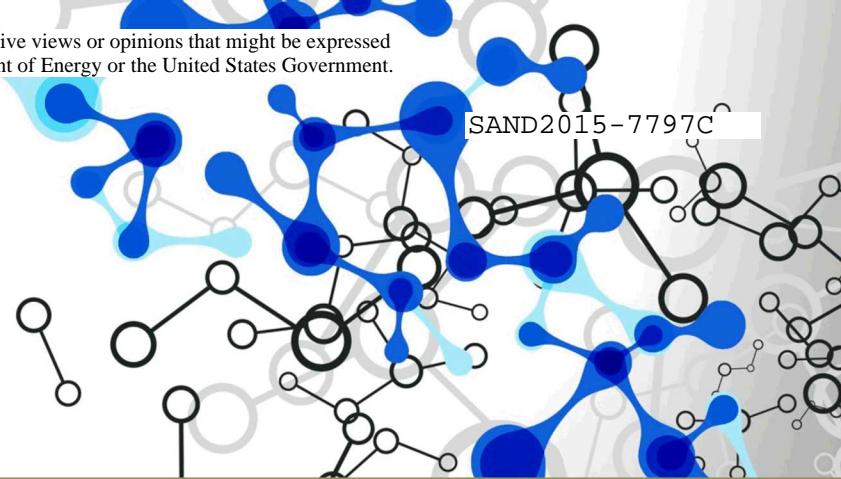


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IBCTR
INTERNATIONAL BIOLOGICAL
and CHEMICAL THREAT REDUCTION



Sustainable Biosecurity Approaches

Ren Salerno

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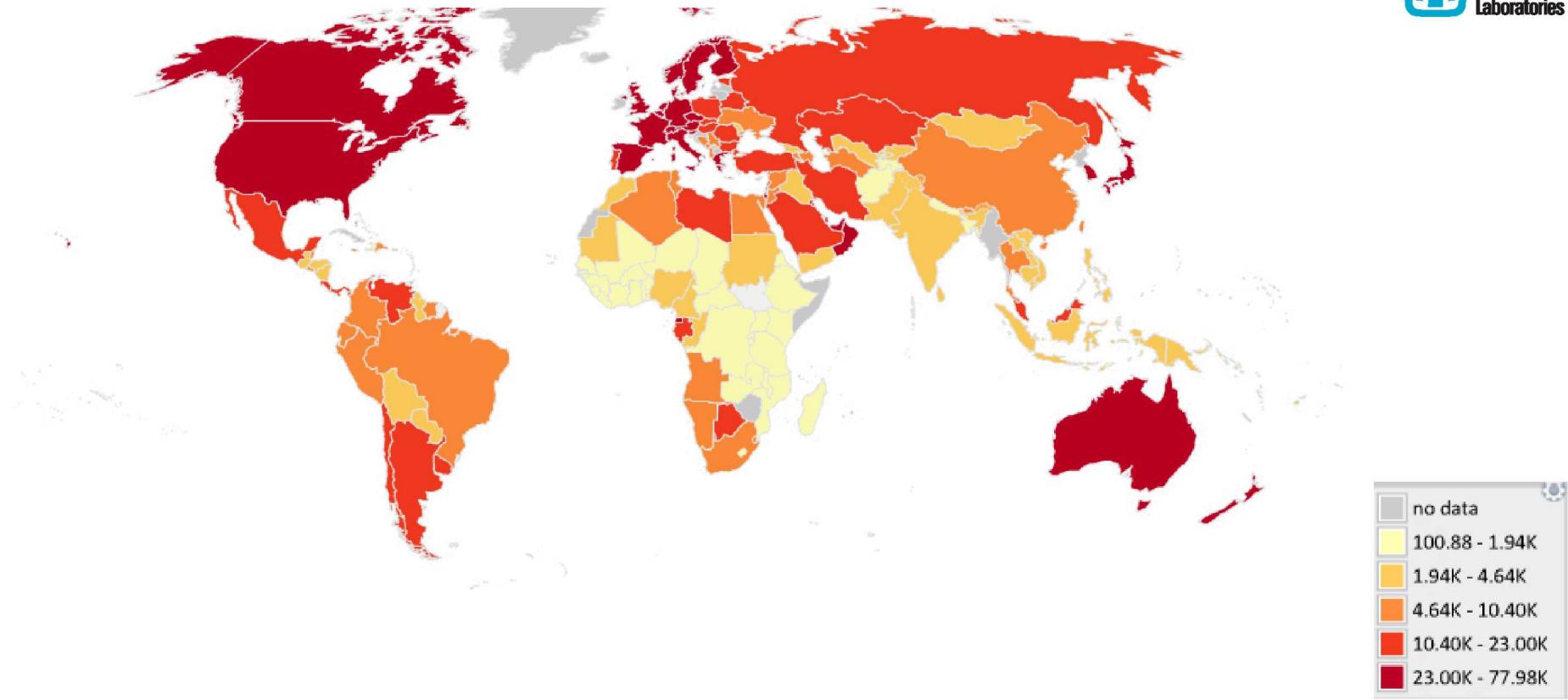


Sustainable Biosecurity Approaches



Presentation overview

- Define the problem
- Biosecurity definition
- Biorisk Management System to support biosecurity
- Biosecurity mitigation measures and international experiences
- Conclusions



Biosecurity laboratory issues are not defined by country income levels but by the risks identified

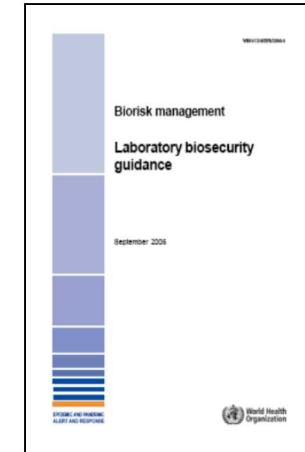
2010 GDP per capita, (PPP constant 2005)

World Bank MIC Data visualizer

Biosecurity: Protecting Legitimate Sources

Biosecurity

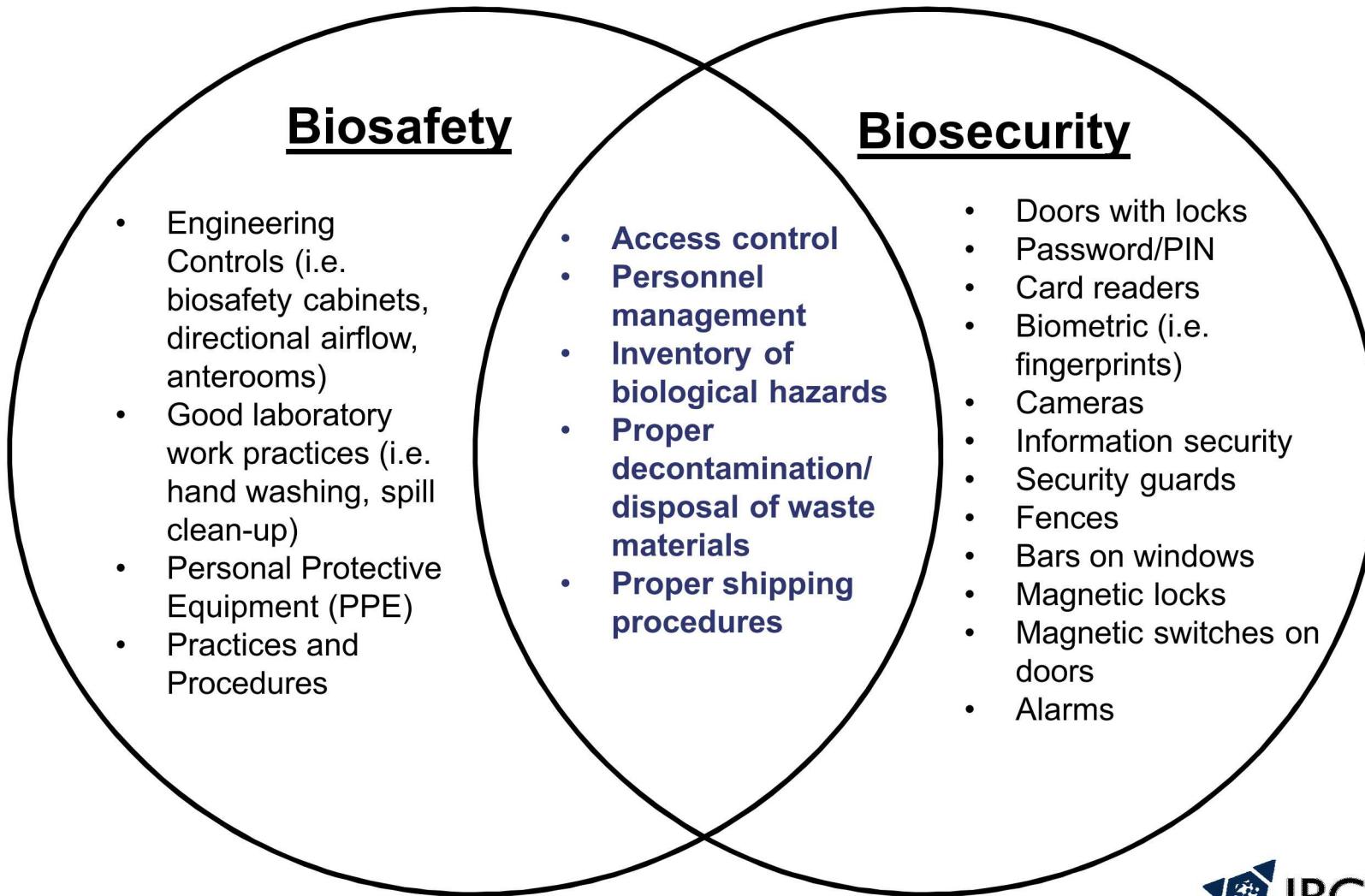
Protection, control, and accountability for valuable biological materials *within laboratories*, in order to prevent their unauthorized access, loss, theft, misuse, diversion, or **intentional** release.²



How does this differ from biosafety?

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

Overlap of Biosafety and Biosecurity



Implementing Biosecurity

- Goal
 - Prevent the unauthorized access, loss, theft, misuse, diversion, or intentional release of biological materials held by legitimate sources
- Strategy
 - Biorisk Management Systems
- Objective
 - Protect **X** asset at **Y** facility from **unauthorized access, loss, theft, misuse, diversion, or intentional release** by **Q** threat
- Tactic
 - Locally relevant biosecurity mitigation measures

Biorisk Management: the **AMP** Model

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

Key Components of Biorisk Management

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

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.

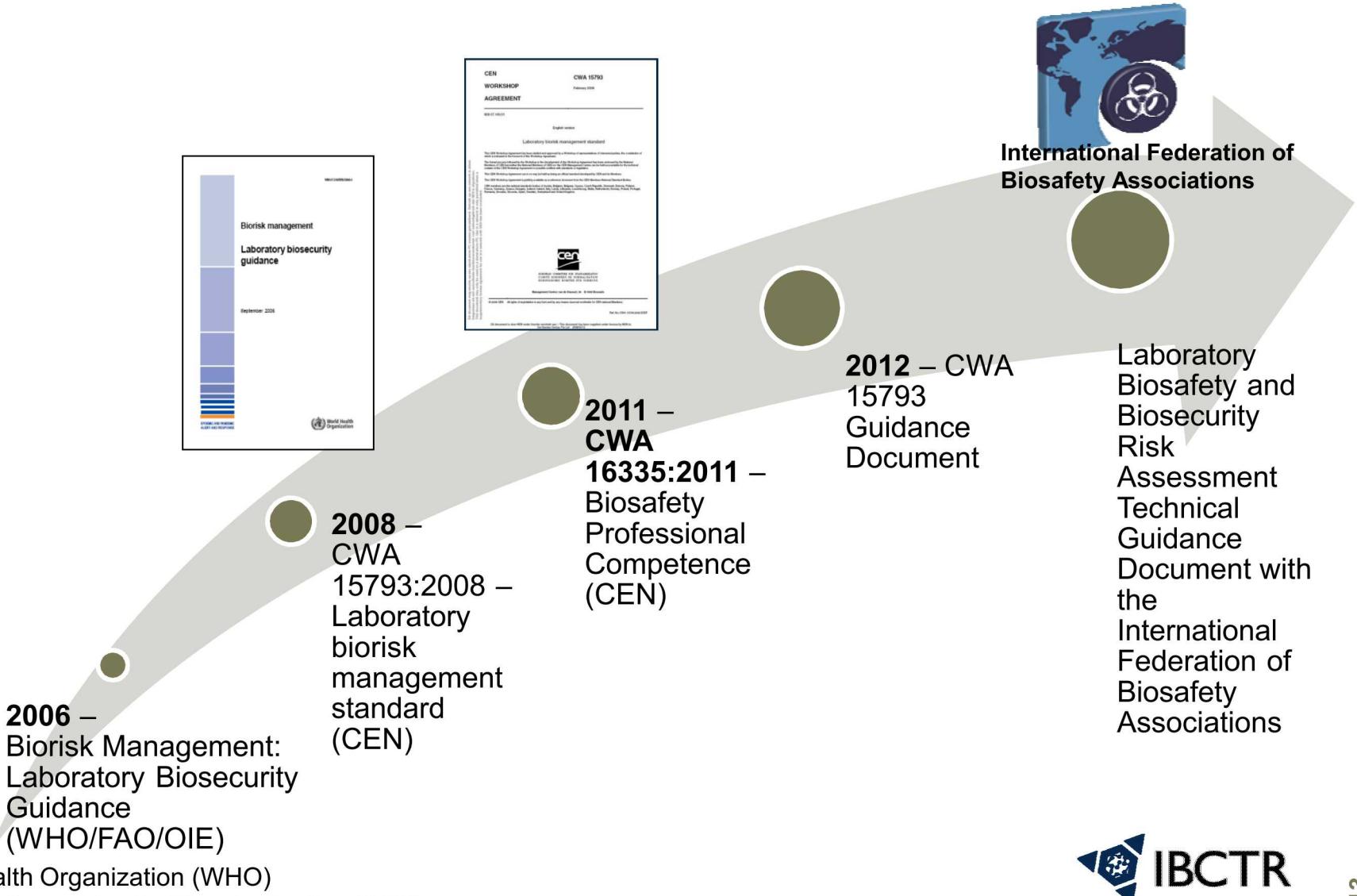


Standards, Regulations, Best Practice



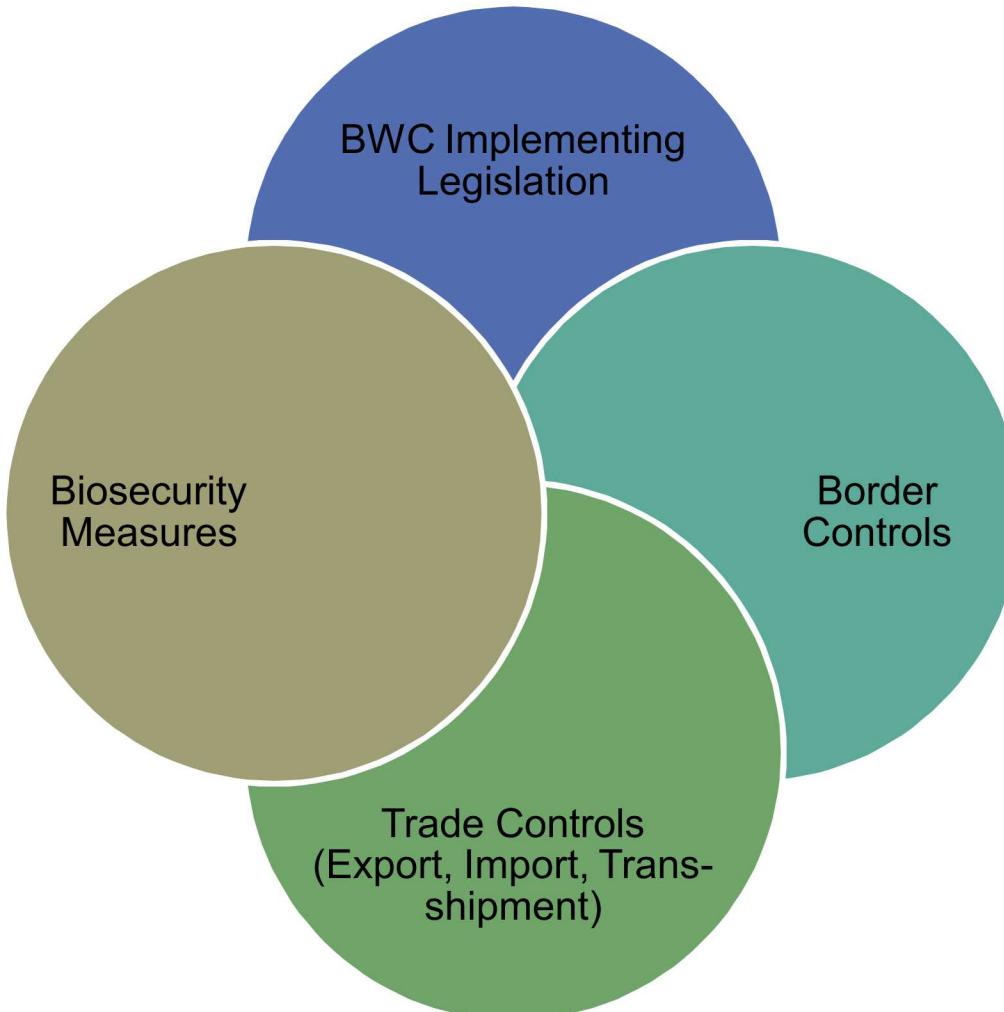
Advancing Biorisk Management

International Technical Guidance



Advancing Biorisk Management

Relevant National Measures



IBCTR's Risk Assessment Methodologies

Risk assessments define the objective of the biosecurity system

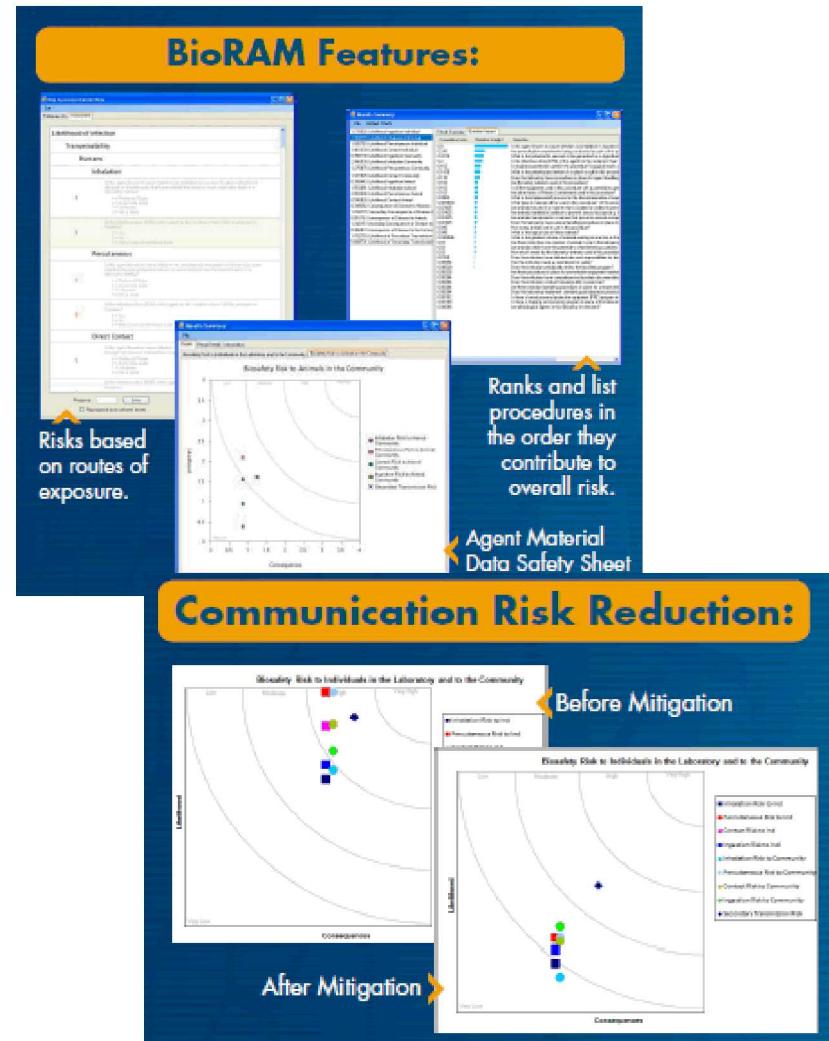
- Assets
- Facilities
- Action
- Threat

Vision

- Create a standardized approaches to risk assessment for biological safety and security
- Create a tool for understanding prioritization and communication

SNL Tools

- Biosafety RAM
- Biosecurity RAM



Identify Legitimate Sources of Biological Materials

- Laboratories
 - Public Health and Animal Health Laboratories
 - *Diagnostic testing*
 - *Quarantine*
 - *Forensics*
 - Research
 - *Pathogen characterization*
 - *Medical countermeasures development*
- Culture collections and repositories
 - Serve biomedical community
 - Eradicated pathogens
- Vaccine production and testing facilities
 - Polio virus
 - Foot and mouth disease virus
- Biotechnology applications



Protecting Legitimate Sources of Biological Materials



- Locally relevant
- Sustainable
- Not impede or significantly alter workflow
 - Do not over-engineer the system
 - Suited to the specific target
 - Must be adaptable and flexible to changing situations
- Security culture
- 5 Pillars of biosecurity
 - Physical security
 - Information security
 - Material control and accountability
 - Transportation security
 - Personnel management



Biosecurity Mitigation Measures

Physical Security



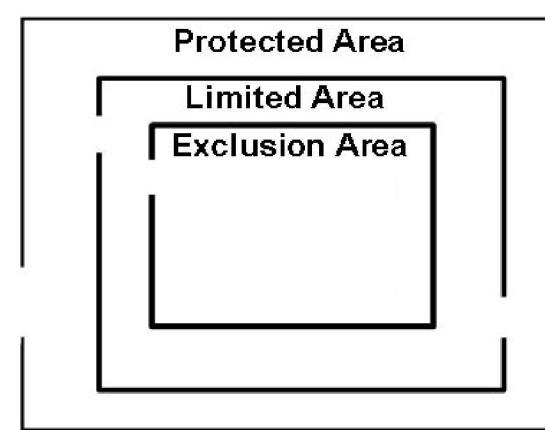
Balance facility wants with location specific mitigation measures



Physical Security

Graded Protection

- Property protection areas
 - Grounds
 - Public access needs
 - Warehouses
- Limited areas
 - Labs
 - Sensitive or administration offices
 - Hallways surrounding exclusion areas
- Exclusion areas
 - High containment laboratories
 - Computer network hubs



Physical security principles

PHYSICAL SECURITY PRINCIPLES

- Detection
 - Sensors
 - Closed-circuit television systems
 - Alarm and assessment
 - Guard force patrols
 - Training procedures
- Delay
 - Perimeter fencing
 - Solid doors with locks
 - Bars on windows
 - Balanced magnetic switches
- Response
 - On site guard force
 - Communication with local police force



Physical Security: Access Control

RESOURCE AND INFRASTRUCTURE INTENSIVE

Biometric scanners

Proximity card readers



SIMPLE SOLUTIONS

Lock and key

Cipher Lock

Policies and procedures



Biosecurity Mitigation Measures

Information Security



Assure that sensitive and valuable information in a laboratory is protected

- Protect information that is too sensitive for public distribution
 - Lab results
 - Patient information
 - Research trial information
- Biosecurity related sensitive information
 - Risk assessments
 - Security system design
 - Access authorizations

SENSITIVE INFORMATION SOURCES

- Generally assumes electronic systems
- Can be simple as data distribution limitations
- Most international partners do not use organizational emails



Biosecurity Mitigation Measures

Material Control and Accountability

Assurance that there is a complete and timely awareness of

- *What* exists in the lab
- *Where* it is
- *Who* is responsible



Challenges

- Bacteria and viruses multiply
- Detection of theft is nearly impossible

Solutions

- Practices and procedures for sample labeling storage
- Consolidate freezers and sample repositories

Biosecurity Risk Mitigation

Personnel Management

- Human factors impact the success of a biorisk management system
 - Reduce risk of theft and fraud
 - Reduce risk of scientific misconduct
- Support procedural and administrative access control requirements
- Verifying credentials
- Culturally relevant
 - Some positions are political appointments



Personnel Management: Security Culture

LABORATORIES OFTEN DO NOT THINK OF THEMSELVES AS NEEDING TO BE SECURE

Most laboratory workers

- Do not consider the idea that their biological materials could be misused.
- Do not want to feel they are “spying” on coworkers

Academic settings value openness, collaborations, and sharing

In a clinical setting, security does not typically consider biological materials

- Patient access is required to laboratories
- Patients deliver their own specimens

In some countries, basic infrastructure challenges trump facility security issues



Biosecurity Mitigation Measures

Transportation Security



Assurance that the rigorous processes to protect biological materials in the laboratory also follow the materials in transportation

- Internal transportation
 - *Within the same institution*
 - *Movement from sample reception to laboratory*
 - *Movement from laboratory to disposal area*
 - *Process and procedure driven*
- External transportation
 - *Movement between institutions*
 - *May involve international and national regulations and standards*
 - *May involve commercial carriers*



Biosecurity Systems Performance

Management and Leadership



- Acceptance testing for security upgrades
- Biosecurity handbook
- Standard operating procedure preparation
- Training on the use and maintenance of biosecurity systems
- Periodic self-assessments and ongoing monitoring

Conclusions

- International technical guidance for biosecurity and is locally adaptable
- Biosecurity mitigation measures are best identified following a thorough risk assessment
- Biosecurity systems encompass more than physical security of biological materials
- Predefined solutions to biosecurity are not sustainable nor locally relevant
- Biosecurity measures selection should incorporate users and management