



# Introduction to Biorisk Management

***ABSA 2011***

**October 28, 2011**

SAND No. **2008-0480P**, 2008-0480P, 2008-1138

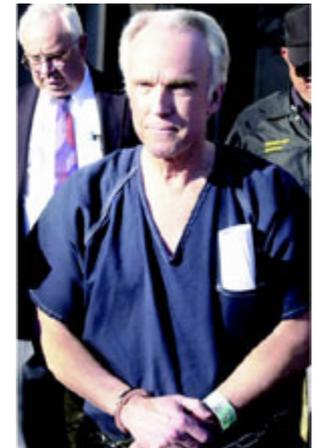
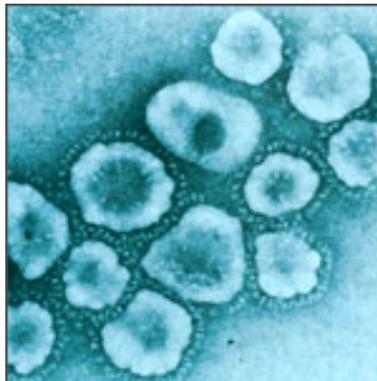
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
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under contract DE-AC04-94AL85000.





# Examples of Safety and Security Issues Arising from Problems in Biorisk Management

- **Texas A&M University, United States, 2006 – 2007**
  - U.S. federal officials suspend all Select Agent research due to failures to report two incidents
- **Pirbright Laboratory, Institute of Animal Health, United Kingdom, 2007**
  - Leaks from pipes in the effluent system caused Foot and Mouth Disease outbreak
  - Pipes were known to need maintenance
- **Professor Thomas Butler, United States, 2003**
  - 30 vials of *Yersinia pestis* missing from lab (never recovered); Butler served 19 months in jail
- **Laboratory-acquired outbreaks of SARS, 2003 – 2004**
  - Singapore—September 2003
  - Taiwan (China)—December 2003
  - Beijing and Anhui (China)—March 2004



Thomas Butler

TAMU Select Agent researcher  
– Dallas Morning News



# How Do You Avoid Similar Problems at Your Institution?

## Laboratory biorisk management programs need:

- Appropriate resources
- Institutional guidelines and operating procedures
- Training
- Oversight

## But:

- How do you decide to allocate your scare resources?
- How do you determine what needs to be addressed in operating procedures?
- How do you determine which training is required for whom?
- How do you determine what level of oversight is appropriate?





# Biorisk Management Systems Approach

**Need a cohesive framework for implementing a program to control biorisks**

- Many elements to integrate

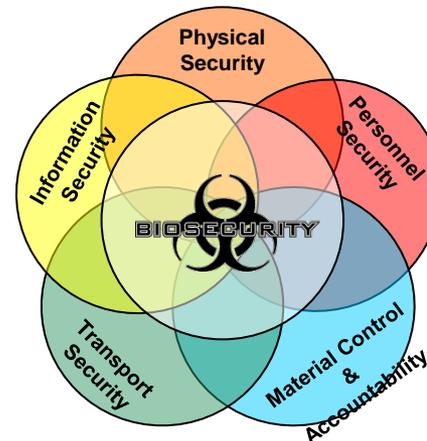
**Example management systems used in labs**

- ISO 9001:2000 – a quality management system
- ISO 14001:2004 – an environmental management system
- OHSAS 18001:2007 – an occupational health & safety management system

**CEN Workshop Agreement, 2008 – laboratory biorisk management system**

- Risk-based approach

**All rely on a “Plan-Do-Check-Act” approach with the goal of continuous improvement**

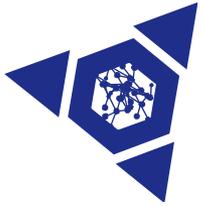


# Strengthening Biological Risk Management



## *Vision for Integrated BioRisk Management:*

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



# Course Outline and Materials

**Course will include lecture, discussion, and activities**

## **Agenda - Key Modules include:**

- Introduction to Biorisk management
- Introduction to Risk **Assessment**
- Introduction to Biorisk **Mitigation**
- Introduction to Biorisk Management **Performance**

**This course is an introduction and summary of the key concepts**

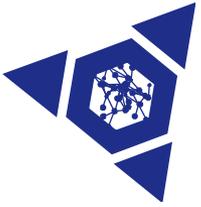


# Biorisk Management – Session 1

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## Biorisk Management



## Group exercise 1

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Split into groups:

In your group, take 10 minutes to discuss and answer the following question:

***What are the risks of working in a laboratory with biological materials?***

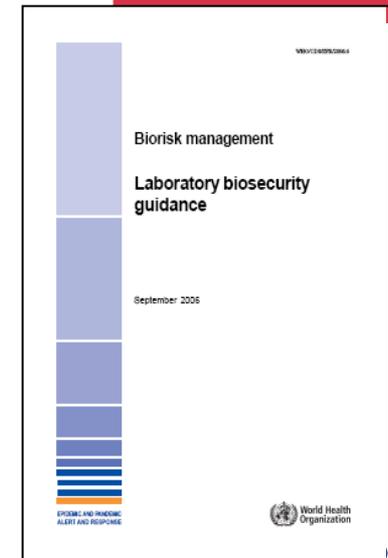
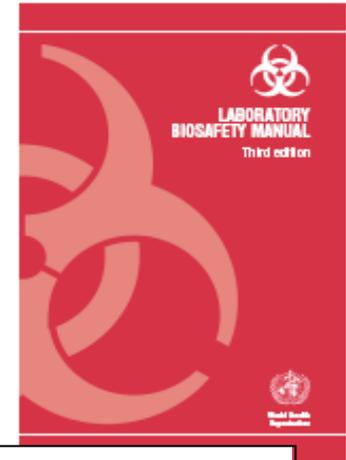
Write down your answers and be prepared to report to the class





# Definitions<sup>1</sup>

- 🦠 **Laboratory biosafety**  
principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release
- 🦠 **Laboratory biosecurity**  
and personal security measures designed to prevent the loss, theft, misuse, diversion, or **intentional** release of pathogens and toxins



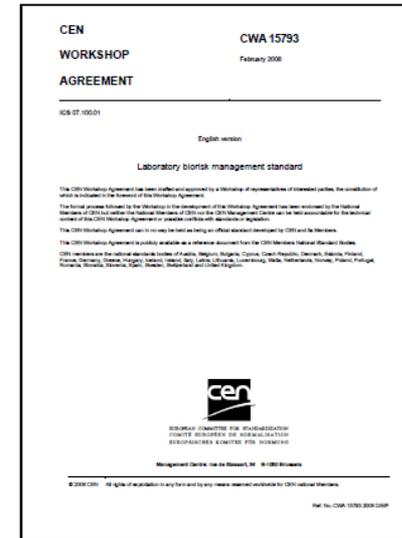
<sup>1</sup>Laboratory biosafety manual, Third edition (World Health Organization, 2004)

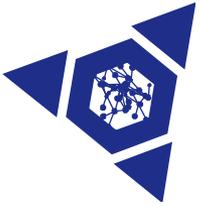


# Laboratory Biorisk Management

⚠ 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

⚠ CWA 15793:2008

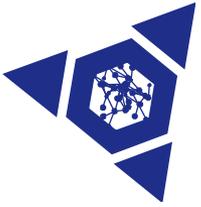




## Biorisk

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- ⊗ The risk associated with biological materials in the laboratory has a **safety** and a **security** component
  
- ⊗ **Biorisk** encompasses **biosafety** and **biosecurity**



## Group exercise 2

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In your group, take 10 min to discuss and answer the following three questions:

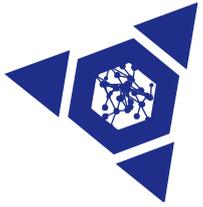
***How do you identify these risks?***

***What are some things you can do to manage these risks?***

***How do you know that your risk management is working, and will continue to work?***

Use *post-it* notes to write down your answers, one idea per note

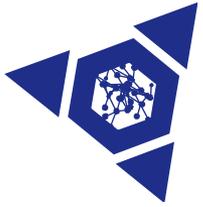




## Biorisk Management: the **AMP** Model

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



# Key Components of Biorisk Management

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## 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





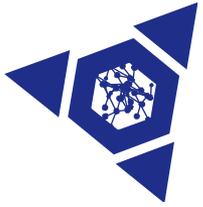
# Key Components of Biorisk Management

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## Biorisk **Mitigation**

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

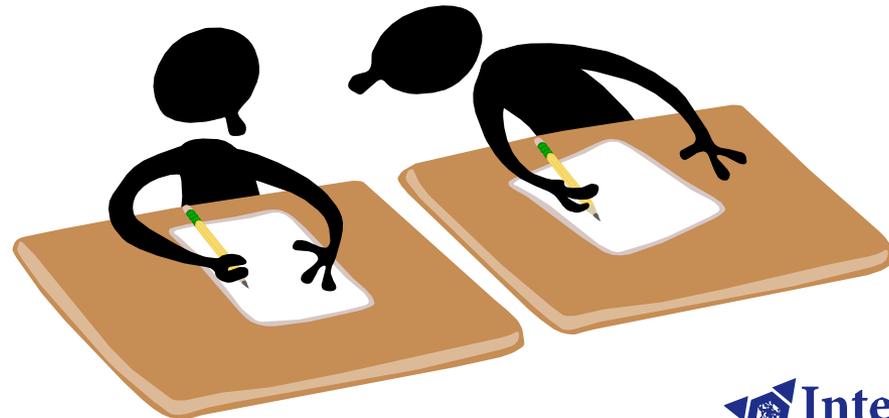




# Key Components of Biorisk Management

## **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.





## Group exercise 3

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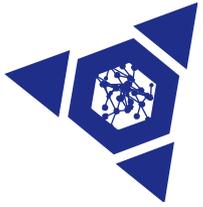
Let's get organized:

Take the *post-it notes*, and place them under one of the following columns:

**Assessment**

**Mitigation**

**Performance**

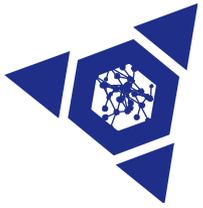


## Key Components of Biorisk Management

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- ⊗ During the next sessions, we will always refer back to the AMP model and individually address the three components

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



**BREAK**



# Biorisk Assessment – Session 2

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



## Group Exercise 3, Step 1

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Consider this scenario:

A young child is left alone in a kitchen while there is pot of water heating on the stove

- ⚠️ What could go wrong? List all the possibilities
- ⚠️ Choose the single most important risk for this scenario
- ⚠️ Identify the hazard associated with that risk
- ⚠️ 10 Minutes. Be prepared to report to the rest of the class



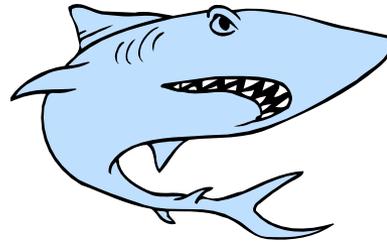
What is a hazard?





# Hazard

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



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





What is risk?





## Risk

- ⚠ Risk is the **likelihood** of an undesirable event, involving a specific hazard, that has **consequences**





## Small Group Exercise 3, Step 2

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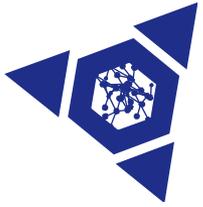
Consider again the young child in the kitchen scenario:

Risk: child being burned by the boiling water

Hazard: pot of water heating on the stove

④ Identify the factors that influence the risk.

④ Write one factor per post-it note



## Small Group Exercise 3, Step 3

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Consider again the young child in the kitchen scenario:

Risk: child being burned by the boiling water

Hazard: pot of water heating on the stove

- ④ Categorize the risk factors as influencing **likelihood** or **consequences** (or both)
- ④ Group post-it notes accordingly
- ④ Evaluate the risk (low, moderate, high)



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

What is the hazard (threat) now?

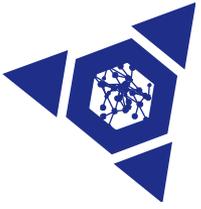




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What is the difference between  
a hazard and a threat?





## Hazard, Threat, and Risk

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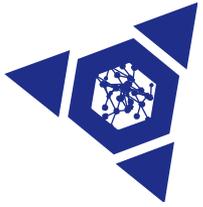
- ⚠ A **hazard** is an inanimate object that can cause harm
- ⚠ A **threat** is a person who has intent and/or ability to cause harm to other people, animals, or the institution
- ⚠ A **risk** can be based on either a hazard and/or a hazard and a threat



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Review: define risk, likelihood,  
and consequences?





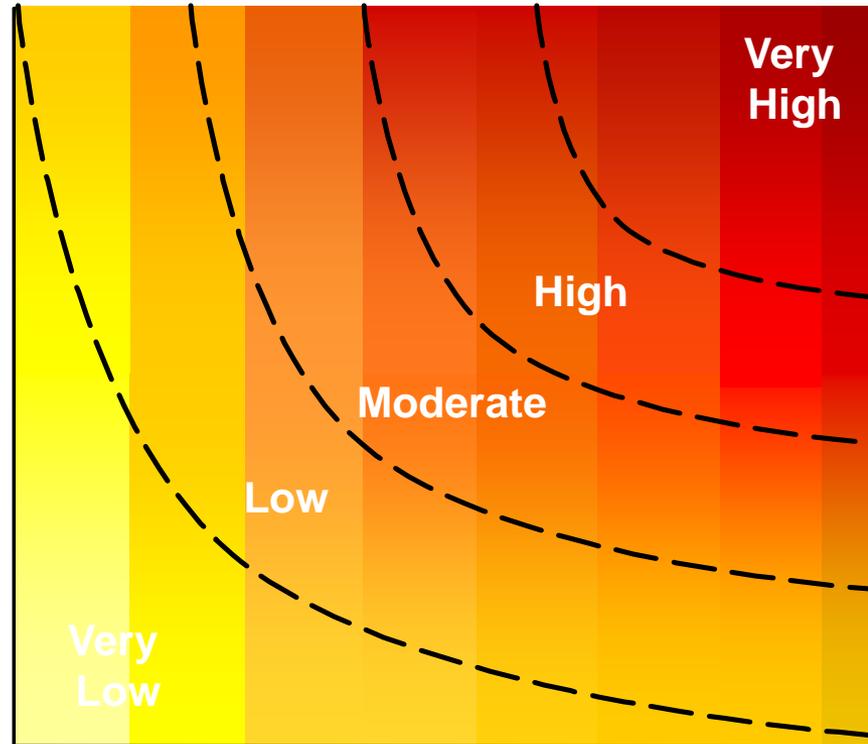
## Risk, Likelihood, and Consequences

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- ⚠ **Risk** is the likelihood of an undesirable event, involving a specific hazard (or hazard and threat), that has consequences
- ⚠ **Likelihood** is the probability an event occurring
- ⚠ **Consequences** is the severity of an event



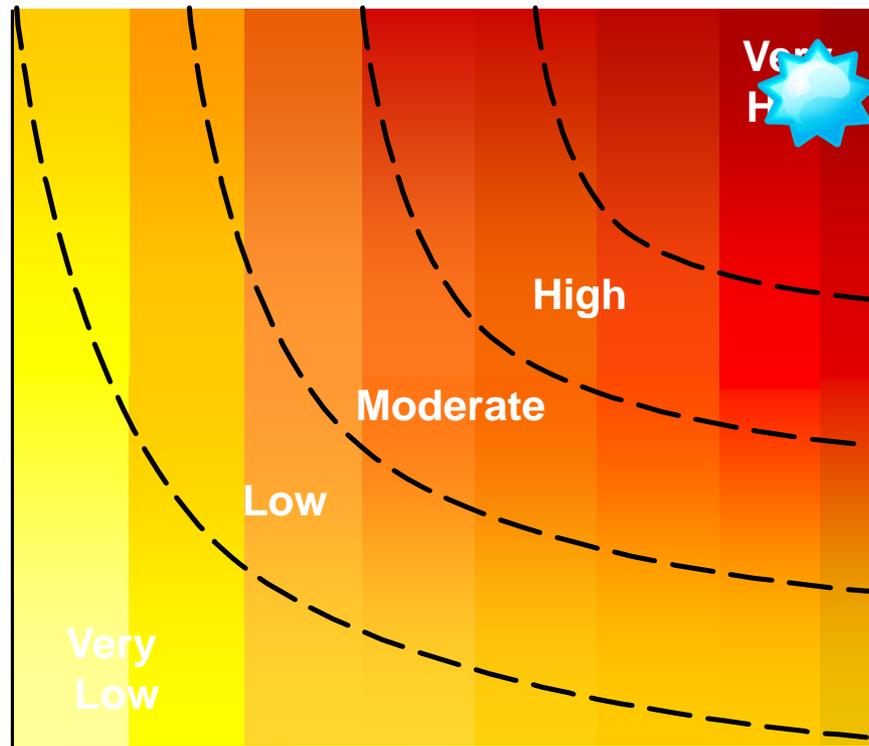
# Risk is a function of likelihood and consequences





# Risk Graph I

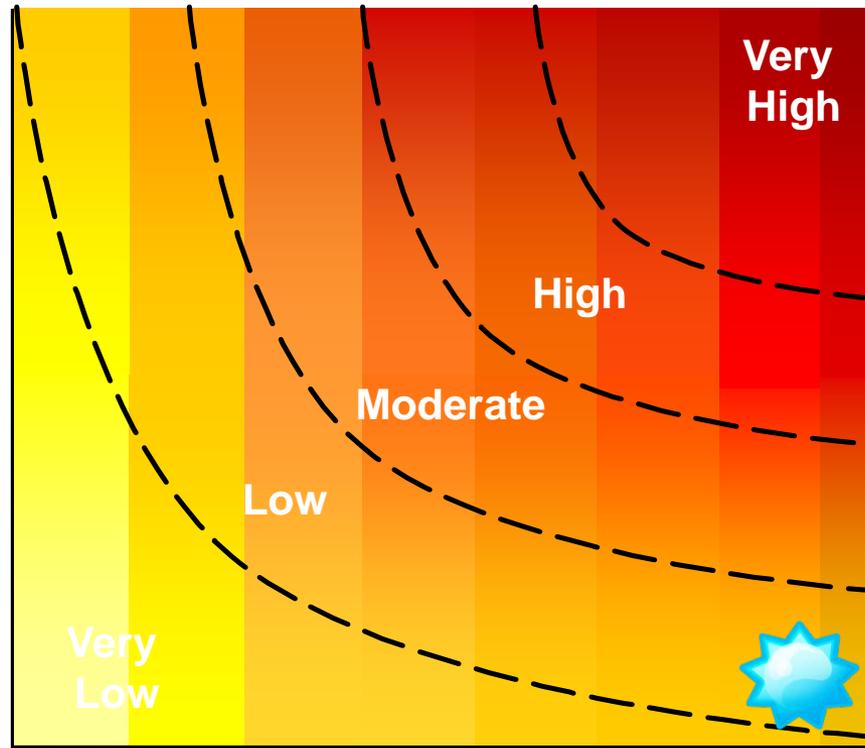
Large amount of boiling water on front of stove, step stool next to stove, child not restrained





## Risk Graph II

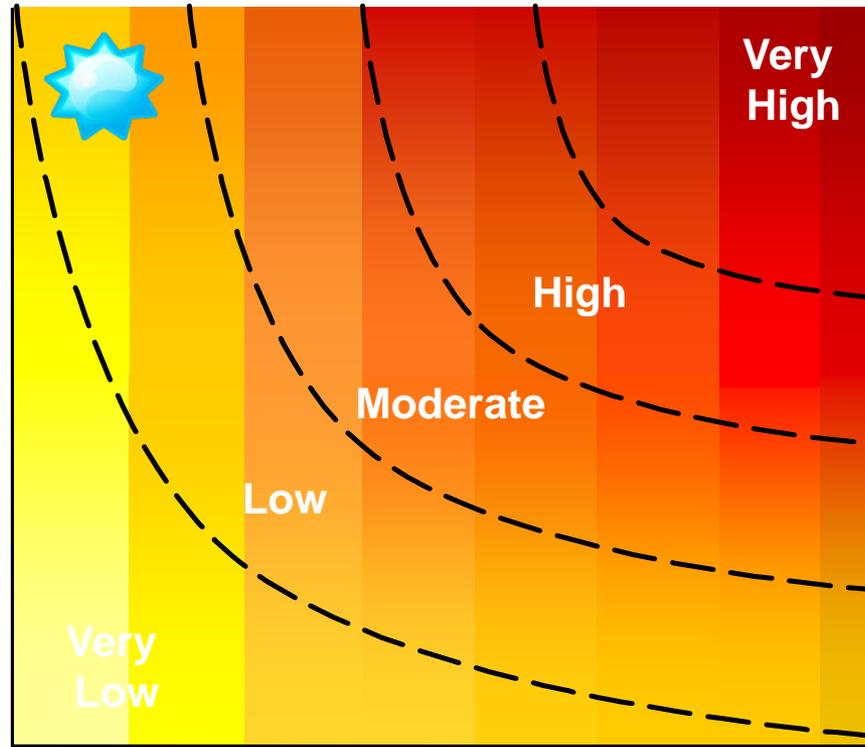
Large amount of boiling water, no step stool, child strapped in a high chair





## Risk Graph III

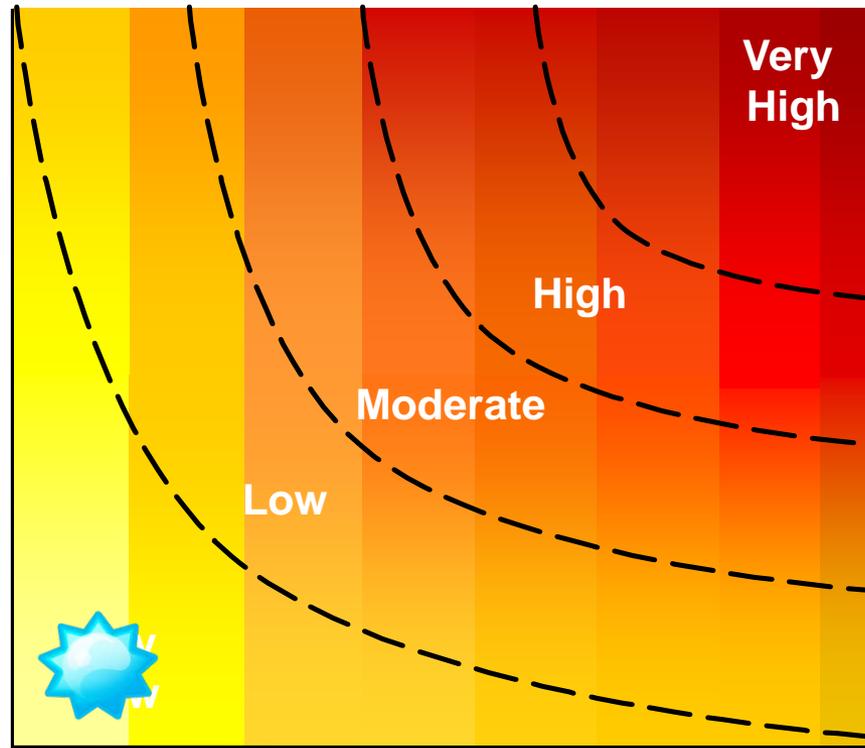
Small amount of cold water in the pan, step stool next to stove, child not restrained

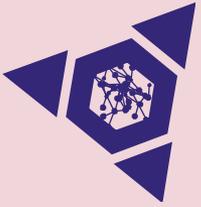




## Risk Graph V

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





## Individual reflection

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- ☣ 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





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# BREAK

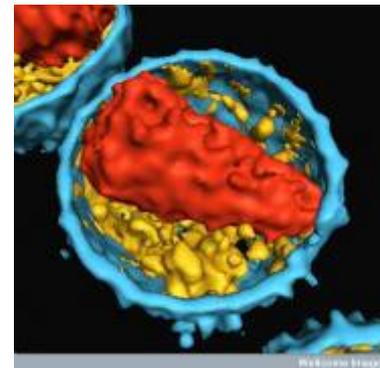
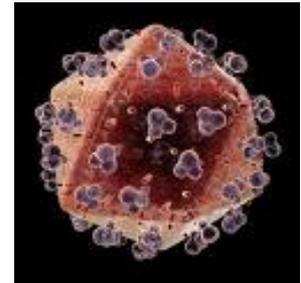


## Group Exercise 4, Step 1

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Consider the first biological scenario (WIV):

- ☠ Define the risks in this scenario
- ☠ Report out to the class



What aspect of biorisk did you focus on?



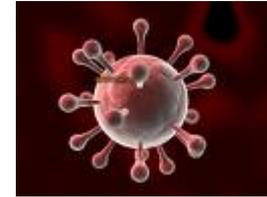


## Group Exercise 4, Step 2

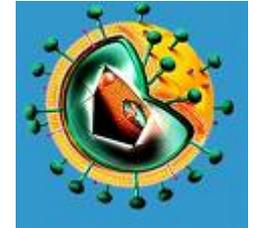
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Using the WIV scenario:

④ Choose one risk to assess



④ Define the hazard and/or threat



④ Can you evaluate the risk of this scenario? If so, what is it (low/moderate/high)?

④ Capture answers on a flip chart, and report to the class



## Group Exercise 4, Step 3

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Using the WIV scenario:

- ⚠️ What information do you need to do a risk assessment? List these factors.
- ⚠️ Use post-it notes, one idea per note, and place your post-it notes on a flip chart.
- ⚠️ Try to group these factors into general categories.





# Agent Properties

- **Pathogenicity / virulence**
- **Infectious dose**
- **Potential outcome of exposure**
- **Potential routes of infection**
- **Stability of the agent in the environment**
- **Morbidity/mortality**
- **Availability of effective therapeutic interventions**



## Laboratory Activities

- **Concentration of the agent**
- **Clinical samples vs. cultures**
- **Volume of material to be manipulated**
- **Use of sharps**
- **Procedures that generate aerosols**
- **Procedures that could result in splash/splatter**
- **Genetic manipulations**
- **Use of infectious agents in animals**



# Laboratory Infrastructure

- Heating, ventilation and air conditioning (HVAC) system
- Open windows
- Public access
- Work surfaces
- Work flow
- Pest control



# Human Factors

- **Level of training and experience**
- **Workload, fatigue**
- **Technique (Good Laboratory Practices)**
- **Handwashing practices**
- **Health and immune status of the workforce**



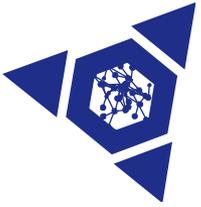
# Mitigation Measures

- **Housekeeping**
- **Waste disposal practices**
- **Use of a Biological Safety Cabinet**
- **Disinfectant use**
- **Vaccination**
- **Engineering controls**
- **Work practice controls**
- **Administrative controls**
- **Use of personnel protective equipment (PPE)**

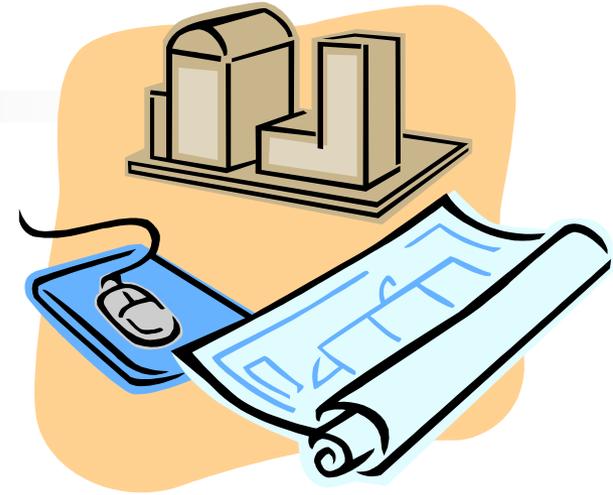


# Environment/Community Factors

- **Presence of the agent in the environment around the lab**
- **Immune status of the community**
- **Population density around the lab: urban vs. rural**
- **Presence of a suitable hosts or vectors**



# BioRAM



☣ **B**iosafety **R**isk **A**ssessment **M**odel

☣ **B**iosecurity **R**isk **A**ssessment **M**odel

☣ Both have relied extensively on external experts from the international community

☣ Available through the following URL:

<http://www.biosecurity.sandia.gov/BioRAM/>



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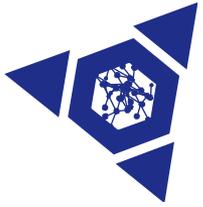
Some bloke wants to know if we've carried out a thorough risk assessment?'



What are the benefits of a robust risk assessment?



**RISK ASSESSMENT**



## Benefits of a Robust Risk Assessment

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- ⚠️ Facilitate a risk assessment process that is reproducible, transparent, repeatable
- ⚠️ Facilitate risk mitigation decisions
- ⚠️ Provide quality control documentation



## Summary

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- ⚠ **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 hazard and threat)
- ⚠ **Likelihood** is the probability of an event occurring
- ⚠ **Consequences** is the severity of an event



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# BREAK



# Biorisk Mitigation

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



# Key Components of Biorisk Management

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## Biorisk **Mitigation**

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





## Group Exercise 5, Step 1

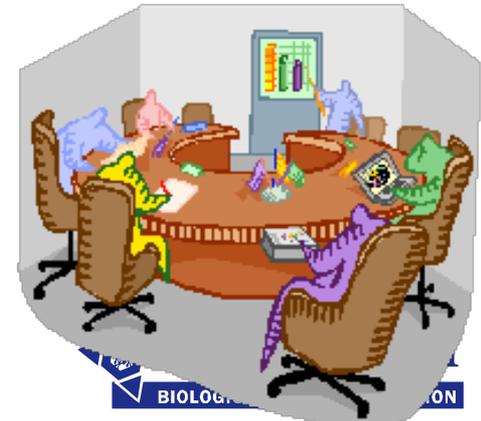
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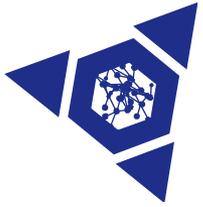
Using the WIV risk assessment scenario, identify six different potential risk mitigation measures

- ☣ At least **Four** for **safety** and
- ☣ **Two** for **security**

Use a *post-it note* for each mitigation measure you identify

Report on your answers to the class





# Mitigation Control Measures

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## Five categories of mitigation control measures:

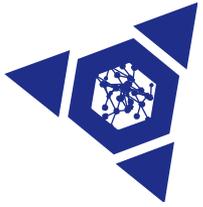
- ⚠ Elimination or Substitution
- ⚠ Engineering Controls
- ⚠ Administrative Controls
- ⚠ Practices and Procedures
- ⚠ Personal Protective Equipment



## Mitigation Control Measures

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

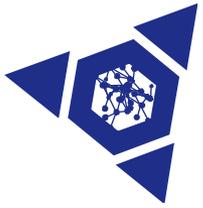




## Mitigation Control Measures

- ⚠ **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

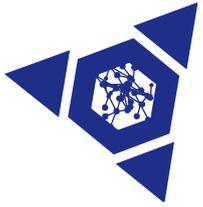




# Mitigation Control Measures

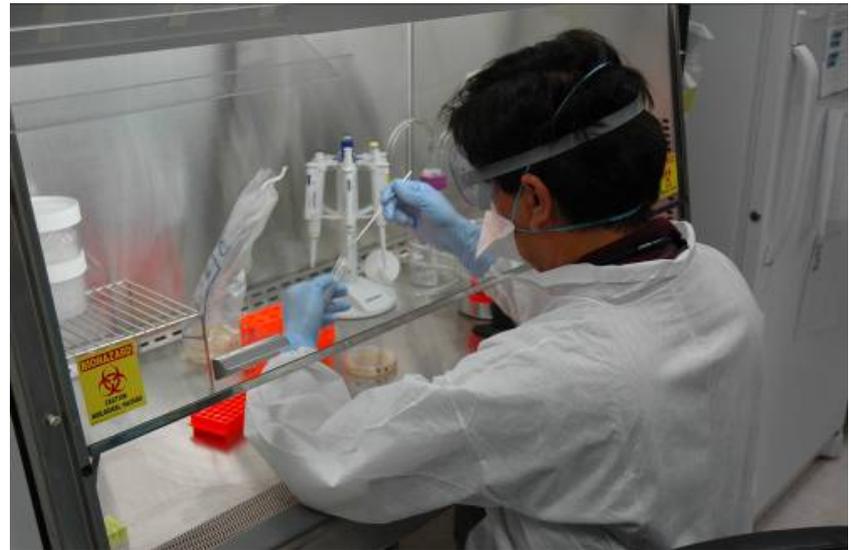
🦠 **Administrative Controls** Policies, standards and guidelines used to control risks

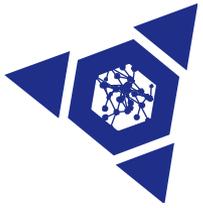




## Mitigation Control Measures

- ☣ **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





## Group Exercise 5, Step 2

Place your *post-it notes* in the appropriate columns on the flip chart:

<b>Engineering Controls</b>	<b>Administrative Controls</b>	<b>Practices and Procedures</b>	<b>Personal Protective Equipment (PPE)</b>
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Report your results to the class





## Group Exercise 5, Step 3

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Considering these **mitigation control measures**:

***Elimination or Substitution***

***Engineering***

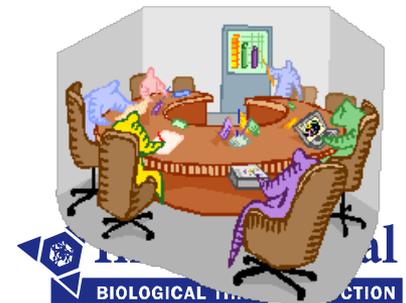
***Administrative***

***Practices & Procedures***

***PPE***

- Identify their advantages and disadvantages

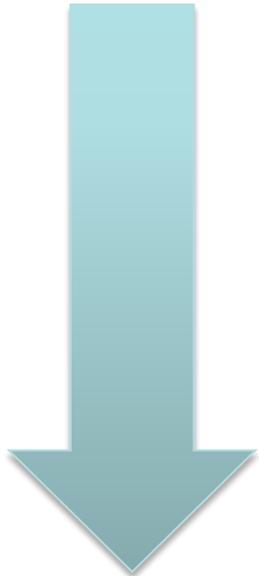
Report your findings to the class





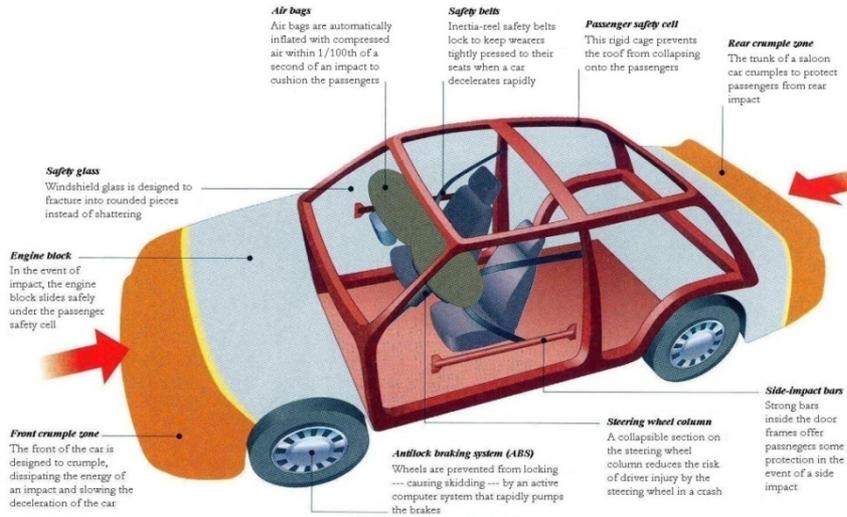
## Advantages/Disadvantages

Control Measure	Advantages	Disadvantages
<b>Elimination or Substitution</b>	Most effective at removing risk	May not be feasible, or may impede laboratory work
<b>Engineering</b>	Efficient, eliminates hazard	Cost, complexity
<b>Administrative</b>	Authority approach	Indirect approach, primarily addresses the human factor
<b>Practices &amp; Procedures</b>	SOP based (standardized approach)	Training and supervision requirements
<b>PPE</b>	Ease of use, relative cost	Does not eliminate hazard, PPE fails exposure happens, uncomfortable, limits ability





# Car vs. Motorcycle Safety





## Video Clip

**Which category of mitigation controls appears in this video clip?**



# Implementing Mitigation Measures

Mitigation measures should be implemented based on a thorough risk assessment.

Ideally, you should first consider elimination or substitution

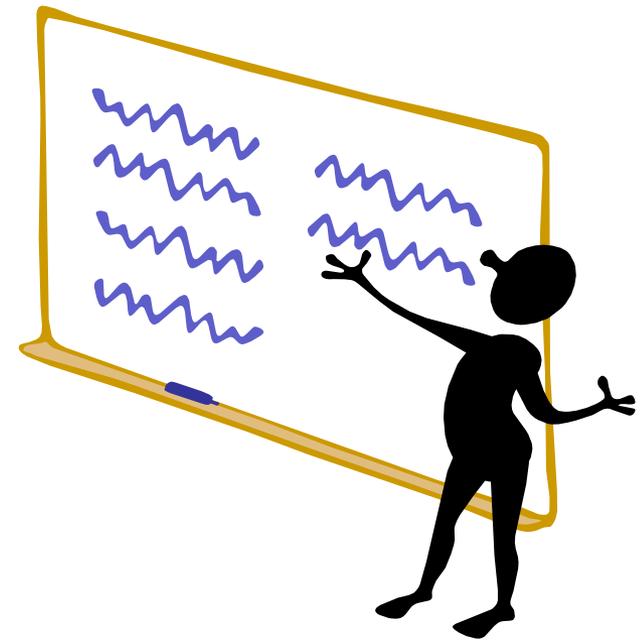
A combination of control measures should be used based on their effectiveness and your ability to implement them





# Robust risk assessment

- ⊗ Justify mitigation decisions
- ⊗ Evaluate the impact of certain risk mitigation strategies
- ⊗ Compare the cost effectiveness of various risk mitigation decisions





# Biorisk Management

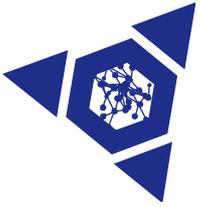
**Biorisk Management =  
Assessment, Mitigation, Performance**



Risk identification  
Hazard/threat identification  
Likelihood evaluation  
Consequences evaluation



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



# Summary

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## Five categories of mitigation control measures

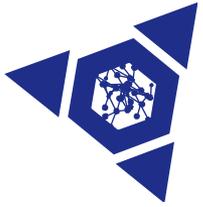
- ⚠ Elimination/Substitution
- ⚠ Engineering Controls
- ⚠ Administrative Controls
- ⚠ Practices and Procedures
- ⚠ Personal Protective Equipment

## Implementing mitigation controls

- ⚠ Should first consider elimination or substitution
- ⚠ A combination of control measures should be used based on their effectiveness and your ability to implement them
- ⚠ Should be based on the results of the risk assessment, “acceptable” risk



**BREAK**



# Access Control Performance Video

- **Secure research facility**
- **Risk assessment determined high likelihood for outside intruder**
- **As you watch, write down all the risk mitigation steps that you see**



## Biorisk Performance – Session 4

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



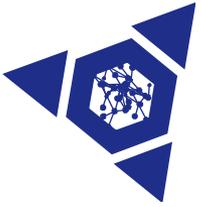
Choose one of the following questions and discuss with your group:

What is **performance**?

In what way does **performance** improve biorisk management?

Or...what specific steps are still missing from the system after assessment and **mitigation**?





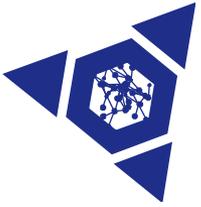
## Performance

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**Performance** is the way in which someone or something functions

**Performance** is the result of all the efforts of a company or organization

**Performance** improves biorisk management: you know that your system works and is sustainable, and that the risk is acceptable



## Group Exercise 6, Step 1

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Split into groups

Review the performance scenario

- ☣ Identify the performance issues/problems in the scenario
- ☣ Write each issue on a separate *post-it* using a felt-tip marker

Place *post-its* on your flip chart

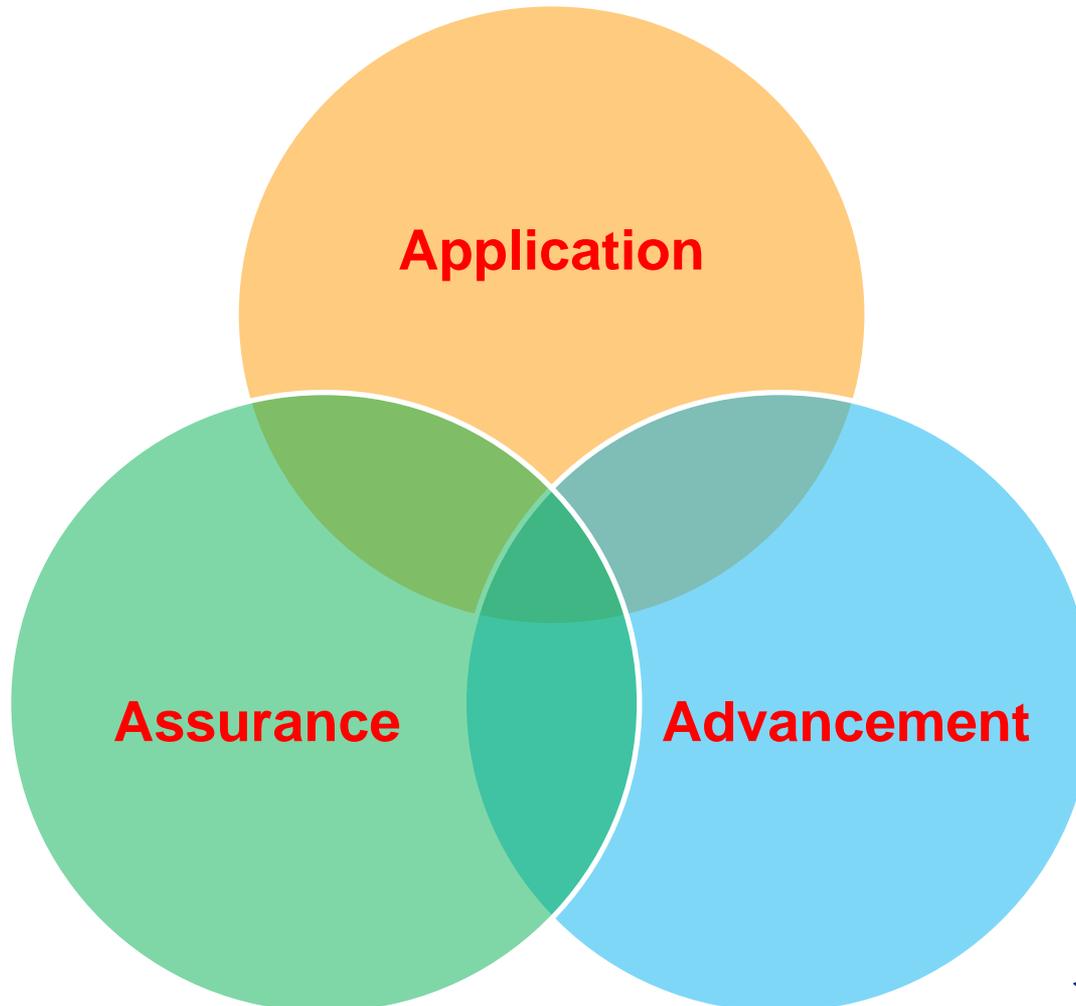
Present to the class

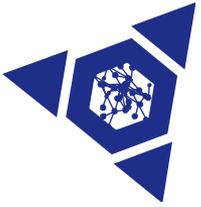




# Performance

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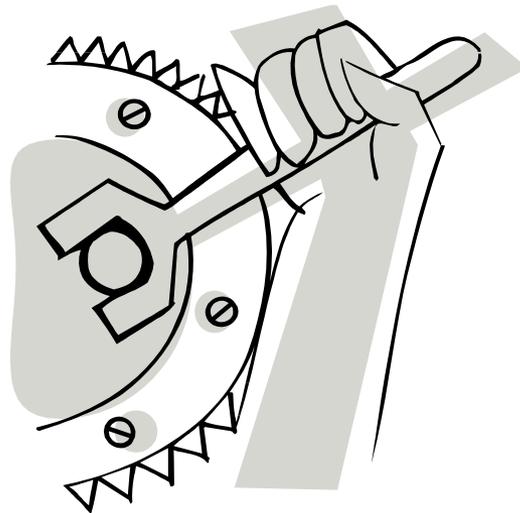


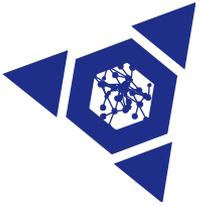


## Performance

### **Application:**

Processes, procedures, structures, and responsibilities to manage biorisk. Applying, working, doing the mitigation





## Performance

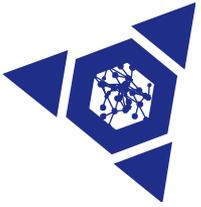
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### **Assurance:**

Systematic process of checking the system through audits and inspections

•

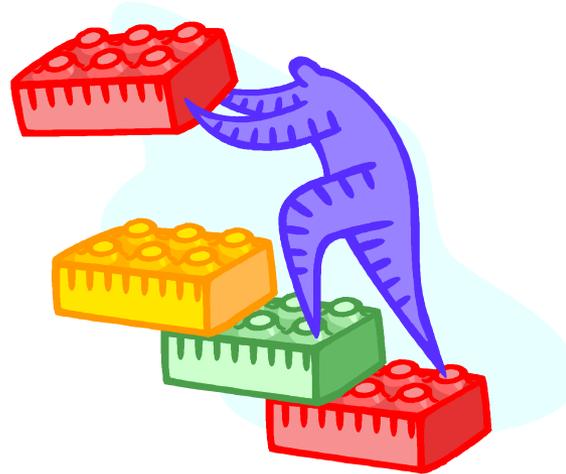


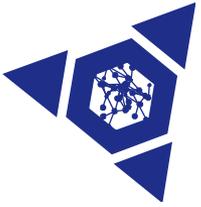


## Performance

### **Advancement:**

Setting and achieving biorisk management goals; improving existing mitigation or adding new mitigation based on internal and external feedback.





# Biorisk Management = Assessment, Mitigation, Performance



Risk identification  
Hazard/threat identification  
Likelihood evaluation  
Consequences evaluation



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



Application  
Assurance  
Advancement



# Putting it all together

## Group Exercise 7, Step 1

---

Individually, carefully read the *Cataract University* exercise

Split into groups

- ☣ Identify **problems** in Assessment, Mitigation, and Performance
- ☣ Use post-it notes, one for each problem
- ☣ Place post-it notes on “university board” in appropriate section

How have these problems affected the university?

Report out results to full group





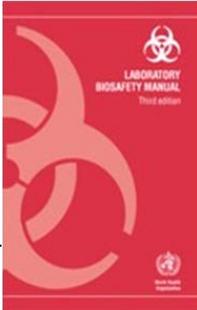
# Awareness and Implementation of CWA 15793:2008

[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)





# International Laboratory Biorisk Management Documents



- **Technical: World Health Organization**
  - Laboratory Biosafety Manual (2004)
  - Biorisk Management: Laboratory Biosecurity Guidance (2006)



- **Management: CEN Workshop Agreements**
  - CWA 15793 Laboratory Biorisk Management Standard
  - CEN WS 55 – CWA 15793 Guidance Document (under development)
  - CEN WS 53 – Biosafety Professional Competence





# What is CEN?

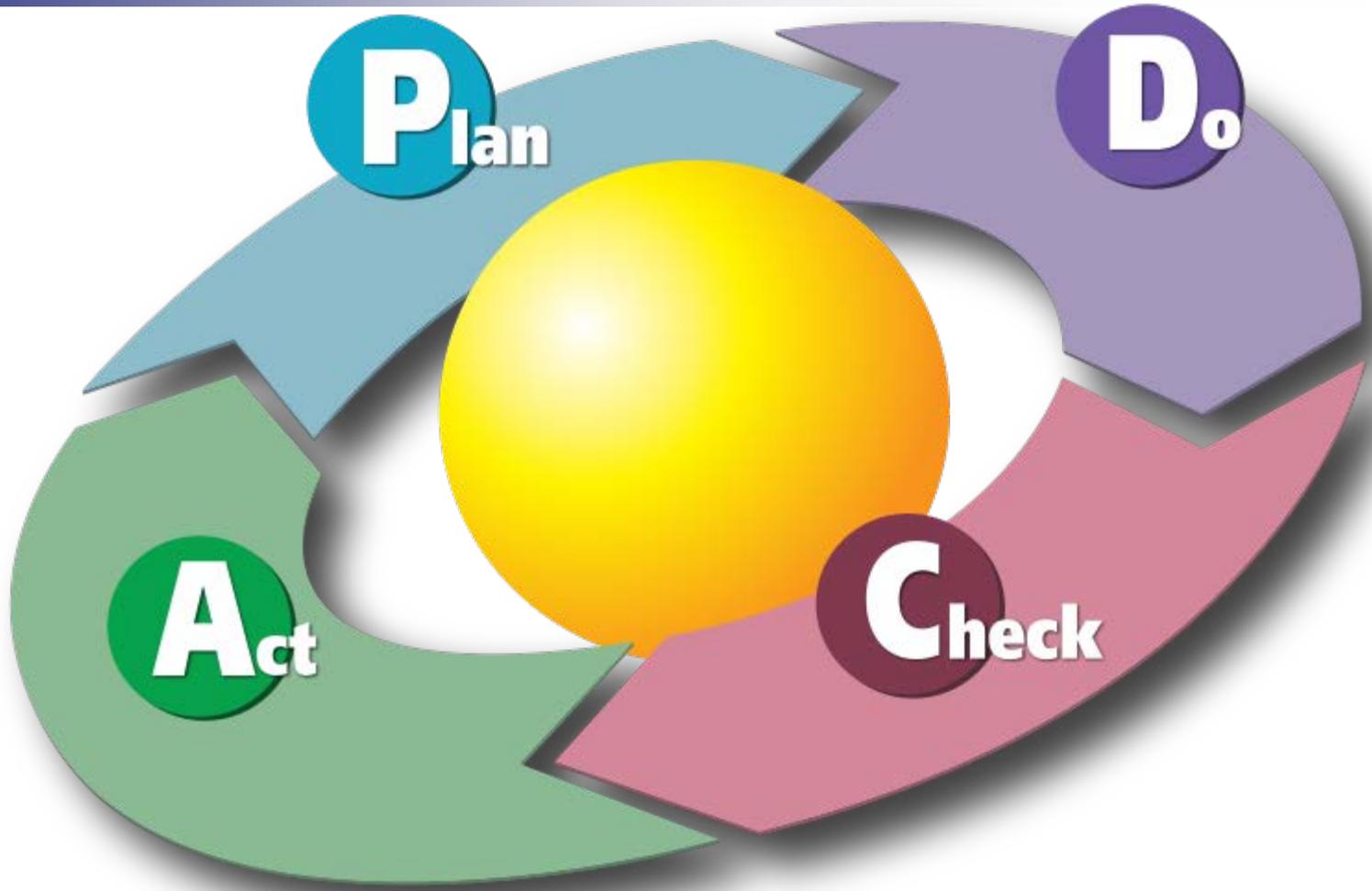
- **CEN = Comité Européen de Normalisation**
- **CEN has 30 national members**
- **Produces technical specifications, technical reports, and European Standards (EN)**
  
- **CEN Workshop Agreements (CWA) produced by**
  - Any interested parties
  - Consensus documents





# CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **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 regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs





# Purpose of the CWA 15793:2008

- **The Standard is used for:**
  - Improving overall laboratory biorisk performance
  - Increasing awareness and the adoption of performance approaches for biosafety and biosecurity
  - Improving international laboratory collaboration and safety harmonization
  - Support laboratory certification/accreditation, audits/inspections



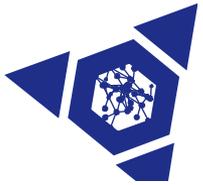


# CWA 15793:2008

- **International Approach**

- Extensive definition section
- Not country specific
- Based on international, acceptable best practices
- Local solutions possible
- The Standard is based around the current WHO Biosafety and Biosecurity Guidelines





## 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 normal operations and times of emergency**



# Reasons for Implementing CWA 15793

## Enables organizations to:

- Establish and maintain a biorisk management system to control or minimize risk to acceptable levels to employees, the community and others
- Provide assurance that the requirements are in place and implemented effectively
- Provide a framework that can be used as basis for training and awareness raising
- Seek and achieve certification or verification by an independent third party



- **Document available on CEN website**  
<ftp://ftp.cenorm.be/PUBLIC/CWAs/workshop31/CWA15793.pdf>
- **Electronic copy provided in your supplementary materials**



## Group Exercise 7, Step 2

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In the same groups, use the table of contents of the CWA15793 to develop recommendations for change at Cataract University

- ☣ Identify ***solutions*** for Assessment, Mitigation, and Performance
- ☣ Identify the specific paragraphs in CWA 15793 that apply to your selected solutions

Record your conclusions on a flip chart

Report the results to class





# CWA 15793:2008

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





## Individual Reflection

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How does AMP apply to your own lab?

How could you improve biorisk management at your own lab, short-term and long-term?

What would be the challenges of implementing AMP?

What would be the benefits of implementing AMP?

Write your answers on a piece of paper; you only have to share your answers if you wish



# Summary I

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How does performance improve biorisk management?

- ☣ You know that your system works and is sustainable, and that the risk is acceptable

Three components of performance

- ☣ Apply, assure, and advance

CWA 15793:2008: Laboratory Biorisk Management standard

- ☣ Plan, do, check, act



## Summary II

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### The AMP model

- ④ Assessment = Plan, Do, Check, Act
- ④ Mitigation = Plan, Do, Check, Act
- ④ Performance = Plan, Do, Check, Act

Mitigation is improved and sustained when performance measures are included



# Biorisk Management = Assessment, Mitigation, Performance



Risk identification  
Hazard/threat identification  
Likelihood evaluation  
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Elimination or Substitution  
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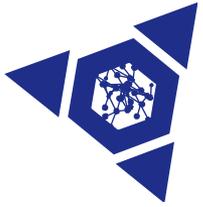
Application  
Assurance  
Advancement

***CWA 15793:2008***

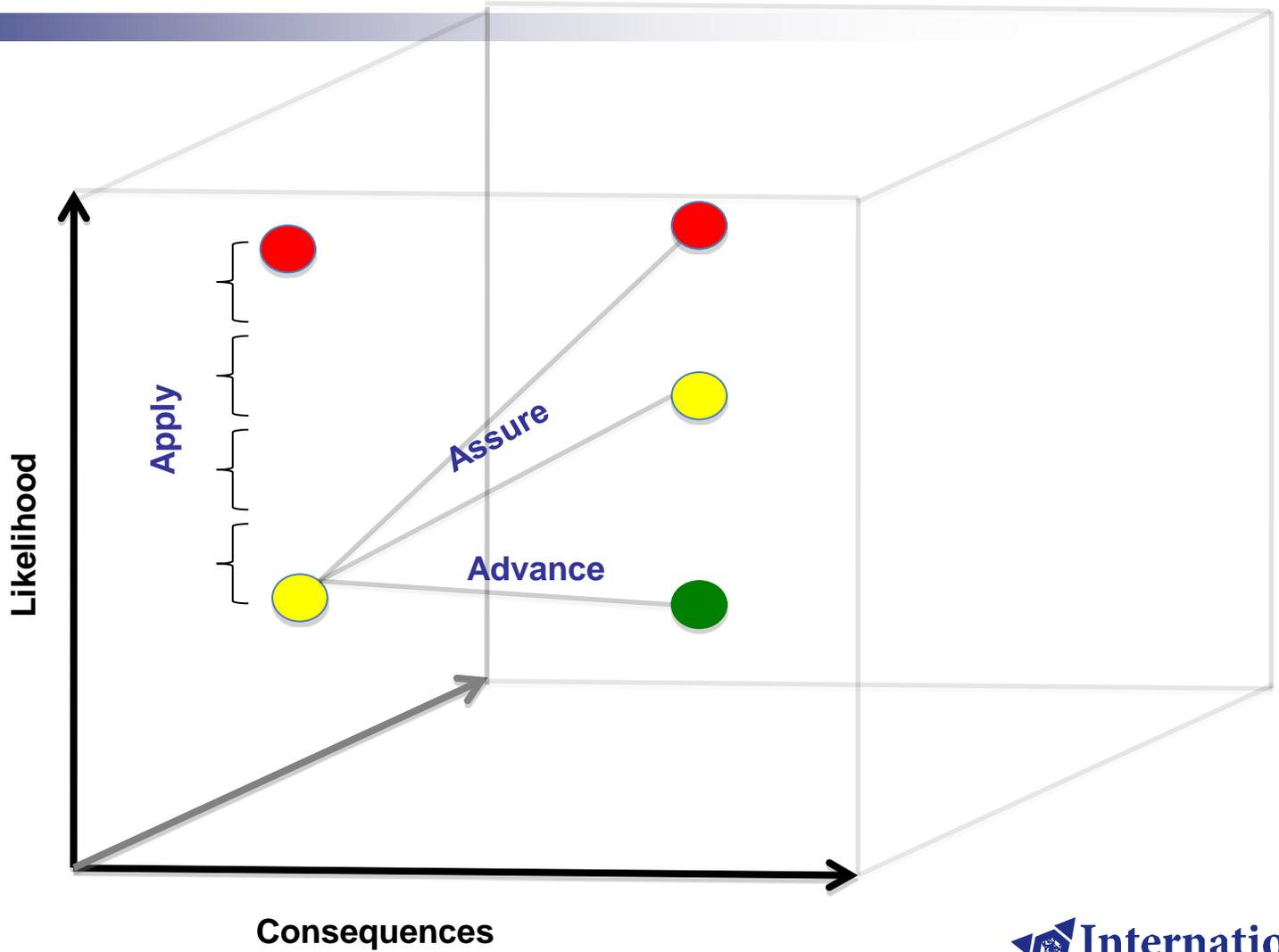


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# OPTIONAL SLIDES TIME AND INTEREST PERMITTING



# How does performance affect risk over time?





## Group Exercise 6, Step 2

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Organize the performance issues that you identified into either

☣ Application

☣ Assurance

☣ Advancement

Present your results to the class

