



Massachusetts Department of Public Health
Bureau of Infectious Disease and Laboratory Sciences

Biosecurity for the Clinical Laboratories

Shoolah Escott, MS, MT(ASCP)
Biosafety Manager
Massachusetts State Public Health Laboratory



Why is Biosecurity Important?

- The year is 1996.
- Disgruntled Texas laboratory technician, Diane Thompson, spikes donuts with *Shigella dysenteriae* Type 2.
- An email is sent out to the lab that there are donuts in the break room.
- 12 people become ill.
- She gets 20 years in prison.

Objectives

- Describe the relationship between biosafety and biosecurity
- Discuss how the elements of a biosecurity plan are important to clinical laboratories
- Describe the impact of the Select Agent Rule on Clinical Laboratories

Why Develop a Biosecurity Plan?

- Protect self and staff
- Protect patients
- Protect records and sensitive information
- Protect your facility and its reputation
- Protect the biological materials
- Protect the public and outside environment

Biosafety vs. Biosecurity

Biosafety Goal:

Protect people from dangerous pathogens

Biosecurity Goal:

Protect pathogens from dangerous people

Biosafety vs. Biosecurity

Biosafety-To reduce or eliminate accidental exposures with biological agents.

- Laboratory practices
- Procedures
- Laboratory facilities
- Safety equipment

Biosecurity-To protect from loss, theft, and subsequent misuse

- Practices
- Procedures
- Facility Design
- Security Measures and Equipment
- Personnel Management Policies/Procedures

Overlap Between Biosecurity and Biosafety

- Good Laboratory Practices
- Risk Assessment and Risk Management
- Inventory and Tracking
- Appropriate Packing and Shipment of Infectious Materials
- Adoption, Implementation, and Accountability
- Training
- Emergency Planning
- Management Oversight

A good biosafety plan is a good start for a biosecurity plan

Conflicts Between Biosafety & Biosecurity

Emergency Response

- Rapid egress of staff
- Rapid access for responders
- Ensure security of assets
- Locks – do they release when there is an alarm or do they stay secure?

Signage

- Warns of safety concerns
- Don't divulge too much information

Elements of a Biosecurity Plan (FIPPA)

- Facility – Physical Security and Access Controls
- Information – Data/Information and Reporting and Communication Records
- People – Personnel and Training
- Procedures – Emergency Response Plans and Transport, Shipping and Receiving
- Assets – Employees, Equipment, and Agents (inventory and accountability)

Challenges to Securing Biological Micro-organisms

- Nature of the Material
- Dual-use Characteristics
- Laboratory Culture



Select Agents and Clinical Laboratories

- Federal regulation and clinical laboratories DO need to know about the regulation and their responsibilities
- Clinical laboratories may be the first to receive and suspect a select agent
- Clinical laboratories do NOT need to register if they do not intend to confirm the identity or maintain stock cultures

Select Agents and Clinical Laboratories

- You should review the current select agent list on the Select Agent Program website and verify that you don't have any in your laboratory
- Contact your LRN Reference Laboratory for more information and guidance
- If you do not know who your LRN Reference Laboratory is then contact your state public health laboratory

Federal Select Agent Program Website



<http://www.selectagents.gov>

Select Agents and Clinical Laboratories

- Responsibilities if an isolate is suspected or confirmed as a select agent:
 - Need to secure specimens and cultures
 - Chain of custody may also be advisable
 - Forward isolates to your LRN Reference Laboratory as quickly as possible
 - Isolates confirmed as a select agent must be destroyed or transferred within 7 days after confirmation and it is properly documented
 - Stock cultures are not maintained

Secure Select Agent

Secure the specimen, isolate, suspect isolate, or toxin from identification to transfer or destruction against:

- Theft – removal by unauthorized personnel
- Loss – unaccounted absence
- Release – agent is outside of primary containment, for example, an occupational exposure due to working with it on the open bench

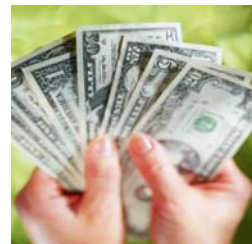
Select Agents and Clinical Laboratories

For specific questions and guidance please consult with your LRN Reference Laboratory or your State Public Health Laboratory or refer to:

- CDC Select Agent Program (<http://www.selectagents.gov/>)
- Federal Regulations 42 C.F.R. 73
- Possession, Use, and Transfer of Select Agents and Toxins, Final Rule

Barriers / Challenges to Implementing a Biosecurity Plan

- Lack of resources
- Lack of management support
- Resistance to change
- Inadequate training
- Insufficient information
- Not a personal value
- **NOT an organizational value**



Effective Biosecurity Planning Requires Collaborative Effort

- Senior management
 - Scientific staff
 - Security officials
 - Safety personnel
 - Engineering and Maintenance staff
 - Information Technology (IT) staff
 - Human resources officials
 - Public Relations/Media spokes person
- Create a Culture of Awareness and Accountability

Areas to Evaluate for Biosecurity

- Access/Physical
- Personnel
- Inventory
- Data & Information
- Transport / Transfer
- Accidents, injuries, emergencies
- Reporting & Communication
- Training and Drills
- Evaluation



Vulnerability

Vulnerability-Exploitable capability or asset, security weakness or deficiency

A weakness that could allow a harmful event (theft, loss, malevolent misuse of assets) to happen

Access/Physical Vulnerabilities

- Easy entry to facility/laboratory
- Poor lighting
- Trees or shrubs that obscure entrances
- Inoperable locks
- Unlocked doors
- Lack of monitoring of entry areas
- Others?

Access/Physical Vulnerabilities

- Visitors
- Unauthorized personnel in restricted areas
- Unsecured storage
- Parking close to buildings
- Multiple entry points
- Others?



Access/Physical Security Measures

- Secure entry points
- Fence perimeter access points
- Install lighting
- Parking checkpoints
- Hire on-site security guards
- Install tamper-proof locks
- Others?

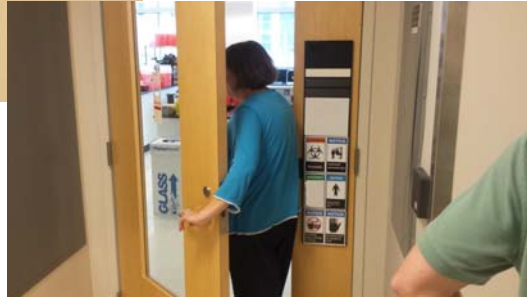


Access/Physical Controls

- Escort visitors
- Require photo ID badges
- Restrict access
- Log in/Log out sheets
- Install video cameras
- Others?



What is happening in these pictures?



What is happening in these pictures?



Internal Security: Card Readers for Building / Elevator Lab Access



Identify security measure or breach



Identify security measures or breach

- Locked Freezers



- Locked Boxes (Shared Equipment)

Personnel Vulnerabilities

- Ignorance of employees' backgrounds
- Disgruntled employees
- Employees with criminal background
- Employee not aware/
comply with security plan
- Tired or stressed employees
- Workplace violence
- Others?

Personnel Security Measures

- Know your employees and coworkers
- Check employee references
- Conduct police background checks
- Include name, photo, and expir. date on ID
- Provide biosecurity training
- Collect ID badges, keys, parking permits when no longer a employee
- Challenge people without badge or ID
- Challenge people who are unknown or in locations restricted areas
- Others?

Inventory and Accountability Vulnerabilities

- Access to highly infectious materials
- Lack of current inventory
- Unsecured storage
- Long term storage of microbes
- Poor records
- Others?

The screenshot shows the homepage of The Daily Texan, dated Friday, March 26, 2004. The main headline is "Tech professor gets 2 years for mishandling plague vials" by Betty Blaney (Associated Press). The article text states: "LUBBOCK - A former Texas Tech University professor was sentenced Wednesday to 24 months in prison for convictions related to his handling of plague-causing bacteria." A photo shows Dr. Thomas C. Butler, Vice President of the Lubbock Academic Journal, hugging his daughter, Kristina. A poll on the right asks "Should the University be involved in the negotiations between ATC's business and UT shuttle bus drivers?" with options Yes, No, and Not Sure. The poll results are not visible.

Inventory & Accountability Security Measures

- Limit access to high consequence agents
- Check integrity of storage containers
- Maintain records
- Check inventory
- Install monitoring devices



Data and Information Vulnerabilities

- Unsecured sensitive data
- Unorganized records
- Documents visible on desk tops
- Lack of passwords
- Lack of locks
- Broad access
- Others?



Data and IT Security Measures

- Centrally locate computer information systems
- Install firewalls
- Limit access to sensitive information
- Change passwords
- Install devices to detect security breaches
- Keep paper records out of view
- Lock file cabinets
- Shred/destroy sensitive records/data/CD ROMs
- Secure personal identifying information
- Others?



Transport of Biological Materials Security Vulnerabilities

- Parking close to building
- Multiple delivery points
- Unidentified persons
- Improperly packaged/shipped packages
- Suspicious letters
- Couriers, drivers and cabs



Transport of Biological Materials Security Measures

- Institute procedures for internal agent transfer
- Institute procedures for external agent transfer
- Adhere to packaging and shipping regulations
- Obtain proper shipping permits
- Develop procedures for hazardous materials
- Maintain accurate records (chain of custody for forensic cases)
- Decontaminate materials before removal

What is happening in this picture?



Accidents, Injuries & Emergency Response Vulnerabilities

- Failure to report accidents, injuries, near hits
- No SOP for responding to accidents & injuries
- No response plan or outdated response plan
- Response plan not coordinated with local responders/authorities
- Unprepared first responders
- Lack of practice and drills
- *Others?*

Accident, Injury & Emergency Response Security Measures

- Develop/review/update emergency plans
- Provide ongoing training
- Collaborate with first responders
- Ensure that responders have access
- Provide tours and training for responders
- Conduct exercises of emergency response

Reporting / Communication Vulnerabilities

- Missing biological agents
- Unusual or threatening phone calls
- Uninformed supervisor
- Unauthorized personnel in restricted areas
 - Personnel, patient records
 - Engineering or architectural plans
 - Security procedures
 - Testing data/results/patient information

Reporting and Communication Security Measures

- Ensure current policies and procedures
- Investigate injuries, accidents, security breaches
- Reconcile inventory discrepancies
- Investigate potential thefts of data
- Post emergency contact information
- Create safe environment for reporting breaches and near breaches of security

Training and Practice Drills

- Train on responsibilities
- Practice drills of several scenarios requiring response and incident reporting
- Identify deficient areas



Develop a Biosecurity Awareness Culture

- Education and Communication
- Management Support
- Organizational values, cultural norms, symbols, awards

A small change in an organization

Ripples

*throughout
the
system.*



Resources

- "Laboratory Security and Emergency Response - Guidance for Laboratories Working with Select Agents". MMWR 2002;51(RR-19): 1-8 <http://www.cdc.gov/mmwr/PDF/rr/rr5119.pdf>
- Biosafety in Microbiological and Biomedical Laboratories (5th Edition) <http://www.cdc.gov/biosafety/publications/bmb15/index.htm>
- Select Agent Program/Select Agent Rule <http://www.selectagents.gov/>
- Suspicious Packages <http://www.fbi.gov/about-us/investigate/terrorism/suspicious-packages-pdf/view>
<http://about.usps.com/securing-the-mail/suspiciousmail.htm>

Additional Training Information

For more MA SPHL training information, please go to:

<http://www.mass.gov/eohhs/gov/departments/dph/programs/state-lab/emergency-prep/training.html>

Cynthia Condon, LRN Coordinator 617-983-6675 cynthia.condon@state.ma.us

For more information on CDC laboratory training please go to: www.cdc.gov/labtraining

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the MA SPHL and CDC.

