

BOSTON  
PUBLIC  
HEALTH  
COMMISSION



# Boston Municipal Requirements for Biocontainment Laboratories

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# Mission

The mission of the Boston Public Health Commission is to protect, preserve and promote the health and well being of all Boston residents, particularly those most vulnerable.

Our mission is met through the provision and support of accessible, high quality, community-based health care, disease and injury prevention and health education.



# Boston Public Health Commission

- The oldest existing health department in the country, the Boston Public Health Commission serves the City of Boston by:
  - Providing emergency medical services;
  - Collecting and publishing data on the health of Boston;
  - Identifying and preventing threats to the public health through policies, education and services; and
  - Filling gaps in health services to underserved populations.



# Topics

- Biological Laboratory Regulation (passed September 19, 2006)
- Disease Surveillance and Reporting Regulation (passed March 30, 2004)
- Recombinant DNA Technology: Use Regulations (passed March 22, 1994)
- Discussion



# Background of Regulations

- To protect the safety and health of the public, lab workers and the environment
- **A uniform set of biosafety requirements for all biological research laboratories in the City of Boston**
- Several of these laboratories are located in residential areas of the City of Boston and **all the laboratories may require the services of emergency first responders from Boston EMS, Boston Fire Department and Boston Police Department.**



# Biological Laboratory Regulations

- Section 1: Definitions
- Section 2: Permit Requirements
- Section 3: Laboratory Oversight
- Section 4: Prohibitions
- Section 5: Notice, Violation Reporting and Non-Retaliation
- Section 6: Guidelines
- Section 7: Community Benefits Program
- Section 8: Permit Fees
- Section 9: Penalties
- Section 10: Severability of Sections
- Section 11: Implementation

# Biological Safety Regulations

- High risk agents:
  - Select Agents in amounts covered by CDC guidelines
  - NIH Risk Group 4 agents
  - SARS Co-V
  - High Pathogenicity Avian Influenza
  - **Vaccinia virus**
  - *Mycobacterium tuberculosis*
  - **Others as designated by BPHC**

# II. Overview of Regulations

## Section 2: Permit Requirements

- Required for all BSL3 & BSL4 research laboratories
  - Document review
    - Biosafety/Lab safety manual
    - **Disease surveillance plan**
    - **Evacuation and emergency response plans**
    - Waste disposal plan
    - **Security plan**
    - **Transportation plan**
    - **Training policy**
    - **Laboratory inspection procedures**
  - Document review
    - Chemical hygiene plan
    - Strain verification policy/procedure
    - IBC roster/Key staff list
    - Commissioning/Decommissioning plan
    - Decontamination
    - Other as listed in Guidelines



# Overview of Regulations

## Section 3: Laboratory Oversight

### ■ Inspections

- High Containment Labs (BSL3 and BSL4)
- Inspection components
  - Review of policies, procedures and on site documents
  - Staff interviews
  - Physical observation and assessment of facility and practices
- Guided by **detailed inspection checklist**
- Conducted by team

# Inspection Criteria

- Review of projects,
- Agents used,
- Documents related to BSL-3 work,
- Equipment conditions,
- Biohazard handling & BSL-3 practices (lab and animal),
- Occupational health programs,
- Training,
- Compliance.

# Inspection Definitions

- **Sat (Satisfactory):**
  - No Actions
- **Uns (Unsatisfactory):**
  - Improvements required. Non-compliance.
- **PHV (Public Health Violation):**
  - Immediate actions required.
  - Examples, failure to report a laboratory acquired infection and exposure to public or community.



# **Emergency Responders City of Boston**

- Under the select agent program, planning and coordination with local emergency responders [(Section 14(c)(6))]**
  - This is a continuous process**



# Open IBC Meetings

- The intent and purpose of public IBC meetings is to inform the public about the research being conducted in their neighborhoods. The discussion at public meeting should include the context and significance of the research, significant safety, social, and ethical implications of the research, and technical aspects of the research.



# Annual Report

- Complete set of IBC minutes. If previously submitted for RDNA regulation state.
- Report of QA/QI. Facility Verification, HEPA Verification, Training, Drills, Inspections, Equipment purchases, Facility Maintenance.
- RO signature on statement



# Permit Fees

- Non-select agent entities must submit an annual financial statement with details of operating expenses. Supporting documentation must accompany the statement and may include tax records or grant information.
- Checks to Biological Safety Office

# Notifiable Disease Reporting

- In Boston, disease reporting is mandated by both state and city laws and regulations.
- **Laboratories** in Boston are required to report specified results indicative of certain infections to both MA DPH and BPHC.
- **Health care providers, institutions, and laboratories are *all* required to report.**



# Health Department Follow-up

- **BPHC uses the case information to investigate, control disease, and prevent further infection**
- Health care providers and institutions are required to furnish follow-up information to BPHC as requested
  - Patient consent not needed
- **Complete case form sent to MA DPH, then to CDC**  
(without identifiers)
  - Used to generate national statistics



# Syndromic Surveillance

- A system for actively monitoring health complaints of individuals entering the health care system as a means of detecting unusual patterns of disease or specific diseases of concern
  - **Key words in chief complaints (i.e. anthrax)**

# BPHC Response to an Unusual Pattern of Illness

## • Unusual pattern identified:

- trace back to medical records and specific emergency department
- review of applicable medical records by BPHC staff

Validation of problem/incident

Problem: NO  
Case Closed

Problem: YES  
Case(s) reviewed, action taken  
using standard BPHC protocol

# BPHC Surveillance: Data Sources

## Reportable Diseases

- Reportable Illness or Exposure in
  - Research/Clinical/hospital Laboratory
  - Staff Using Select Agent or Other Priority Pathogens

## Death Certificates

Inspectional Service Reports

**BPHC**

## Syndromic Data

- Acute Care Visits
- Boston EMS Calls
- Boston EMS Trip Sheets
- Poison Control Calls
- Health Centers – Urgent Care Visit Volume
- Sentinel sites (as needed)

## Environmental Data

- Weather
- Pollen Counts
- News Reports
- Environmental Detection Systems



# BPHC Guidelines for Laboratories

- They apply to laboratories using:
  - CDC defined Select Agents (including Overlap Agents) in amounts covered by CDC guidelines
  - NIH Risk Group 4 agents
  - SARS Co-V
  - High Pathogenicity Avian Influenza
  - **Vaccinia virus**
  - Others as designated by BPHC

# Medical Surveillance Program: What is Reportable?

- Illness (potentially related to lab work)
- Significant Exposures
- Absenteeism
- Other
  - Mechanical failures
  - Spills
  - Animal bites

# Medical Surveillance Program: Significant Exposures

- Workers must be evaluated by the Occupational Health officer (OHO) or designee, if exposure to agents occurs
  - Each institution **must develop and submit to BPHC a plan** to determine whether significant exposure occurred and to monitor **significantly** exposed workers

# Medical Surveillance Program: Significant Exposures

- OHO (or designee) is required to report any **significant** exposure to agents covered by these guidelines within **one** business day
  - Follow-up information must be provided to BPHC as requested
  - **BPHC must be consulted before the worker is allowed to return to work**
  - Occupational Health officer (or designee) must send BPHC documentation that an exposed person has been cleared to return to work within **3 business days** of clearance



# Medical Surveillance Program: Absenteeism

- Absenteeism  $\geq$  **two consecutive** days due to illness in a worker in a laboratory using agents covered by these guidelines must be evaluated by the Occupational Health officer (or designee)
  - Each institution must provide BPHC with their protocol for follow-up of workers in laboratories working with covered agents
  - Occupational Health may need to work with Human Resources to develop a system



# Recombinant DNA Permits

- Description of how the IBC functions
- Roster and CV IBC members
- Health and Safety Manual
- Training Program
- Large Scale must have approval



# Recombinant DNA con't

- Medical surveillance
- Annual Report
- Register each RDNA experiment not exempt from NIH Guidelines on BPHC Project Registration form



# Contact Information

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