Biosafety Overview for Public Health Laboratories (PHLs)

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Outline

• Precedent and Context
• Building blocks of biosafety programs
  – Risk Assessments
  – Work Practices
  – Engineering Controls
  – Occupational Health
  – Spill Cleanup
  – Disinfection
  – Competencies
• Resources and Regulations
Laboratory Response Network (LRN)

- All 50 states, DC and selected local PHLs are members of the LRN-B at the Reference Level
- Significant expertise in working with select agents
- LRN-B Reference labs have:
  - Regular inspections
  - Mature biosafety programs
  - Risk assessment experience
  - Annual trainings and drills in place that address Biosafety
- Move some of these practices to the entire PHL
Biosafety Risk Assessment to break the Chain of Infection

- Reservoir of pathogen
- Portal of escape
- Transmission
- Route of entry/infectious dose
- Susceptible host
- Incubation period
- Illness

Proper Work Practices
- Personal Protective Equipment (PPE) and Engineering Controls
- Occupational Health
- Immunization
- Treatment
- Surveillance
Biosafety Risk Assessment Process

Factors to consider:
- Infectious agents
- Procedures to be performed
- Vaccines or treatments available
- Route of transmission
- Volume or conc. of agent
- Training of staff
Modes of Transmission:
- Aerosol
- Injection
- Absorption (mucus membrane or dermal)
- Ingestion

Counter Measures:
- **Work Practices** – Training, SOPs, hand washing, etc.
- **Engineering Controls** – Biosafety Cabinet, centrifuge safety cups, controlled access, etc.
- **PPE** – Lab coat, gloves, face shield, goggles, PAPR, etc.
- **Occupational Health** – Immunization, treatment, surveillance, etc.
- **Other** – Disinfection, waste management, emergency procedures, spill clean up, etc.
Work Practices: Recognize Behavior Patterns

Worker is pivotal in controlling the safe outcome of any operation!


Work Practices: Training

• How well are workers trained for the tasks?

• Do workers meet a level of competency before being allowed to work?

Training should include:

– Safe handling practices (sharps, pipetting, etc.)
– Use of safety equipment (BSC/centrifuge safety cups, etc.)
– Decontamination procedures
– Emergency Procedures (Spill clean-up, evacuation, etc.)
– Use of autoclave/waste disposal.
Engineering Controls: Containment Equipment

- BioSafety cabinet (BSC)
- Centrifuge safety cups
- Autoclave
- Decontamination equipment
- BSL-3 lab and HVAC system
# Engineering Controls: BSC

Use the BSC to protect against aerosols and splashes

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Average Bacteria CFU recovered/ft from air during the procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening petri dish</td>
<td>0</td>
</tr>
<tr>
<td>Opening screw capped test tube</td>
<td>4</td>
</tr>
<tr>
<td>Picking colony from plate</td>
<td>0.005</td>
</tr>
<tr>
<td>Streaking on smooth agar plate</td>
<td>0.26</td>
</tr>
<tr>
<td>Pipette inoculating test tube</td>
<td>0.26</td>
</tr>
<tr>
<td>Syringe and needle withdrawal from rubber-cap bottle</td>
<td>16.0</td>
</tr>
</tbody>
</table>

**Engineering Controls: BSC**

Use the BSC properly

- Minimize traffic around BSC
- Do not impede air flow
- Allow room for operation to conveniently perform the work without entering and exiting the BSC
- Allow BSC to run 10 mins. before and after use
Engineering Controls: BSC Maintenance

- Ensure your BSC is certified at least annually by an accredited field certifier
- Read the manual! Be familiar with the performance characteristics of the model in use
- Review the report and understand what was measured.

Annual Preventive Maintenance by whom? Are they certified?
Personal Protective Equipment

- Safety glasses and googles – offer varying degrees of eye protection against splashed infectious agents.
- Face shields – In addition to protecting the eyes, also offers protection to other mucus membranes (nose and mouth) and some dermal areas of the face.
- Gloves (latex, nitrile, neoprene) – offer protection to the dermal areas of the hands.
- Lab coats, Tyvek gowns, etc. – offer protection to the dermal covered dermal areas.
- N95 respirator and PAPR (Powered Air Purifying Respirators) – offer protection to the respiratory system.
Occupational Health

• New employees may receive:
  • TB Testing
  • base-line serum draws
  • vaccinations
  • respirator medical clearance and fit-testing

• BSOs need to recognize:
  • Host factors that place individuals at risk (immunocompromised status, recent injuries, etc.)
  • Vaccinations (required, agent specific, contraindicated, etc.)
  • Disease symptoms
  • Post exposure management (treatments, prophylaxis, etc.)
  • Reporting exposures, illness and surveillance
Spill Clean Up of Infectious Materials

- Small volume spill = Minimal aerosols produced:
  - Cover the spill
  - Saturate with disinfectant
  - Wear PPE to clean up
  - Autoclave material
  - Disinfect floors and countertops

- Large volume spill = Major aerosols produced:
  - Evacuate immediately
  - Do not reenter for at least 4 hours
  - Decontaminate with formaldehyde gas or other agent
  - Reenter using appropriate protection
Disinfection

Factors to consider when choosing disinfectant:

– Concentration of the disinfectant
– Concentration of the pathogen
– Type of agent
– Time of contact
– Organic material
– Environmental conditions (pH, temp, humidity, etc.)
Levels of Disinfection

• Sterilization: complete elimination of all forms of microbial life
• High-level disinfection: destroys all microorganisms except bacterial spores
• Intermediate-level disinfection: inactivates TB, nonspore forming bacteria, most viruses and most fungi
• Low-level disinfection: kills most bacteria (not TB), some viruses, and some fungi
  – Hospital-type germicides used primarily for housekeeping such as quaternary ammonium compounds ("quats")
Descending Order of Resistance to Disinfectants

**Most Resistant**
- Bacterial Spores - Clostridium sp. and Bacillus sp.
- Mycobacteria - M. tuberculosis
- Nonlipid or small viruses - polioviruses, coxsackie virus, rhinovirus
- Fungi - Trichophyton sp., Cryptococcus sp., Candida
- Vegetative Bacteria - Pseudomonas, S. aureus, Salmonella
- Lipid or medium sized viruses - Herpes simplex, Cytomegalovirus, RSV, Hepatitis B, HIV, ebola

**Most Sensitive**
Competency Assessment Tools

• Competencies: Action-oriented statements that delineate the essential knowledge, skills, and abilities required for the performance of work responsibilities.

• Practitioners
  – Assessing current skills
  – Creating career development plans
  – Planning specific training to meet educational needs
Important Resources: Biosafety & Biosecurity Plan

- How work is safely performed
- Risk Assessment
- Protocol driven PPE requirements
- Traffic control / access restriction
- Use of safety equipment
- Sanitation – Cleaning & Disinfection
- Waste Management
- Training
Resources

5th Edition

Biosafety in Microbiological and Biomedical Laboratories

Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition


Author: Editors: Diane O. Fleming, Biosafety Consultant; Debra L. Hunt, Duke University Health System

Book ISBN or Item Number: 978-1-55581-339-0
Biosafety Regulations and Standards

- CDC
- OSHA
- NIOSH
- EPA
- JCAHO
- CAP
- CLSI
- CLIA
Biosecurity In the Public Health Laboratory
-An Overview
Overview

• Biosecurity Defined
• The Need for Biosecurity?
• Goals of Biosecurity –Comparison to Biosafety
• Components of a Biosecurity Program and Plan
• Biosecurity Risk Assessment
• Biosecurity in the Select Agent Program
Biosecurity

Originally defined as a set of preventative measures designed to reduce the risk of transmission of infectious diseases in crops and livestock, quarantined pests, invasive alien species and living modified organisms.

For this presentation: Preventative measures put into place to prevent the use of dangerous pathogens and toxins for malicious use.
The Need for Biosecurity

- 2001 Anthrax Attacks
  - Five deaths
  - 17 sickened
  - Thousands treated with antibiotics
  - Identified by FBI as the worst biological attacks in US history
  - USAMRIID researcher identified as suspect
The Need for Biosecurity

- **1984 Salmonella Attack, Oregon**
  - Food poisoning of 751 citizens in The Dalles
  - Deliberate contamination of salad bars using *Salmonella Typhimurium*
  - Aim was to incapacitate the voting population
  - Largest bioterrorist attack in US history
  - Linked to Rajneesh Foundation who had obtained culture from ATCC
• 1996 *Shigella dysenteriae* type 2, Dallas Texas
  – 12 staff developed acute diarrhea from eating muffins and doughnuts left in the break room
  – Anonymous email invited staff to eat the pastries
  – Laboratorian convicted
  – Investigation showed that beads of frozen reference culture of *S. dysenteriae* type 2 had been removed

*An Outbreak of Shigella dysenteriae Type 2 Among Laboratory Workers Due to Intentional Food Contamination*
Shellie A. Kolavic, DMD, MPH; Akiko Kimura, MD; Shauna L. Simons; Laurence Slutsker, MD, MPH; Suzanne Barth, PhD; Charles E. Haley, MD, MS *JAMA*. 1997;278(5):396-398.
The Need for Biosecurity

• Some other Biosecurity Incidents
    • 30 vials of *Yersinia pestis* missing from lab (never recovered); Butler served 19 months in jail
  – 1995: Larry Wayne Harris, a white supremacist, ordered 3 vials of *Yersinia pestis* from the ATCC
  – 1964-1966: Dr. Mitsuru Suzuki was a physician with training in bacteriology
    • *Shigella dysenteriae* and *Salmonella typhi*
    • Sponge cake, other food sources
    • He was later implicated in 200 – 400 illnesses and 4 deaths
Why an Increased Focus Now?

• Events of 2001
  – Select Agent Program
    • PHL, Academia, Private Labs
  – Changes to program
  – Tier 1

• Ebola, 2014
  – Need address Biosafety and Biosecurity Practices
Goals of Biosecurity

-Some Definitions

Biosafety
Development and use of administrative policies, work practices, facility design, and safety equipment that protect workers, other persons, and the environment from exposure to biohazardous agents or materials

Biosecurity
Development and use of preventative measures that protect high-consequence biological agents and toxins (and/or critical relevant information) from theft and consequential malicious intent/misuse
Goals of Biosecurity

- Common Themes of Biosecurity and Biosafety

- Culture of safety and security
- Management oversight and acceptance
- Trained and qualified staff
- Risk assessment and management
- Graded protection
- Plans and exercises
- Inventory management
- Controlled laboratory access
- Emergency planning
# Goals of Biosecurity

-Possible conflicts/differences between Biosafety and Biosecurity!

## Conflicts

- **Signage**
  - Can identify information about biological agents/toxins
- **Emergency Response, e.g. a spill**
  - Aim is to distance yourself from the spill
  - Has the biosecurity been compromised?

## Differences

- **Acceptable risk for Biosafety**
  - Minimal level of acceptable risk likely determined by institution, regional and or national policy
- **Acceptable risk for Biosecurity**
  - Minimal level of acceptable risk likely determined by funding and infrastructure as well as policy
Concepts of Biosecurity
What is Needed for a Biosecurity Program?

• Management – program and personnel
• Physical and information security
• Inventory and accountability
• Transport considerations
• Plans – Response, security
• Communication
• Training and exercises
• Re-evaluations
Who is Involved in a Biosecurity Program?

- Senior management
- Laboratory staff
- Human resources
- IT staff
- Safety/Biosafety officer
- Security staff – including local law enforcement
- Building manager
What is a Biosecurity Plan?

- Site Specific
- Systematic design for implementing security goals
- Will include a risk assessment
- Provides means to protect assets according to the risk assessment
- Provide a means to mitigate hazards and vulnerabilities
- Will include any agreements with external agencies
- Is reviewed and understood by all appropriate staff
- Is re-evaluated yearly and after every security incident
- Is verified through exercises and drills, followed by revision if necessary
Challenges to An Effective Biosecurity Program

- Resources
- Managerial support
- Change can be difficult
- Time and commitment
- Increased need for training
- Some staff might not see the value
Biosecurity Risk Assessment

• Risk
  – Risks can be to an individual, surrounding community, environment
  – Generally defined as the likelihood that an adverse event involving a hazard or threat will happen, and the consequences of that occurrence
  – Is a function of likelihood and consequences
  – Always dependent on the situation
  – There must be a situation in which the threat can cause harm
Biosecurity Risk Assessment

• Risk Assessment
  – At its most basic level
    • What can go wrong?
    • How likely is it and how likely are we to see it coming?
    • What are the consequences?
  – Goals
    • Allow for a better understanding of the risks
    • Determine acceptability of the risks
    • Help define strategic risk mitigation measures
  – Use a structured and repeatable risk assessment to reach these goals
Biosecurity Risk Assessment

Biosecurity Risks:
• Result from a person who has malicious intent and potential access to a hazardous material or facility
• Focus on:
  – Theft of a biological agent
  – Equipment
  – Information
  – Misuse
  – Diversion
  – Sabotage
  – Unauthorized access
  – Intentional release
Biosecurity Risk Assessment

- Defines the laboratory assets, threats, facility vulnerabilities, current biosecurity program, impact of an event
- Structured and repeatable process
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

1. Define the Situation:
   • What - Identify and Define the Assets to be Protected
     – Biological agents and toxins (what, how many, where stored)
     – Equipment
     – Backup generator
     – Intellectual property & Sensitive information
     – Animals
   • Who – Define the Threats
     – Adversarial types and capabilities
       • Researchers, disgruntled employees, terrorists, animal rights activists, criminals (sell items)
     – Motives
     – Means
     – Scenarios and likelihood of attack
   • Where – Define the Facility and Security Environment
     – Vulnerabilities of facility
     – Who has access
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

2. Define the Risk:
   • Unauthorized person stealing valuable biological material for malicious use
   • Authorized person stealing valuable biological material for malicious use
   • Unauthorized person stealing valuable biological material for personal gain
   • Authorized person stealing/destroying valuable biological material for personal gain
   • Unauthorized/authorized person stealing equipment
   • Unauthorized/authorized person stealing intellectual property (information)
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

2. Define the Risk, cont:
• For each risk, there may be one or more assets to consider
• Consider the location of each asset (long term, transit) and implemented security
• Do you need one assessment or multiple?
• Eliminate unnecessary or unrealistic risks if possible
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

3. Characterize the Risk:
   • Assets Assessment
     – Define the likelihood of targeting the asset (asset dependent). What makes it attractive?
       • Equipment has a cost, biological material has a potential for harm
       • Consequences from theft, misuse, destruction
   • Adversary Assessment
     – Key to determining vulnerability of facility
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

3. Characterize the Risk, cont:

**Insiders**
- High Risk
- Access
- Unarmed?
- Knowledge
- Opportunity

**Outsiders**
- Low Risk
- Limited access
- Armed?
- Limited knowledge
- Repair person
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

3. Characterize the Risk, cont:

Environmental Threats

- Hurricane
- Earthquake
- Flood
- Blizzard
- Tornado
- Sink hole
- Fire
- Power outage
Biosecurity Risk Assessment
-Doing a Biosecurity Risk Assessment

3. Characterize the Risk, cont:
Facility Vulnerability Assessment
• The likelihood of successful acquisition of the asset
• Based upon the:
  – Location of asset
  – Facility's vulnerabilities
  – Capabilities of the adversary
• Utilize the five pillars of biosecurity
  – Physical security
  – Personnel reliability
  – Material control and accountability (inventory)
  – Transportation (within and between facilities)
  – Information Security

Biosecurity Risk Assessment

- Performance Indicators

• Some Tools Used as PIs
  – Audits
  – Inspections
  – Questionnaires
  – Interviews
  – Training Evaluations
  – Incident Reports

• Cannot have “It’s a Wonderful Life” for Biosecurity!
Biosecurity and Select Agents

- Federal Regulations 42 CFR 73 (CDC), 7 CFR 331, 9 CFR 121 (APHIS)
- Regulations at www.selectagents.gov
- Security plan
  - Guidance Document
  - Security Plan Template
    - Risk assessment
    - Physical security
    - Personnel security
    - Tier 1 Security
- SA program for Clinical labs
Resources

• [http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf](http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf) – Biosafety in Microbiological and Biomedical Laboratories

• [www.selectagents.gov](http://www.selectagents.gov)

• Laboratory Biorisk Management: Biosafety and Biosecurity (2015). Salerno and Gaudioso
APHL Biosafety and Biosecurity Resources

Chris N Mangal, MPH
Director, Public Health Preparedness and Response

January 20, 2016
What is APHL?

• A non-profit, non-governmental US based organization

• Over 800 members from state and local public health laboratories, state environmental and agricultural labs and others federal agencies and academic institutions.

• Advocates at the national level to shape public health policy and to secure increased support/resources for member labs

• Provides training, model practices and technical assistance domestically and internationally
Public Health Preparedness and Response (PHPR) Program Goals

1. Improve the capability and capacity of member laboratories to safely respond to biological, chemical, radiological threats, and other public health emergencies

2. Promote information and technology transfer from the CDC and other agencies to members to support preparedness functions

3. Expand and enhance relationships among member laboratories, clinical laboratories, first responders, CDC, FBI, and other agencies

4. Provide support for the Laboratory Response Network (LRN)

5. Shape legislation, regulations and promote policies that support laboratory preparedness
Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Ebola Supplemental Funding

• Project A: Healthcare Infection Control Assessment and Response ($80 million)
• Project B: Enhanced Laboratory Biosafety and Biosecurity Capacity ($21 million)
• Project C: Global Migration, Border Interventions, and Migrant Health ($5 million)
Biosafety

- New Component of PHPR Program
- 2015 – APHL listed as SME in ELC Ebola Supplemental Cooperative Agreement
- 2015 – APHL applied for and received $2.2 million cooperative agreement with CDC (3 years)
  - 2 FTEs Hired
  - Serve as SME, support for public health labs (PHLs)
  - Assist PHLs with outreach to clinical labs
Pre-Award Activities

• APHL Annual Meeting & Ninth Government Environmental Laboratory Conference
  – Preconference Session: Tools to Enhance Laboratory Biosafety and Biosecurity Workshop
  – Session on Biosafety: CDC, APHL
• Established Biosafety and Biosecurity Committee
• Competencies Based Position Description
• Biosafety Checklist
• Guidance Tool for ELC Ebola Supplemental
• Guidance for Performance Measures
• Communications/Media Messaging
Cooperative Agreement with CDC

• Strategy 1: Enhance Public Health Laboratory Biosafety Capacity
  – Support implementation of PHLs work plans
  – Develop/deliver tools, materials and guidance documents: repository of tools
  – Ensure access to educational/training opportunities

• Strategy 2: Improve Laboratory Coordination and Outreach
  – Coordinate national efforts to improve PHL Biosafety Capacity
  – Conduct outreach with and engage clinical lab partners
Biosafety and Biosecurity Committee

- Provide leadership and guidance on policies and practices which impact Biosafety and Biosecurity in state and local governmental laboratories.
  - Serve as an information resource to assist public health laboratories with implementing the Enhanced Laboratory Biosafety and Biosecurity Capacity activity outlined in the Epidemiology and Laboratory Capacity Cooperative Agreement.
  - Inform and assist APHL to establish a repository for biosafety and biosecurity tools and promote the use of such tools.
  - Advise and assist in the development of a “community of practice” for biosafety officers in state and local governmental laboratories.
  - Collaborate with partners to design a core curriculum for biosafety and biosecurity and deliver training materials, including convening workshops for biosafety officers.
  - Promote APHL’s position statement on biosafety and encourage a culture of biosafety and biosecurity within all laboratories.
APHL in Action: Biosafety & Biosecurity

- Outreach to Public Health Laboratories
  - Completed Quarterly Calls with all ELC Awardees
  - Presentations at National Meetings

- Training
  - E.g. webinars, workshops, packaging and shipping courses

- Community of Practice for Biosafety Officials
  - Collected contact info/established ListServ

- Online Repository – coming soon!
  - Website with biosafety and biosecurity

- Public Policy
  - Member approved position statement
Resources for Biosafety Officials and Partners

**A Biosafety Checklist: Developing A Culture of Biosafety**

**Background**

There is an inherent risk in a laboratory handling any infectious agents. Biosafety practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Reports indicate that biosafety lapses highlight the need to enhance the culture of biosafety across the laboratory community in the United States. The Association of Public Health Laboratories (APHL) has developed a Biosafety Checklist: Developing A Culture of Biosafety to serve as a starting point for laboratories to assess the biosafety measures that they have in place.

**Intended Use**

A Biosafety Checklist: Developing A Culture of Biosafety is intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents. It is designed to provide laboratories with the broadest recommendations for components that should be considered for inclusion in any laboratory’s biosafety policy. The checklist consists of six sections:

1. Introduction
2. Safety Practices
   - Personal Protective Equipment (PPE)
   - Laboratory Practices
3. Risk Assessment
   - Laboratory Practices
4. Compliance
   - Laboratory Practices
5. Administrative Oversight
   - Laboratory Practices
6. Risk Assessment
   - Laboratory Practices

This checklist is for your laboratory’s internal use only. The questions in this checklist are included to guide biosafety discussion within your laboratory and do not address biosafety practices. Some questions may not be applicable to every laboratory and some laboratories may want to add additional questions to perform their risk assessments. This tool can be modified to meet your laboratory’s needs as necessary and information gained from this tool can be used to help set:

**Biosafety Officer Competency-Based Position Description Template**

Program/Department: Public Health Laboratory

Position Title: Biosafety Officer

Reports to: Laboratory Director / Operations Director / Division Director

Previous Incumbent: Name (New position)

Job Position Summary:

The Biosafety Officer within the public health laboratory will ensure adequate biosafety training and practices to avoid potential hazards associated with the handling of biological materials, the spread of multi-drug resistant pathogens and threats of emerging pathogens, and acts of biological terrorism. The person in this position develops and monitors adherence to laboratory biosafety programs, provides related workforce training for biosafety for the agency and sentinel clinical laboratories, assists public health and clinical laboratories with biosafety risk assessments and risk mitigation plans, and works closely with key system partners and public health officials to improve communications and emergency management and response practices. Efficient communication skills, knowledge of microbiology and general laboratory practices, and experience in laboratory safety, training and outreach, and quality management systems are necessary for this position.

**In Development:**

- Sentinel Site Visit Tools
- Risk Assessment Templates for PHLs
- Visiting Biosafety Officials Program
- Partners Forum
- APHL pre-conference workshop
- National Meetings
What can PHLs to do help?

• Timely Feedback – communicate needs to APHL and CDC; provide feedback on tools and participation in surveys

• Utilize BSO listserv!

• Share success stories/models

• Engage sentinel clinical laboratories and other clinical partners

• Collaborate within lab and across states
  – Leverage existing connections and resources (e.g. Laboratory Response Network)
Biosafety and Biosecurity Contacts

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