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

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<tr>
<th>LOCATION</th>
<th>AGENT</th>
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<tbody>
<tr>
<td>Boston Children’s Hospital</td>
<td>• Tuberculosis</td>
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<td>Boston University (NEIDL)</td>
<td>• Tuberculosis</td>
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<td>• Plague</td>
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<td>Dana-Farber Cancer Institute</td>
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<td>Harvard School of Public Health</td>
<td>• Tuberculosis</td>
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<td>Tufts University</td>
<td>• Tuberculosis</td>
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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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