

**BOSTON
PUBLIC
HEALTH
COMMISSION**



City of Boston Biological Safety Regulations and Laboratory Oversight

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Director of Biological Safety
Boston Public Health Commission
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Boston Public Health Commission

- Local health authority within Boston
- Directive from the Mayor to coordinate all Biosafety issues related to Level 3 and 4 laboratories in Boston
- As the lead, BPHC collaborates and works with
 - Boston Fire Department
 - Boston Police Department
 - Emergency Medical Services
- Assumes the responsibility for all Biosafety issues related to planning, training and equipment



Boston Public Health Commission Regulations

- Recombinant DNA Technology: Use Regulations
- Biological Laboratory Regulation
- Disease Surveillance and Reporting Regulation



Goals and Objectives

- Protect the safety and health of the public and lab workers
- Increase public confidence and awareness of lab safety procedures and regulations
- Increase reporting requirements to BPHC



Development of Regulation

- April 2005 Advisory group of lab safety experts
- November 2005 Draft regulations released
- December 2005 – January 2006
 - Public hearing and written comments (60)
 - Small and large group meetings: City council, Community reps, Scientific reps
- September 2006 Regulations approved
- March 2007 Guidelines approved

Permit Requirements

- Documentation required for all BSL3 & BSL4 research laboratories
 - Biosafety/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
 - Key staff list



Research Projects

- All BSL-3 and BSL-4 projects must be presented to BPHC at least thirty (30) days before research may begin



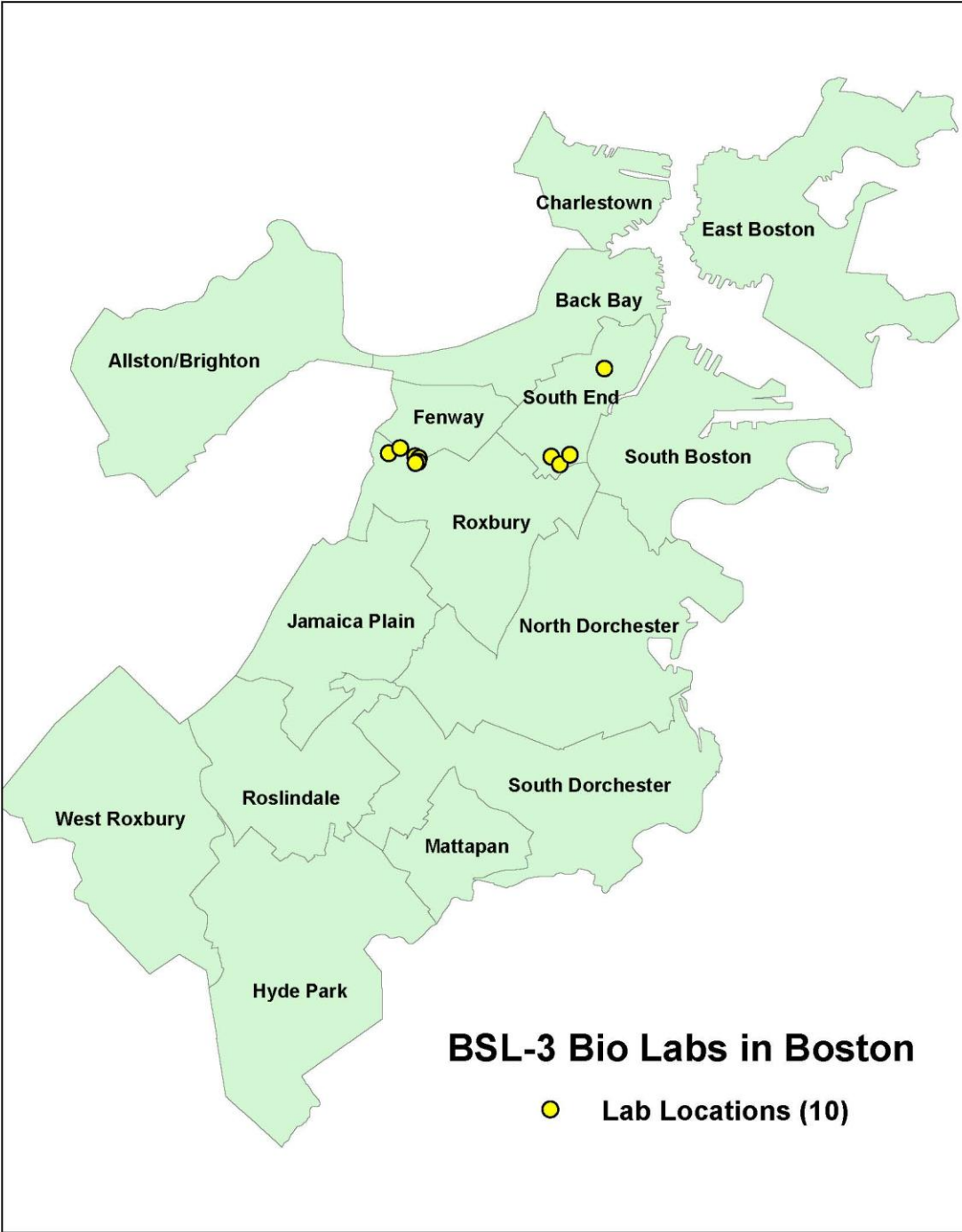
Restrictions

- Recombinant DNA use requiring containment defined by the NIH Guidelines as “BL4” shall not be permitted in the City of Boston
- Ban on weaponization and classified research



Community Benefits Program

- All entities permitted for the operation of a BSL4 laboratory shall establish and maintain a Community Benefits Programs to support local health and safety needs
- The entity shall file with the Commission an annual report detailing the operations of the program





Inspections

- Inspection of new and existing laboratories
 - BSL3 minimum annually
 - BSL4 minimum twice a year
 - Inspections may be unannounced
 - Subject to inspection after exposures or incident
 - Guided by detailed inspection checklist
 - Conducted by team
- Review documents, staff interviews, and assessment of facility and practices



Incident reporting

- Upon discovery of incident
- Reporting requirement
 - Illness
 - Spill or accident resulting in overt exposure
 - Unexplained absenteeism >2 days
 - Failure of mechanical system
- Follow-up information must be provided to BPHC as requested



Annual Report

- Complete set of IBC minutes
- Report of Quality Assurance/Quality Improvement
 - Facility Verification, HEPA Certification, Training, Drills, Inspections, Equipment purchases, Facility Maintenance
- Responsible Official's signature on statement



Permit Fees

- Annual fee ranges from \$2,500 to \$10,000 for BSL3 laboratories
- \$50,000 annual fee for BSL4
- Non-select agent entities must submit an annual financial statement with details of operating expenses



Fines and Citations

- Monetary fines
- Permit may be issued with conditions, revoked, suspended, modified or not renewed
- Immediate closure of laboratory

BSL4 Permit Review Process

- Review of permit application by BPHC
- Review of permit and projects by Boston Biosafety Committee
- Inspections of BSL4 laboratory space
- CDC review



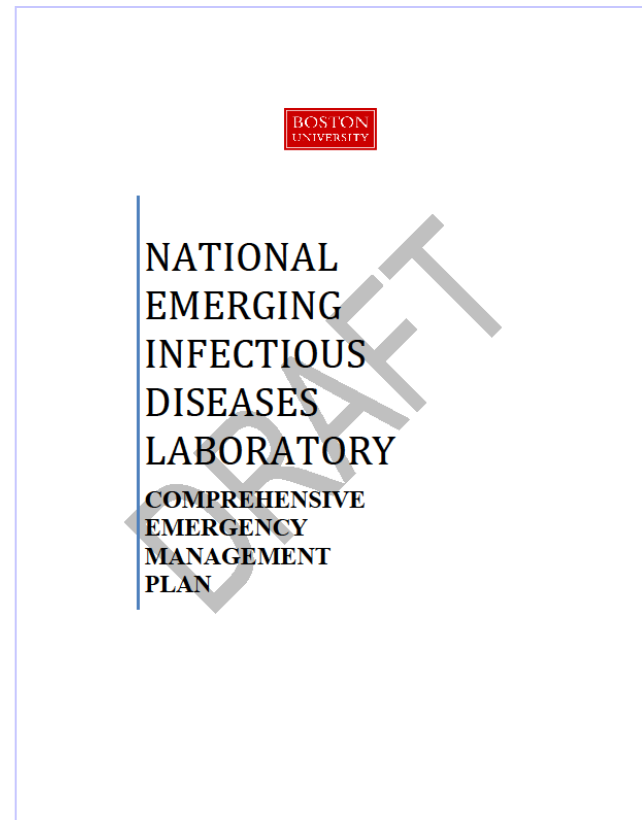


Boston Biosafety Committee

- Six members of the BBC live in Boston
- Technical assistance to BPHC related to permit applications and emerging BSL3/BSL4 issues
- Review of summaries of all proposed BSL4 research applications prior to final BPHC approval
- Review of policies, procedures, manuals and programs adopted by individual institutions

Collaborations with Biosafety Working Group

- Planning training, tours, and emergency response drills
- Comprehensive Emergency Management Plan
- City departments send representatives to meetings



BPHC Biosafety

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- Leon Bethune, MPH
- Anita Barry, MD, MPH
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<http://www.bphc.org/whatwedo/healthy-homes-environment/biological-safety/Pages/Biological-Safety.aspx>