Introduction to Biosafety and Biosecurity

SAND2014-16538PE

15 August 2014

Presentation Overview

- Introduce Sandia National Laboratories
- Define common biorisk terms and their relationship
- Describe the AMP model of biorisk management
- Outline the five pillars of biosecurity risk mitigation

What is Sandia National Laboratories?

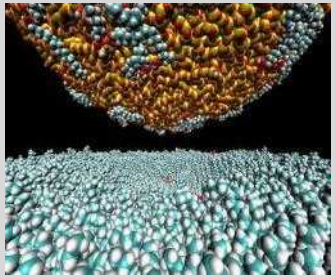
US Department of Energy (DOE)/ National Nuclear Security Administration (NNSA)

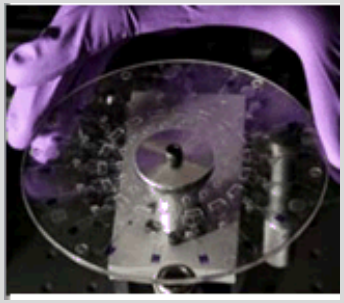
Primary mission:

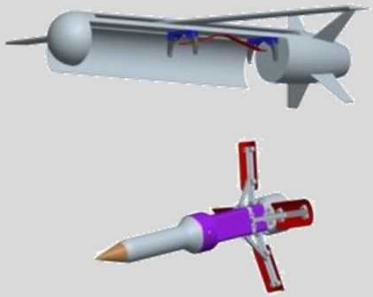
- Science and engineering to meet US national security needs
  - Weapons Engineering and Product Realization
  - Defense Systems and Assessments
  - Energy, Nonproliferation and High Consequence Security

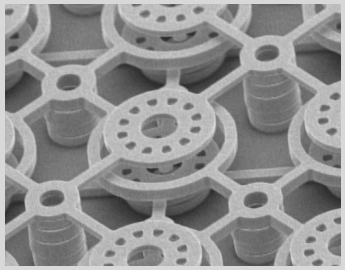
SNL Research and Capabilities

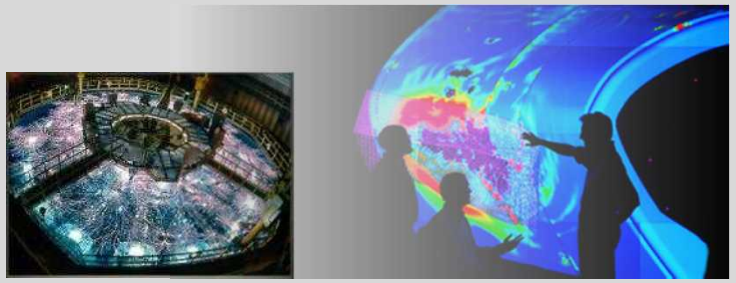
- **SNL Programmatic Areas**
  - Nuclear Weapons
  - Defense Systems and Assessments
  - Energy, Climate, and Infrastructure Security
  - International, Homeland, and Nuclear Security
- **SNL Research Areas**
  - Bioscience
  - Computing and Information Science
  - Engineering Science
  - Geoscience
  - Materials Science
  - Nanodevices and Microsystems
  - Radiation Effects and High Energy Density Science











SNL International, Homeland, and Nuclear Security

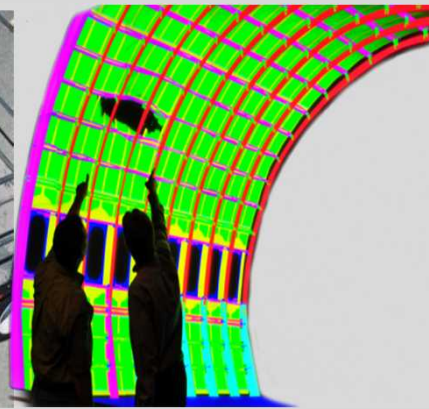
Program Areas

- WMD Counterterrorism & Response
- Global Security & Cooperation
- Homeland Defense & Force Protection
- Homeland Security

Areas of Expertise

- Countering Bioterrorism
- Nuclear, Radiological, and Chemical Risk Reduction
- Nonproliferation and Arms Control
- Physical Security
- Emergency Response
- Systems Analysis and Engineering
- Border Security
- Aviation and Airworthiness Security





International Biological Threat Reduction

- Innovative solutions for countering biological threats globally
- Promote the responsible use of biological agents, equipment, and expertise globally.
- Strengthen capacities to safely, securely, and responsibly detect, handle, and control dangerous biological agents.
- Improve understanding and management of the risks associated with accidental and deliberate misuse of biological agents.

IBTR Core Capabilities

- **Laboratory biorisk management**
  - Biorisk management standards and regulatory frameworks
  - Core biorisk management program documents
  - Lab design / programming expertise
  - Facility specific biosafety and biosecurity threat, vulnerability, and risk assessments
  - Biorisk (biosafety and biosecurity) upgrades
- **Biothreat identification and analysis**
  - Global analysis
  - Country and regional analyses
- **Capacity building and outreach**
  - Biorisk management training
  - Training centers
  - Law enforcement
- **Building inherently safer and more secure biomedical capabilities**
  - Surveillance and control
  - Public and vet health
  - Incident detection and response

IBTR's Global Experience

CBEP Biorisk Implementation

- Primarily support new country engagement
- Technical assistance in:
  - Biological Risk Assessment and Prioritization
  - Global Biorisk Management Curriculum
    - Development and training
  - Biorisk Core Documents
  - Laboratory planning / programming / biorisk management
  - Tabletop and full scale exercises to assess disease detection and response capabilities

Global Biorisk Management Curriculum (GBRMC)

Biosafety & Biosecurity training materials

- Strategic
- Sustainable
- Anywhere, anytime
- Well-branded
- Well-managed
- Customizable

GBRMC in Action










SNL Conclusions

- **SNL is a US Government National Laboratory**
  - Federally-funded research and development center (FFRDC)
  - Mission to provide technical advice and support on national security issues to USG
- **Technical reach-back**
  - Disease detection, microfluidics for medical diagnostics, bioinformatics
  - Security specialists
  - Systems analysis
  - Modeling and simulation
  - Bioforensics, environmental restoration
  - International nuclear nonproliferation experience
- **IBTR has 10+ years of global collaborative biothreat reduction experience**
  - Multi-disciplinary team
- **SNL has infrastructure for international engagement**
  - International business services
  - International programs building, including training, technology, and demonstrations area
  - Extensive global travel and work experience
    - *Demonstrated ability to work in high and extreme risk countries*
    - *Host visiting scholars at Sandia*
    - *Arrange meetings in 3rd party countries to advance projects*

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Differences Between Biological Agents and Other WMD

- Dual-use
  - Materials
  - Technologies
  - Expertise
- Synthetic biology
  - De-novo synthesis
  - Turning non-pathogenic material into virulent organism
- Wide variety of materials
  - Deadly to incapacitating
  - Human, animal, zoonotic, plant
- Self-replicating
  - Minute quantities of concern
- Not detectable at a distance

- Present in many types of facilities
  - Research laboratories, clinical laboratories, hospitals
  - Private and public sector
- Present at multiple locations within a facility
  - In laboratory, in storage, in animals, in waste stream
- Naturally-occurring
  - Few notable exceptions:
    - Variola major virus
    - 1918 Influenza virus
    - Rinderpest

Jonathan B. Tucker, "Biosecurity: Limiting Terrorist Access to Deadly Pathogens," Peaceworks No. 52, United States Institute of Peace, November 2003.

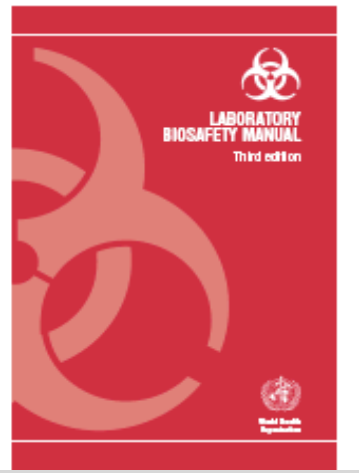
Nature of Biology is Changing

- Rapid technological advances
- Technologies becoming more available
  - Geographically
  - Individuals

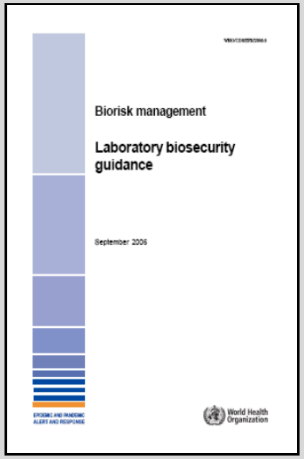
DNA extraction kit for 10 year old kids, sold by Japanese National Museum of Emerging Science and Innovation

Definitions

- **Biosafety**: containment principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release[1]



- **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)

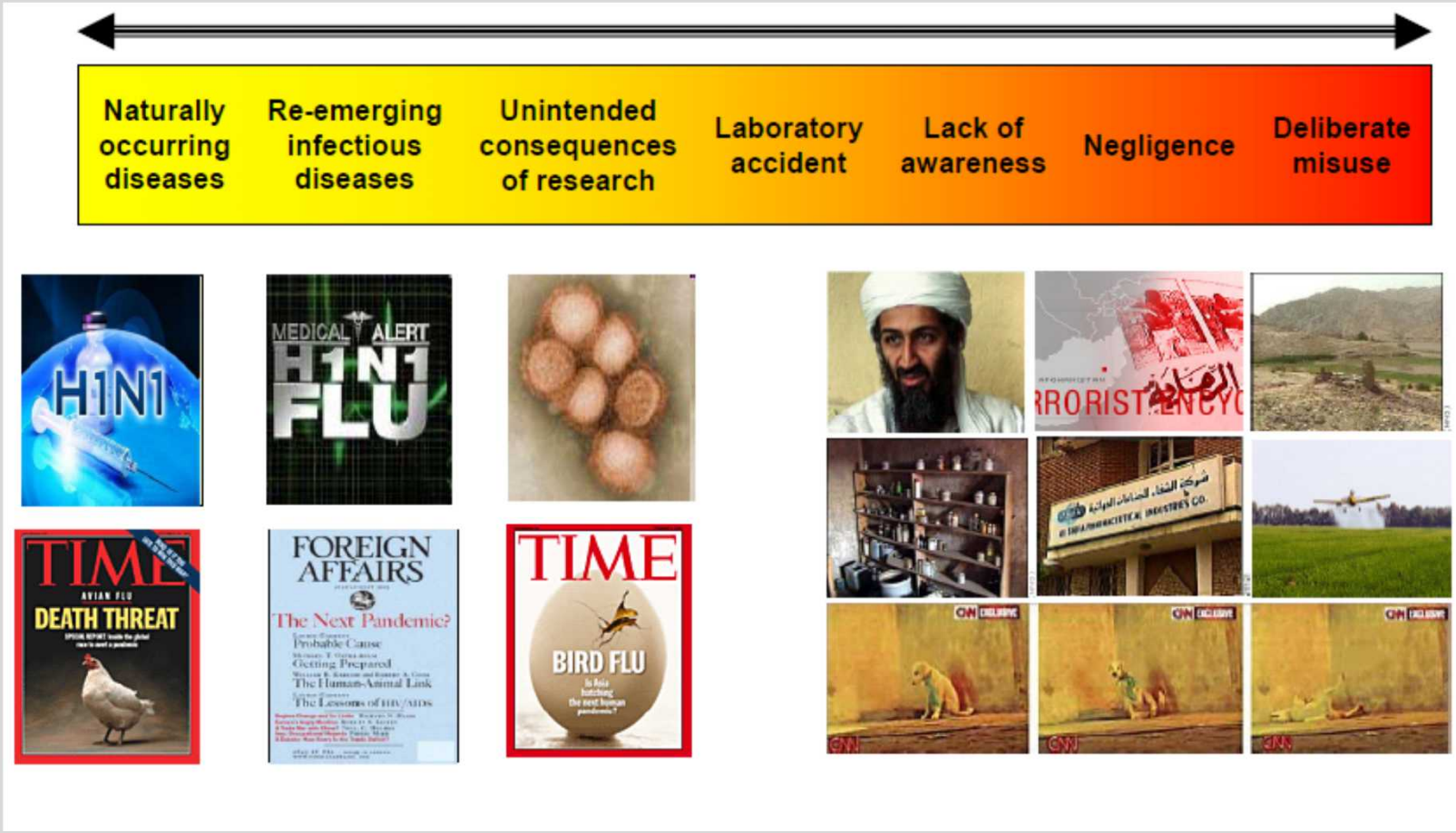
[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

What is Biorisk?

- A risk associated with biological agents and toxins

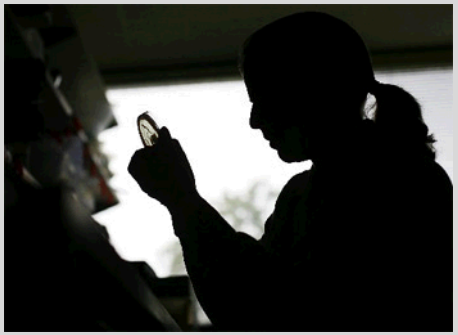
Biorisk = biosafety + biosecurity risks

Spectrum of Biological Risks



Safety and Security Issues in Laboratories

- 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 *Yesinia 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



TAMU Select Agent researcher – Dallas Morning News

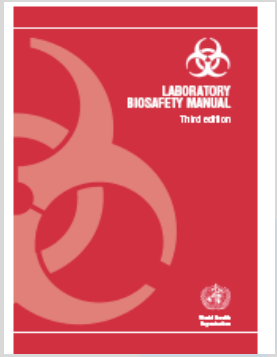
Thomas Butler

How Can These Biorisks be Addressed?

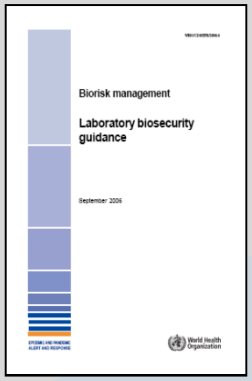
- **Biorisk management** is a system or process to control **safety** and **security** risks associated with the handling or storage and disposal of **biological agents and toxins**

Selected Key International Documents

World Health Organization (WHO)
European Committee for Standardization (CEN)



2004 – Laboratory Biosafety Manual, 3rd Edition (WHO)



2006 – Biorisk Management : Laboratory Biosecurity Guidance (WHO/FAO/ OIE)

2008 – CWA 15793:2008 – Laboratory biorisk management standard (CEN)

2011 – CWA 16335:2011 – Biosafety Professional Competence (CEN)

2012 – CWA 15793 Guidance Document

Technical guidance

Presentation Overview

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Biorisk Management: The AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Key Components of Biorisk Management

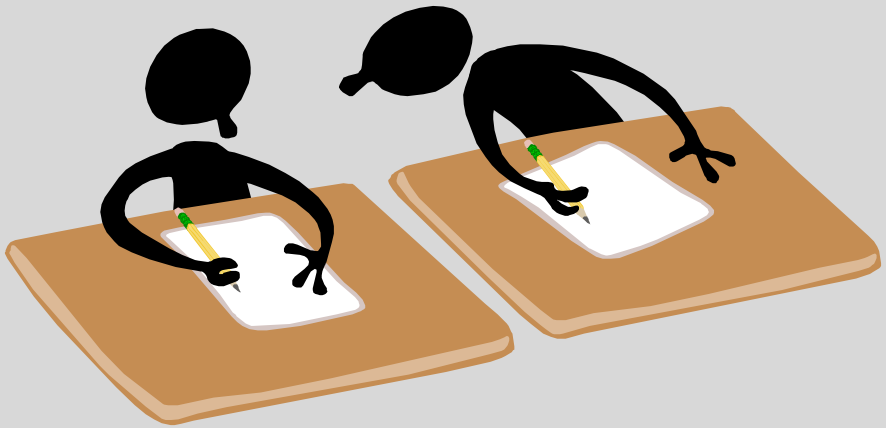
- Biorisk **Assessment**
  - Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

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.

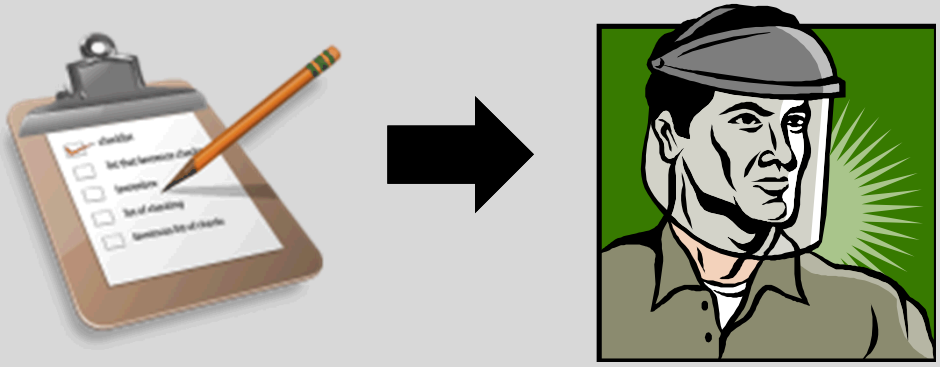


Biosafety Risk Assessment

A **biosafety risk assessment** is an analytical procedure designed to characterize and evaluate ***safety*** risks involving biological agents.

Biosafety Risk Assessment

A **biosafety risk assessment** allows a group working with biological agents to determine the relative level of risk its different activities pose, and helps guide **risk mitigation decisions** so these are targeted to the risk being evaluated.



Definitions

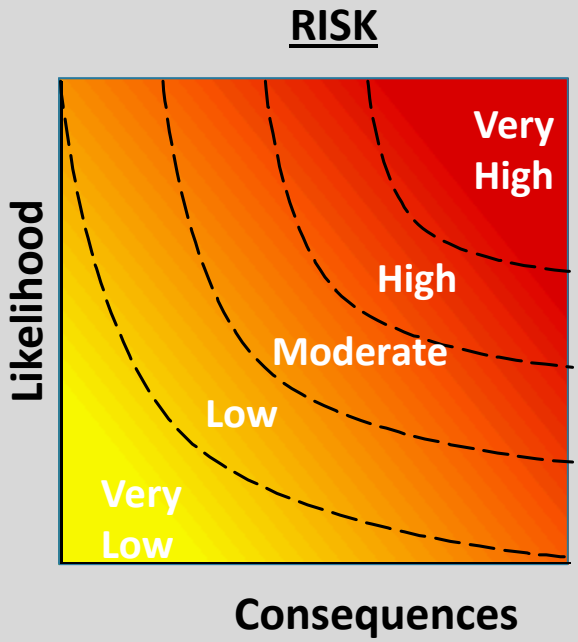
Difference between hazard, threat, & risk

- **Hazard**
  - *Something* that has potential to do harm
- **Threat**
  - *Someone* with potential to do harm using a specific **hazard**
- **Risk**
  - In a given scenario or event involving a specific hazard, the likelihood and consequence of a *particular outcome*

Risk Assessment

- Risk is a function of
  - Probability an incident will occur **(likelihood)**
  - Severity if the event occurs (**consequences)**

Risk = *f*(Likelihood, Consequences)



Risk Characterization and Evaluation

- Once hazard is identified, need to consider hazard properties that affect likelihood and consequence
  - For biological agents this can include but is not limited to:
    - Agent properties
      - Route of exposure
      - Infectious dose
      - Environmental stability
      - Availability of medical countermeasures
    - Activities being conducted with biological materials
      - Aerosol generating procedures
      - Vaccine challenge studies
- Evaluate the risk

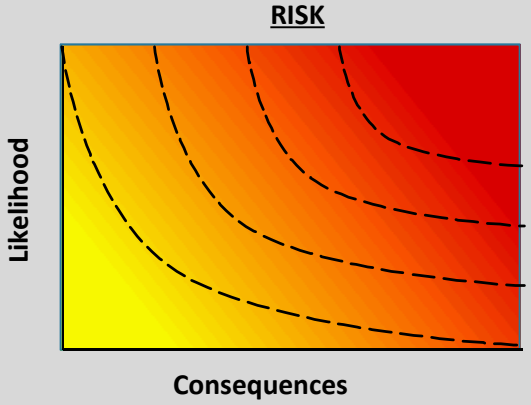
Risk Assessment

What is the risk of being attacked by a tiger?

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

You are in an open field next to a very hungry , aggressive, adult tiger.

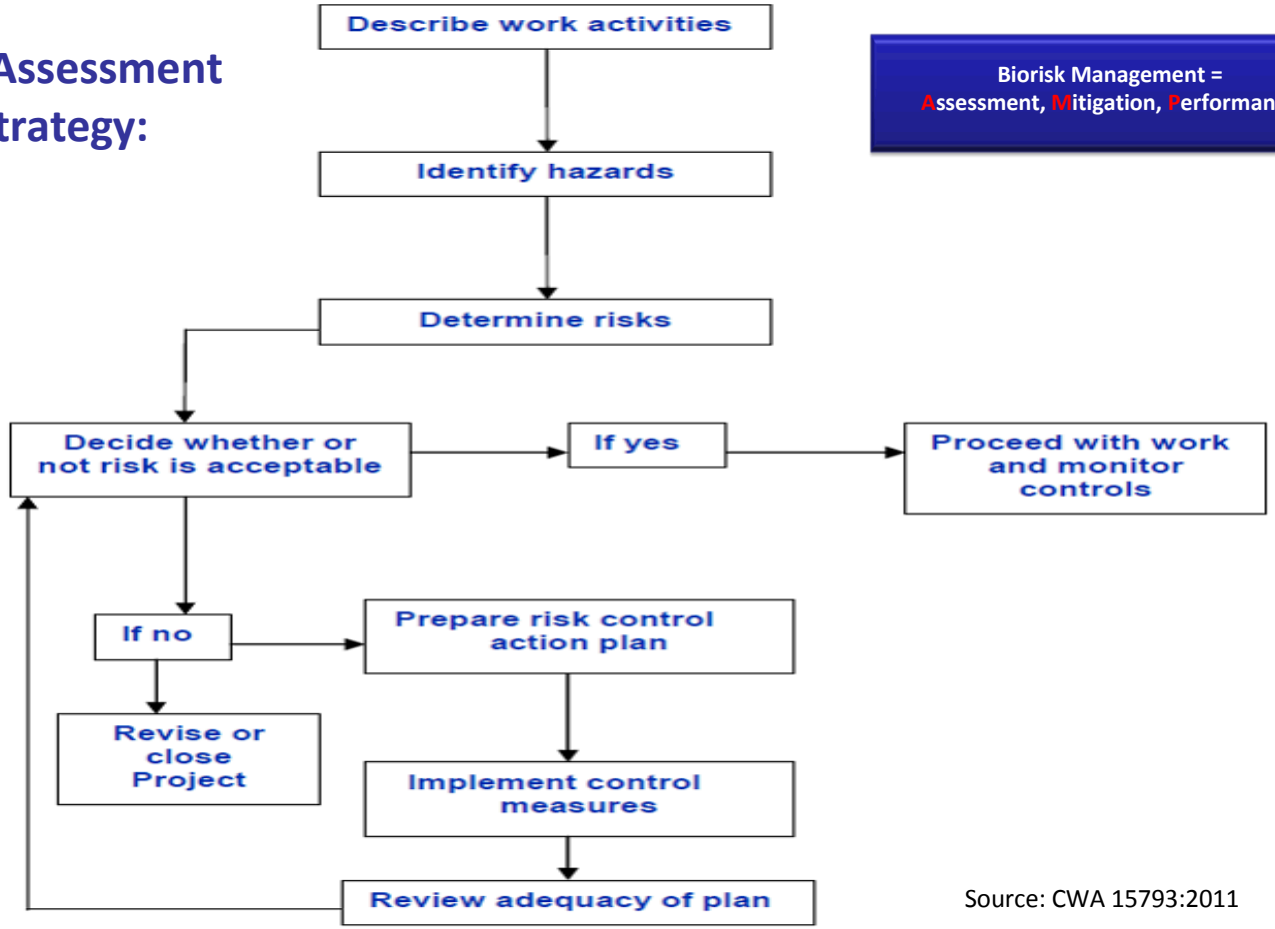
The tiger is unrestrained and sees you as food.



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

Risk Assessment Strategy

Risk Assessment Strategy:



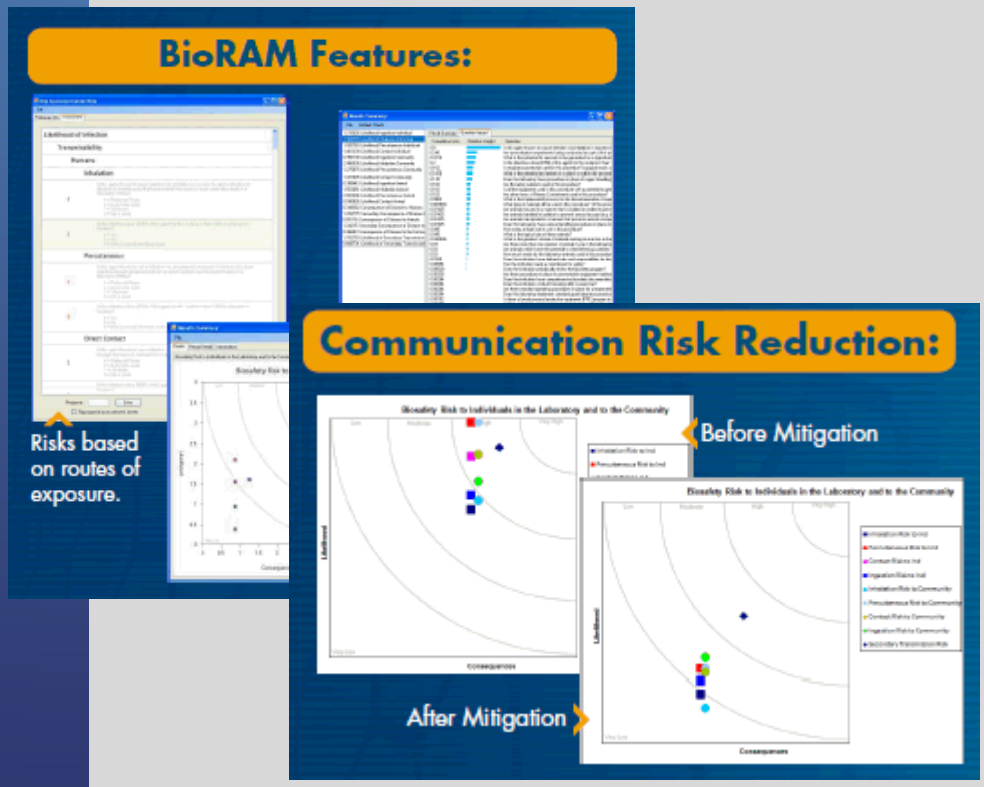
Biorisk Management = Assessment, Mitigation, Performance

Source: CWA 15793:2011

Biosafety and Biosecurity Risk Assessment Methodology (BioRAM)

BioRAM Vision

- Create a standardized approach to risk assessment.
- Create a tool for understanding prioritization and communication in a laboratory environment.



Biosafety

- 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: The consequences of disease from accidental exposure.
- Risks: The risks to laboratory workers, risk of accidental exposure to human and animal community, and risks of secondary infection.

Biosecurity

- Likelihood: The likelihood of targeting a laboratory based upon the agent's potential for malicious use and the likelihood of successful acquisition of the agent from the laboratory.
- Consequences: The consequences of disease from malicious release.
- Risks: The risks to the human and animal community.

BioRAM

BioRAM uses 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.

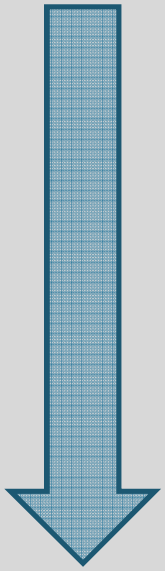
http://biosecurity.sandia.gov/BioRAM/

Risk Mitigation

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

Categories of Mitigation Measures

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



Activity

- Find the biosafety mitigation cards
  - Each card contains a category of mitigation measures and the corresponding definition
- We will review a series of images
  - Select the card that matches the type of mitigation measure demonstrated in the picture
  - After selection, we will discuss the mitigation measures and some advantages/disadvantages

GBRMC

Biosafety Mitigation

Biosafety Mitigation

Biosafety Mitigation

GBRMC

Biosafety Mitigation

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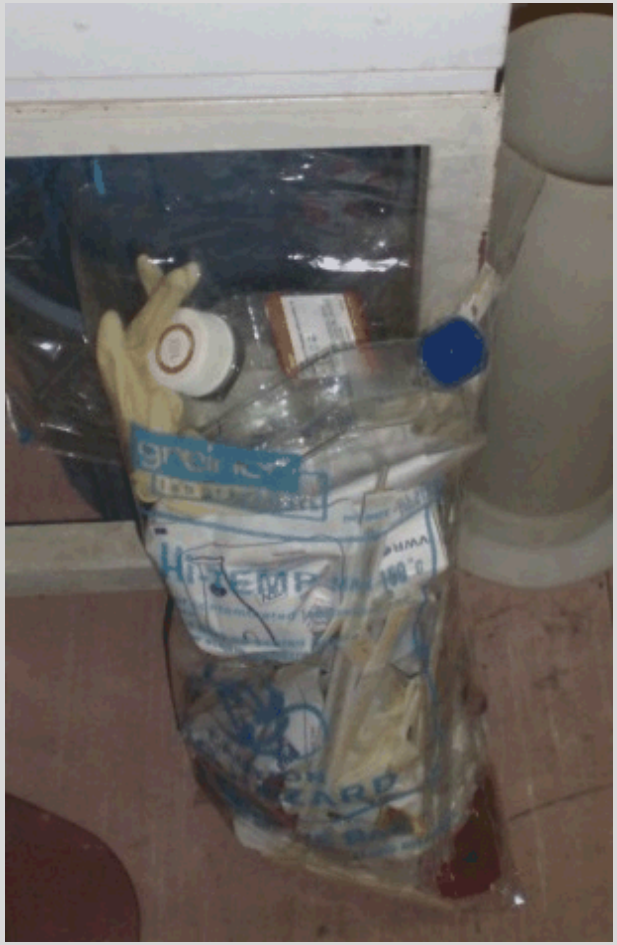
Biosafety Mitigation

Advantages and Disadvantages of Biosafety Risk Mitigation Measures

Mitigation Measure	Advantages	Disadvantages
Elimination or Substitution	Immediate reduction of risk	Not always available or possible
Engineering	Efficient, eliminates hazard	Cost, 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**, *if* **PPE fails personnel are exposed**, uncomfortable, limits ability, only protects the user

Biosafety Risk Mitigation



Performance

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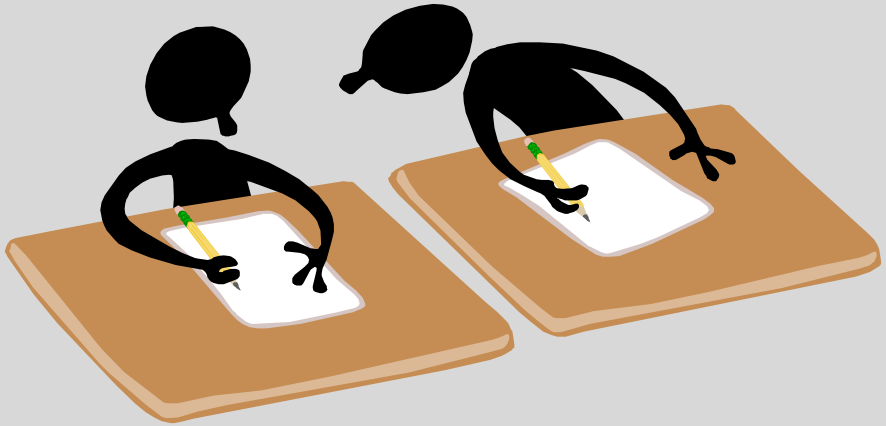
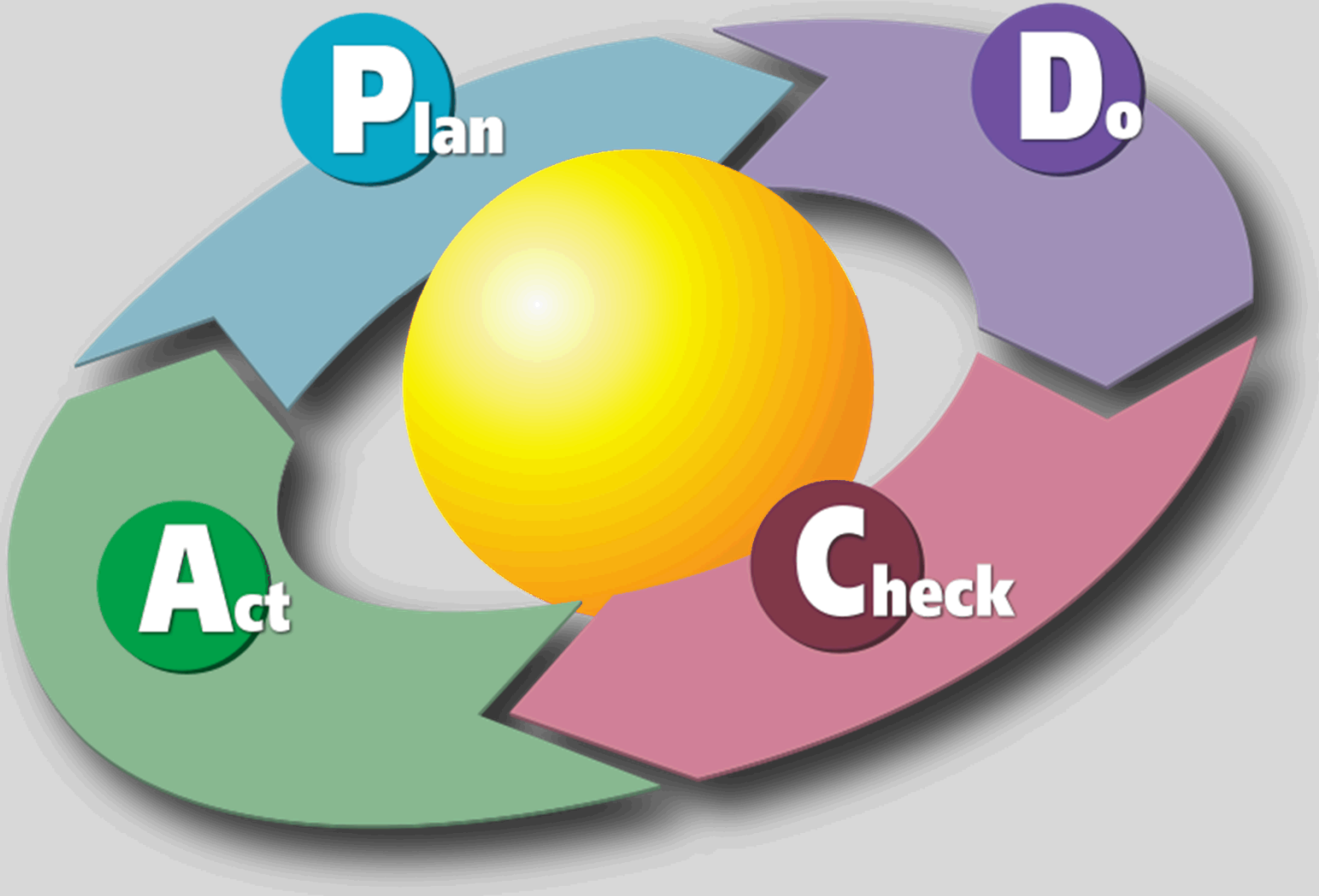
Another aspect of performance is the process of continually improving the system.



Performance Indicators

- The only way to document effective performance is to measure it
  - Activity based
  - Outcome based
  - A measurement is not necessarily a number
- Performance indicator measurement collection should be integrated into routine activities.
  - Establish performance measurements during development of system objectives, roles, and responsibilities

GBRMC



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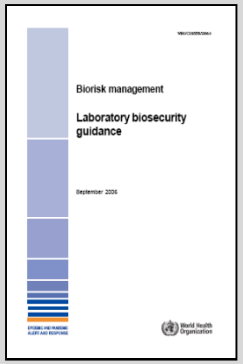
Biosecurity: Protecting Legitimate Sources

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.[1]

How does this differ from **biosafety**?



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

Security Culture

- Laboratories do not often think of themselves as needing to be secure
  - Most laboratory workers do not consider that their materials could be misused
  - Academic settings value openness
  - Security does not typically consider biological materials

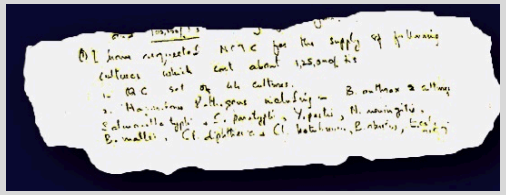
Awareness Training

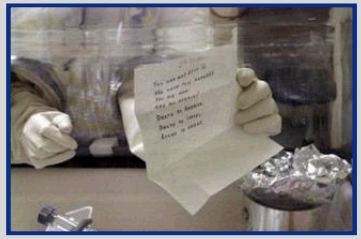
Promoting **security awareness** in employees is one of way breaches in security can be recognized.

Lab workers should be **aware** of who should be and should not be in their work areas and potential consequences of unauthorized persons accessing these areas.

Biosecurity Threats

- **People outside bioscience facilities** who want to obtain pathogens with the intent to commit malicious acts or cause harm
  - Extremists purchasing pathogens: *Salmonella typhi*, Anthrax, *Clostridium botulinum*, *Yersinia pestis*
  - Stealing: Pathogen collections, Select agents, research animals





- **People within bioscience facilities** using their position to commit malicious acts
  - Stealing pathogens: Anthrax, *Shigella dysenteriae*, *Salmonella typhi,* toxins
  - Research theft: intellectual property – data, materials, cultures

Biosecurity Risks

- Risk of theft
  - Biological agents
  - Equipment
  - Information
- Risk of deliberate release
  - Sabotage
  - Malicious actor

Risk = *ƒ*(Likelihood, Consequences)

Biosecurity Risk Assessment

- Characterize biological agents and threats
  - Evaluate pathogens/toxins, and equipment at a facility (Asset Assessment)
  - Evaluate adversaries who might attempt to steal those pathogens or toxins (Threat Assessment)
- Characterize the facility
  - Evaluate the likelihood the facility will be targeted
  - Evaluate the likelihood of a successful theft (Vulnerability Assessment)
- Characterize the risk
  - Evaluate the overall likelihood and consequences of each scenario
- Determine acceptable and unacceptable risks
- Systematic (repeatable)

Biosecurity Risk Mitigation

- Biosecurity Risk Mitigation
  - Process whereby risks identified and characterized during a risk assessment are reduced through active intervention, be it physical or procedural.

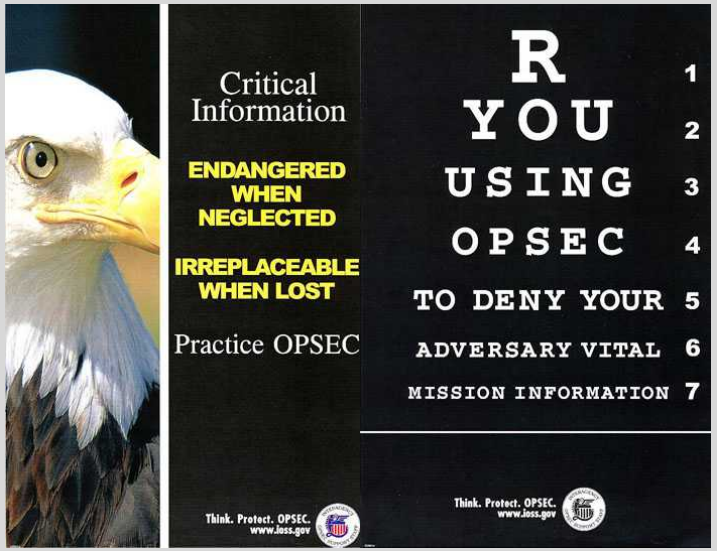
Biosecurity Risk Mitigation

1) Physical Security
2) Personnel Management
3) Material Control & Accountability
4) Transport Security
5) Information Security

Activity

- Find the biosecurity mitigation cards
  - Each card contains a category of type of mitigation measure and the corresponding definition
- We will review a series of images
  - Select the card that matches the type of mitigation measure demonstrated in the picture
  - After selection, we will discuss the mitigation measures and how they fulfill the system objectives

Biosecurity Mitigation



Biosecurity Mitigation

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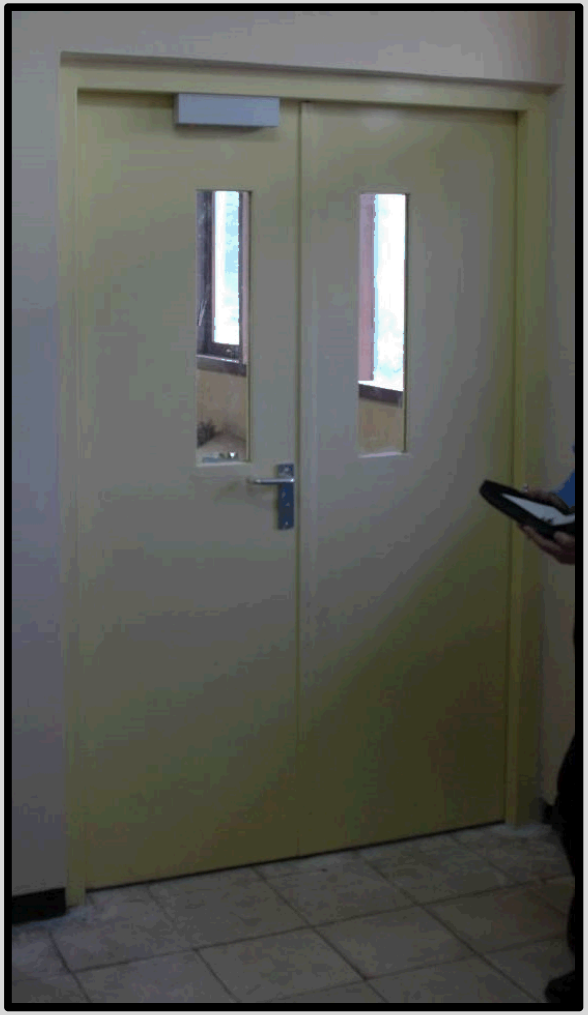

Biosecurity Mitigation

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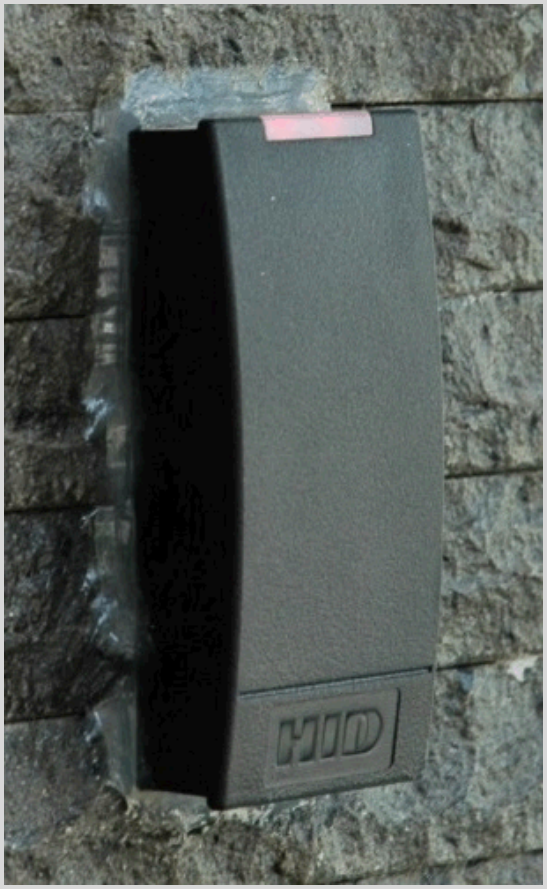
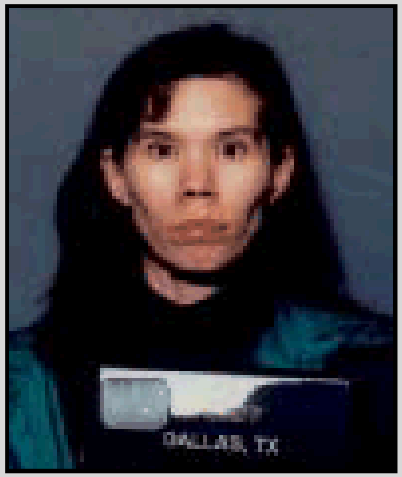
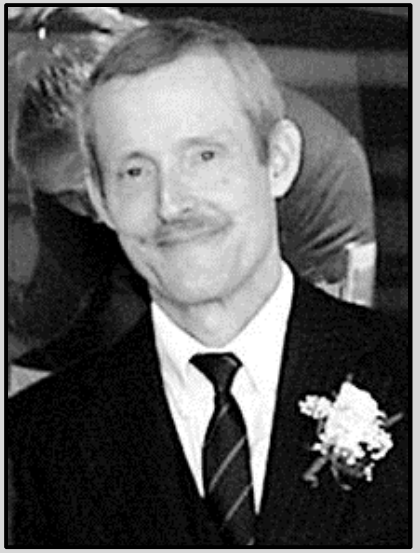


Biosecurity Mitigation





Biosafety and Biosecurity Integration

Biosafety Risks

Biosecurity Risks

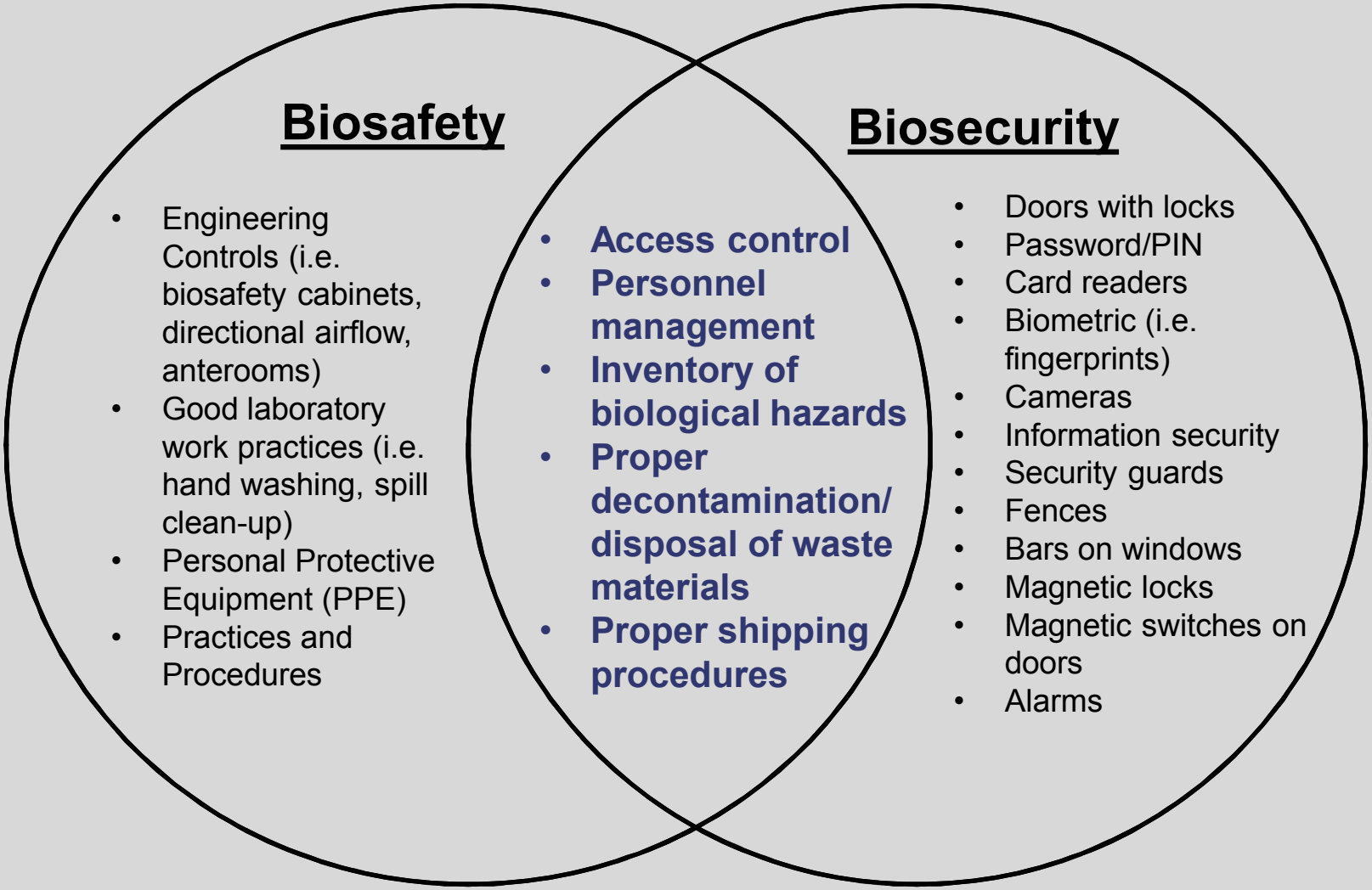
Biosafety

Integration Process

Biosecurity

Biorisk Management

Example Biosafety and Biosecurity Mitigation Measures



Summary

- GBRMC library is an outcomes based biorisk management training materials library built on best practices and brain-friendly training techniques
- Biosafety, biosecurity, biorisk, and biorisk management system are common biorisk terms that relate to and support each other
- AMP (Assessment, Mitigation, and Performance) is a simple but powerful model for managing biorisks
- Biosecurity encompasses protections beyond physical security of pathogens and related materials

End of the Module

Thank You!