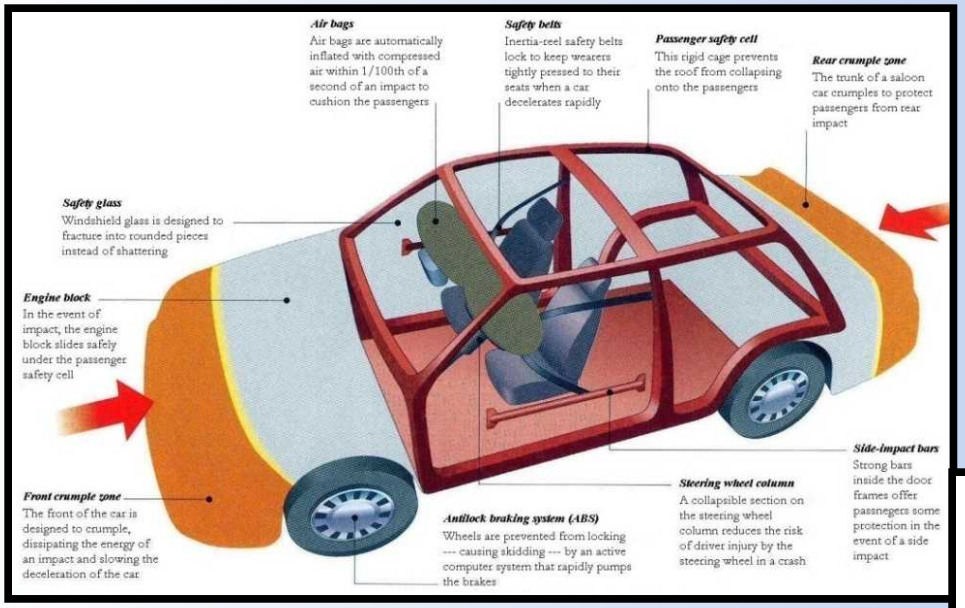
# Hierarchy of Controls

- Elimination or Substitution
- Engineering Controls
- Administrative Controls
- Practices and Procedures
- Personal Protective Equipment



Control methods at the top of the list are, **in general**, more effective and protective than those at the bottom.

# Car Safety vs. Motorcycle Safety



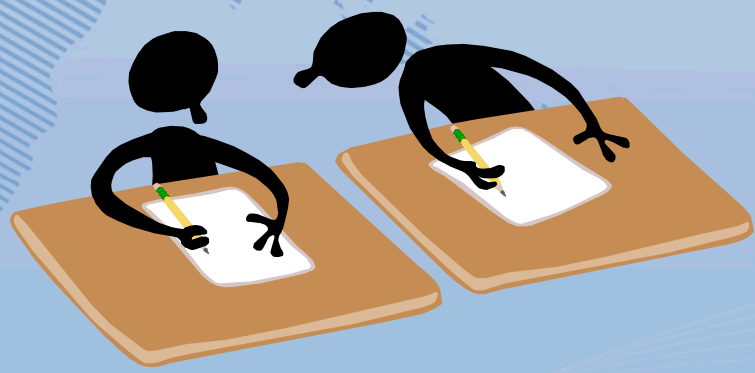

Car safety is all about engineering systems

Motorcycle safety is all about PPE

# Key Components of Biorisk Management

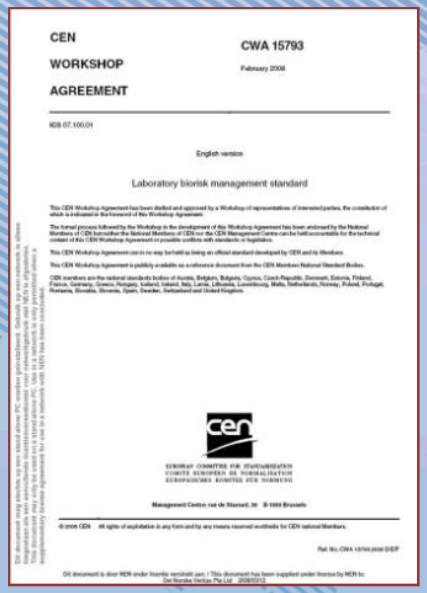
- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

**Question:**
*How do you know that the management system is working and will continue to work?*



# CWA 15793:2011 Examples of ~~Topics Covered:~~

- Biorisk Management Policy
- Hazard identification, risk assessment and risk control
- Roles, responsibilities and authorities
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review



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CWA 15793

February 2008

English version

Laboratory biorisk management standard

# Example: Waste Management

**4.4.4.5.3 Waste Management**

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- The standard is not a technical document
- Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives
  - **Provides Biorisk management framework for the day-to-day functions of the institute / organization during both normal operations and times of emergency**

# Individual Reflection

**Question:**

If you could make three changes to the management system at your facility today, what are your top three priorities?

# Review of Biorisk Management

- Biorisk Management = Biosafety + Biosecurity
- Biorisk Management System is a means to reduce Biorisk
- AMP = Assessment, Mitigation, Performance
- CWA 15793 outlines a comprehensive, international biorisk management system framework

# Key Messages

- A risk assessment is defined as a procedure that analyzes a particular process or situation in order to determine the likelihood and consequences of a certain adverse event and will be unique to each laboratory.
- To be comprehensive, a laboratory biosafety risk assessment should consider every activity and procedure conducted in a laboratory that involves infectious disease agents.
- A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk.
- Risk Evaluation is a crucial intermediary step between Risk Characterization and taking active steps towards mitigating risk and is the process of determining whether a particular risk is in fact acceptable or not to a facility or institution

# Thank You!