

# **PERMITTING PROCESS OF BIOSAFETY LEVEL 4 FACILITY: A REGULATOR'S VIEW**

**NEBSA 2018 BIOLOGICAL SAFETY SYMPOSIUM  
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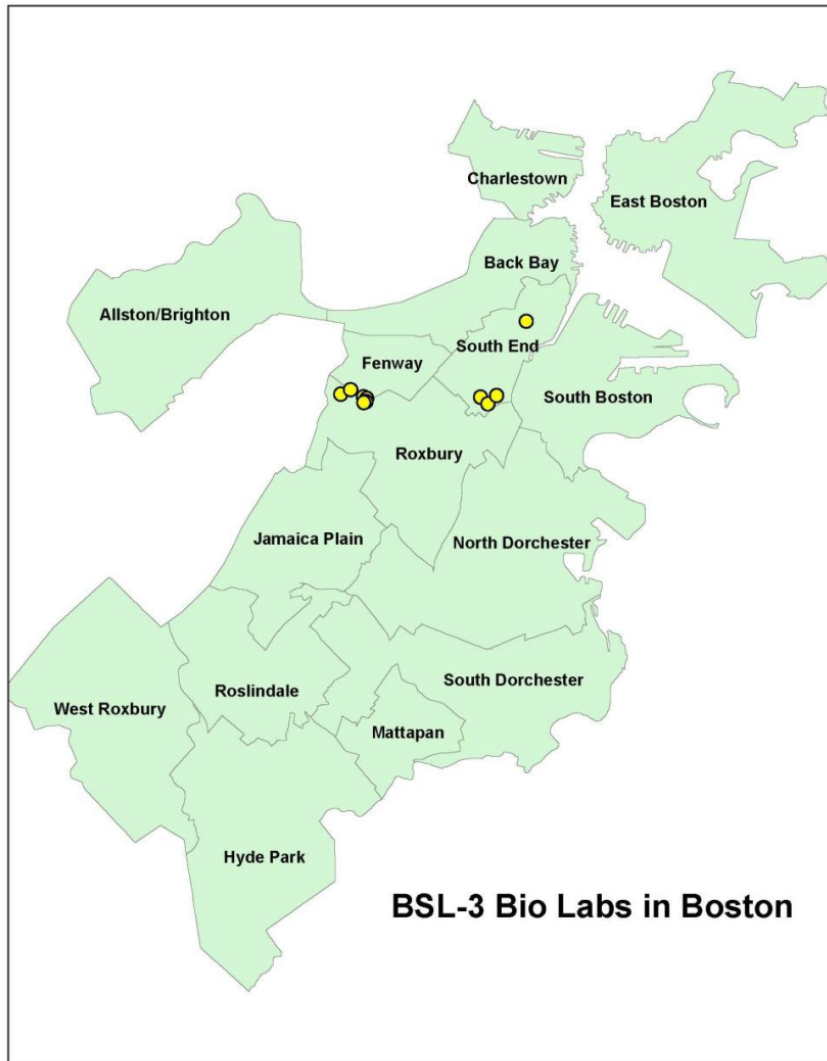
# **BPHC Biological Regulations: Goals**

- To protect the safety and health of the public, lab workers and the environment.
- Create a uniform set of biosafety requirements for all biological research labs in the City of Boston.
- Increase public confidence and awareness of lab safety procedures and regulations.
- Increase reporting requirements to BPHC.

# **Boston Regulatory Framework**

- **Biological Laboratory Regulations (2006)**
  - ✓ Research in BSL-3 and BSL-4 labs in Boston
  - ✓ 7 BSL-3 and 1 BSL-4 permitted
- **Recombinant DNA Technology: Use Regulations (1994)**
  - ✓ 33 entities permitted
- **Disease Surveillance Regulations (2004)**
  - ✓ Healthcare facilities, doctors and labs required to report infectious diseases

# Regulated Labs: BSL-3 & BSL-4



LOCATION	AGENT
Boston Children's Hospital	<ul style="list-style-type: none"> <li>• Tuberculosis</li> </ul>
Boston University (NEIDL)	<ul style="list-style-type: none"> <li>• Tuberculosis</li> <li>• Plague</li> <li>• Tularemia</li> <li>• Ebola</li> <li>• Marburg</li> </ul>
Dana-Farber Cancer Institute	<ul style="list-style-type: none"> <li>• HIV</li> </ul>
Harvard School of Public Health	<ul style="list-style-type: none"> <li>• Tuberculosis</li> <li>• HIV</li> </ul>
Tufts University	<ul style="list-style-type: none"> <li>• Tuberculosis</li> </ul>

# Permit Requirements: BSL-3 & BSL-4

- ✓ Biosafety or Lab Safety Manual
- ✓ Disease surveillance plan
- ✓ Emergency response plan
- ✓ Waste disposal plan
- ✓ Security plan
- ✓ Transportation plan
- ✓ Training procedures
- ✓ Facility commissioning document
- ✓ Decontamination and decommissioning plans
- ✓ Laboratory inspection procedures
- ✓ Strain verification policy
- ✓ IBC roster
- ✓ List of key staff

# **Boston Biosafety Committee**

- **Provide technical assistance and advice to BPHC**
  - ✓ Regulation and permitting of research labs
- **Members appointed by BPHC Executive Director**
  - ✓ Boston residents, research scientists
  - ✓ Biosafety officers, occupational health physician
- 45% (5/11) are Community Members
- Held 11 meetings between 2013-2015
- Most recent BBC meeting held in August 20, 2018





# BSL4 Permit Review

- Review of application and projects by BPHC and BBC
- Lab inspection
- Review by consultant
- Approval by Executive Director



**2003: Grant submitted to NIAID**



**2006: NEIDL groundbreaking**



**2006/2007: Boston residents file state & federal lawsuits against BU**



**2009: BPHC hires Emergency Management consultant**

**2012: BPHC approves BSL-2  
research at NEIDL**



**Oct 2013: BPHC approves BSL-3  
research at NEIDL**



**Oct 2013: BPHC convenes Boston  
Biosafety Committee**



**May 2014: Massachusetts Superior  
Court dismisses 2007 lawsuit**

**2016: BPHC hires consultant with BSL-4 research experience**



**Dec 2016: CDC approves BSL-4 research at NEIDL**



**Dec 2017: BPHC approves BSL-4 research at NEIDL**



**August 2018: BSL4 agents transferred to NEIDL**

# Challenges and Delays During Permitting

- Unique situation with both local and federal oversight
  - ✓ BPHC Biological regulation
  - ✓ CDC Federal Select Agent Program
- Proposed Boston City Council ordinances to prohibit BSL4 research

# Challenges and Delays During Permitting (cont'd)

- Lawsuits by Boston residents
- Media requests for information
- Renovation of Patient Isolation Unit
  - ✓ Coordination of BMC and BU
  - ✓ Training of staff
- Changes from time of application to start of work
  - ✓ Personnel
  - ✓ SOPs

# Community Outreach

- Cooperation with city agencies
  - ✓ Meetings to review plans and facility
  - ✓ Drills/exercises, training and tours
  - ✓ Emergency Management Plan
- Meetings with Community Groups
- Community members on BBC
- Communication with City Hall during process





# BSL-4 Suit Training of BPHC Staff



# Future Challenges

- Review new BSL-4 projects
- Train Emergency Responders
- Train BPHC staff
- Incident response
- Communicate with residents and city agencies



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