

Laboratory Biosecurity

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Objectives



- Define Biosecurity
- State the purpose of biosecurity
- Identify differences between Biosecurity & Biosafety
- Discuss biosecurity & biosafety overlap
- List Biosecurity strategies
- Discuss the components of Biosecurity plan

What is Biosecurity?



BIOSECURITY Definition (WHO)

"Laboratory biosecurity – the containment principles, technologies and practices that are implemented to prevent the intentional exposure to pathogens and toxins, or their intentional release."



Why Implement a Laboratory Biosecurity Program?

- Improve security
- Increase emergency preparedness
- Protect reputation/image
- Mitigate liability exposure
- Protect public health
- Protect employees
- Protect research

Biosecurity is part of Biosafety



Biosecurity and Biosafety are components of good laboratory practice.





Biosafety vs. Biosecurity



<u>**Biosafety</u>:** Reduce or eliminate accidental exposure of individuals and the environment to potentially hazardous and biological agents.</u>

Biosecurity: The protection of pathogens, toxins, and sensitive information from loss, theft and subsequent misuse.

Biosafety vs. Biosecurity

(Simply stated...)



Biosafety:

- Protect people from dangerous pathogens.
- Limited lab access while work is in progress

Biosecurity:

- Protect pathogens from dangerous people.
- Limit access to labs that contain certain biological agents

Biosafety & Biosecurity Similarities



Biosafety and Biosecurity are complementary.

Biosecurity relies on a sound biosafety program.

 Biosecurity practices reinforce and strengthen biosafety



Biosecurity Objective

Protect Against:

- Loss, Theft
- Diversion of dangerous pathogens
- Minimize intentional misuse.

Biosecurity Strategies



- Protect defined assets against defined threats
- Define risk by evaluating probabilities and consequences
- Integrate security technologies and procedures
- Apply a graded protection approach
- Impact operations only to the level required.

Similar Implementation Strategies

- Policies and Practices
 - SOP
 - Training
- Equipment

Facility Design







Biosecurity and Biosafety Overlap



- Risk assessment & risk management
- Personnel screening
- Control & accountability
- Transport protocols
- Physical security elements
- Training
- Emergency planning
- Management oversight

Biosecurity and Biosafety Overlap



- Inventory and tracking of biological materials
- Shipment of infectious materials must adhere to safe packaging, documentation and transport
- Good laboratory practices
- Adoption, implementation and accountability
- Training on general practices, SOP, and awareness of risks and hazards



Must be resolved to accommodate both Biosafety and Biosecurity objectives.

Example: Signage Requirements

- Biohazard signage: risks in lab list
 BSL
- Contact name/ number
- Agent
- **Medical requirements**
- **PPE required**
- Listing agent may compromise security Modify signage to disclose hazards; not to disclose specific agent(s)

Microbes Multiply



- They grow, mutate etc.
- Found in the environment, animals, Petri dishes, tubes, flasks
- In cell cultures, clinical specimens, animal carcasses, wastes
- In incubators, freezers, refrigerators, freezedried forms
- Safe-guarding all this is very complicated
- Knowing "working" quantities impossible

Balancing Security with Work



- Scientist may be unaccustomed to working in a security conscious environment
- Security experts may want more procedures than are compatible with current projects

Strategy: Facilitate open collaboration and mutual respect to reach same goals.

Barriers/Challenges to Implementing a Biosecurity Program

- Resources
- Management support
- Resistance to change
- Inadequate training
- Insufficient information
- Others?



Developing a Biosecurity Program



Collaboration with representatives:

- Senior management
- Scientific staff
- Security officials
- Safety personnel
- Engineering staff
- Information Technology (IT) staff
- Human resources officials

Risk Assessment



Definition:

An evaluation of the probability and consequences of undesirable events caused by an adversary that could affect the defined assets.

<u>Goal:</u>

To determine which events the security system must be designed to protect against

Vulnerability Assessment

Definition:

A systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.

Source: MMWR, December 6, 2002 / 51(RR19);1-8





Allow management to make informed decisions to ensure that the cost of protective measures are proportional to the risk.

Five Step for <u>Biosecurity</u> Risk Assessment

(Outlined in the CDC/NIH BMBL)

- 1. Identify and prioritize assets
- 2. Assess potential threats and vulnerabilities
- 3. Analyze the risk of specific security scenarios
- 4. Design and develop an overall risk management program
- 5. Re-evaluate institution's risk posture and protective objectives

Step 1: Identify and Prioritize Assets

- Identify agents, materials, equipment, personnel
- Evaluate potential misuse or weaponization
- Evaluate consequence of misuse
- Prioritize assets based on consequence of misuse





Step 2: Assess Potential Threats and Vulnerabilities



- Identify types of <u>outsiders</u>
- Identify types of <u>insiders</u>
- Evaluate <u>motive</u>, <u>means</u>, <u>opportunity</u> for potential adversaries

Threats

<u>Outsider</u>

Low risk Public access to info May be armed May carry tools

Strategy

Detect & Contain

Insider

High risk

Unescorted access

Non-violent

Knowledge of facility

Opportunity

Strategy

Know employees

Step 3: Analyze the Risk of Specific Security Scenarios



- Develop list of possible security scenarios.
- Evaluate probability of each scenario materializing and its consequences.
- Prioritize or rank scenarios by risk for management to review.

Step 4: Design and Develop an Overall Risk Management Program



Management:

- Makes final decision on items that require protection, with advise from committee
- Oversees, implements, trains, and maintains biosecurity program
- Develops "Risk Statement"
- Develops "Biosecurity Plan"
- Ensures resources to achieve measures in biosecurity plan.

Step 5: Re-evaluate Institution's Risk Posture and Protection Objectives

<u>Re-evaluate and modify:</u>

- Biosecurity risk statement
- Biosecurity risk assessment process
- Biosecurity program/plan
- Biosecurity systems

Re-enforce:

 Implementation, training, annual re-evaluation of security program.



Developing a Security Plan

- Site specific process
 - Systematic approach
- Involves:
 - Biosecurity Risk / Vulnerability Assessment
 - Risk Management Process & Policies
 - Both are critical processes

Developing a Security Plan

Institution Responsibilities:

- Management commitment
- Delegate program oversight
- Ensure Resources & Manpower
- Delegate enforcement
- Ensures comprehensive "Biosecurity Program"
 - Development and implementation
 - Encompasses laboratory and animal programs
 - Integrated with facility-wide security plans







Components of a Biosecurity Plan

- 1) Program Management
- 2) Physical Security and Access Control
- 3) Personnel Management
- 4) Inventory & Accountability
- 5) Information Security
- 6) Transport of Biological Material
- 7) Accidents, Injuries & Emergency Response
- 8) Reporting & Communication
- 9) Training, Practice, Drills
- 10) Updates and Re-evaluation

Program Management

- Management Commitment
 - Establishes a "Culture of Responsibility"
- Establish Chain-of-Command
 - Roles and Responsibilities
- Ensure
 - Resources (funding)
 - Manpower (staffing)
- Delegate enforcement authority

Program Management

- Develops Biosecurity 'Risk Statement"
- Makes Risk Management Decision
- Develops & Implements Biosecurity Plan
 - Written / Documented Plan with SOP's
 - Tiered / Combination Approach
- Commits Enforcement
 - Annual Evaluations

Physical Security



Physical Security/Access Control



- Prevents unauthorized material removal
 - Building / Laboratory / Storage Areas
 - Consolidate products, to possible extent
- Establishes control area
- Limits access

Physical Security/Access Control

(cont...)

- Limits Access:
 - Establishes authorized personnel
 - Detects unauthorized entry
- Considers "escorted entry" needs
 - Visitors, Maintenance, Emergency Staff

Access Controls

Examples









Access Control

Examples





Personnel Management

- Employee Security
- Evaluates "trust level"
 - Integrity of individual



- Good character vs. Illegal activities
- Methods: Police background checks, Credit checks, Personal references



Accountability



Management defines:

- What materials are subject to accountability
- Documentation reporting procedures
 - Record keeping practices
 - Electronic files vs. Log books
 - Inventory procedures
 - Working stocks vs. Repository stocks

Integrated with Information Security



Information Security

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Information Security

- Protect sensitive information or data
 - Security plans
 - Access controls
 - Agent inventories Storage
- Written security policies / practices
- Data access
 - Limited (official use only)
 - Restricted (classified)

Transport of Biological Agents



- Movement of materials:
 - Internal (between laboratories or storage)
 - External (transfers or shipments)
- Process maintains:

Control, Accountability & Containment

Documented records (chain-of-custody)

Transport of Biological Agents

- Advance coordination
 - -Communication
 - -Authorization
 - -Acknowledged receipt
- Transport service
 - -Trustworthy operations
 - -Reliable personnel
 - -Timely delivery





Reporting and Communication

- Establish "Chain-of-Notification"
- Involve: Public Relations & Legal Office
- Establish roles & responsibilities
- Develop written policies.

Reporting and Communication

Internal reporting policies:

- Exposures, accidents, other emergencies
- Missing materials
- Unauthorized personnel or entry
- Local authority & Community notification:
 - When, Who, How, Point-of-Contact

Security Updates & Reevaluations

- Annual review and update
- After any biosecurity incident
- Document the evaluation process
- Comprehensive process:
 - Risk assessment process
 - Risk Statement
 - Biosecurity plan
 - Biosecurity systems



- Institutional commitment
- Collaborative input
- Risk Assessment/ Risk Management
- Implement comprehensive program
- Reevaluate & Update

Key Messages



- Understand what needs to be protected
- Apply highest security to the most critical assets
- Employ a graded security approach
- Reduce risk to acceptable level
- Obtain strong management support.



Resources





Laboratory Biosecurity Manual

- WHO Laboratory Biosafety Manual Third Edition
 - http://www.who.int/ihr/biosafety/publications/en/ind ex.html
- WHO Biorisk management: Laboratory biosecurity guidance, September 2006
 - http://www.who.int/ihr/biosafety/publications/en/ind ex.html

Resources



- <u>Biosafety in Microbiological and Biomedical</u> <u>Laboratories (e-5th edition)</u>
 - Section VII: Principles of Laboratory Biosecurity
 - New BMBL chapter
 - http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
- Laboratory Biosecurity-CD
 - New CDC training product
 - www.cdc.gov/od/ohs/biosafety

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Thank You

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