Boston Municipal Requirement and Safeguards for Biocontainment Laboratories

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Outline

I. Development of regulations
II. Overview of regulations
III. Implementation
IV. Best Practices
   - Biosafety Working Group

I. Development of Regulations

- Purpose of Regulations
  - Protect the safety and health of the public, lab workers and the environment
  - Increase public confidence and awareness about lab safety procedures and regulations.

I. Development of Regulations

- Strongest local regulations in the nation
- No other municipalities have local plans
- Boston is the only city with 3 regulations

I. Development of Regulations

- Public comments and concerns
  - Economic impact
  - Burdensome reporting
  - **Confidentiality - proprietary information**
  - **Security/Safety**
  - **Opposition to BSL4**
  - Increased community involvement

II. Overview of 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

II. Overview of Regulations

Section 2: Permit Requirements

- Required for all BSL3 & BSL4 research laboratories
- Document review includes:
  - **Biosafety/lab manual**
  - **Evacuation and emergency response plan**
  - **Disease surveillance plan**
  - Waste disposal plan
  - Security plan
  - Transportation plan
  - Chemical hygiene plan
  - Strain verification policy
  - Risk management program
  - IBC roster
  - Key staff

II. Overview of Regulations

Section 3: Laboratory Oversight

- **Maintain compliance will all regulations (NIH, USDA, CDC, SA program, BMBL, OSHA)**
- Reporting applies to research 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
  - *Mycobacterium tuberculosis*
  - Others as designated by BPHC

II. Overview of Regulations

Section 3: Laboratory Oversight

- Reporting is *mandatory*
- Reporting requirement covers:
  - Illness
  - Significant exposures
  - Unexplained absenteeism
  - Animal bites

II. Overview of Regulations

Section 3: Laboratory Oversight

- Incident reporting – upon discovery, not > 24 hours
  - Mechanical or security system
  - Containment systems and practices
- Disease surveillance:
  - Health care providers, institutions, and laboratories are ***all*** required to report.

II. Overview of Regulations

Section 3: Laboratory Oversight

- Continued progress requires continued research
  - **Individual and community safety are key considerations**
  - ***Local public health and public safety are the first and primary responder for incidents in the local community.***

II. Overview of Regulations

Section 3: Laboratory Oversight

Inspections

- 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

III. Implementation

- Management Systems
  - Program staff
  - Data management
  - Current permits
    - 6 Entities, with 8 permits
    - 2 select agent labs and 6 non-SA
    - Future permits – NEIDL and 2 non-SA
  - Coordination
    - City Work Group (09/06)
  - Training plan

IV. Best Practices

- **Collaborations**
  - Biosafety working group
  - Biosafety officers
  - Entities (institutions)
- **Inspection results**
  - Occupational health
  - Special practices
  - Training programs

IV. Best Practices

Collaborations with biosafety working group

Mission

- *To ensure that every plan, document, and safety preparation is in place to our satisfaction.*
- *To assist with implementation of the strongest local regulations in the nation.*
- *Medical and economic importance should be balanced in terms of safety, best practice and compliance.*

IV. Best Practices

Collaborations with biosafety working group

- The focus on:
  - The BSL-4 laboratory (NEIDL)
  - Review of emergency response plans
  - Other issues related to the BSL-4, including **transportation** of select agents.
  - Consideration of BSL-3 labs in reviews and training.
- Unified group for about 2 years.

IV. Best Practices

Collaborations with biosafety working group

- Directive from the Mayor to coordinate all Biosafety issues related to level 3 and 4 labs
- As the lead, BPHC collaborates with:
  - Boston fire department
  - Boston police department
  - EMS and other agencies
- Assumes the responsibility for all Biosafety issues related to planning, training and equipment.

IV. Best Practices

Collaborations with biosafety working group

- Led efforts in major decisions
- Built relationships with key individuals
- Identified key issues
- Made recommendations on proposed biological laboratory regulations.

IV. Best Practices

Collaborations with biosafety working group

Successful biosafety meetings

- Active participation
- Communication among members
- Collaborative team effort
- Problem solving and results-oriented project management

IV. Best Practices

Collaborations with biosafety working group

Meeting achievements:

- A successful plan for training, inspections, and future emergency response drills
- The foundation for strong support and future initiatives.
- Assisted with implementation of regulations
  - Participation at inspections
  - Empowered team to help regulate labs

IV. Best Practices

Collaborations with biosafety working group.

Successful plans

- Applied Laboratory Emergency Response Training (ALERT) for first responders
  - General awareness training
  - Intro to lab environment
    - Fire suppression, security, engineering controls
  - Lab emergencies
    - Decontamination, medical, disease control
  - Building emergencies
    - Explosions, rescue scenarios, shutting down systems

IV. Best Practices

Collaborations with biosafety working group

Successful plans

- Increased awareness of high containment processes.
- **“planning and coordination with local emergency responders [(section 14(c)(6)]”**
- Pilot training for 360 people

IV. Best Practices

Collaborations with biosafety working group

- Boston is *potentially* setting the standards for other communities.
- The regulations are unique and the collaborations with the city agencies have been outstanding.
- Is Boston a pioneer?

IV. Best Practices

Inspection results

- Top rating: Satisfactory
- Occupational Health Programs
- Special practices, i.e. centrifuge in fume hood and lab techniques (observations)
- Training programs

Questions?

- What did I cover that you did not know?
- What didn't I cover that you thought I would?
- What is the one thing you will remember?