

**BOSTON
PUBLIC
HEALTH
COMMISSION**



City of Boston Biological Safety Regulations and Laboratory Oversight

**Julien Farland MS, RBP
Director of Biological Safety
Boston Public Health Commission
February 10, 2014**



Outline

- Introduction to BPHC Laboratory Regulations
- Development of BSL3/BSL4 Regulation
- Specific Regulatory Requirements
- Boston Biosafety Committee



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 about lab safety procedures and regulations
- Strengthen ability of Boston institutions to monitor safety by increasing role and authority of IBCs and biosafety offices
- 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 (100+): City council, State legislature, Community reps, Scientific reps
- June, 2006 Revised draft regulation released
- September 2006 Regulations approved
- March 2007 Guidelines approved



Components of Regulation

- All BSL-3 and BSL-4 projects must be presented to BPHC at least thirty (30) days before research may begin
- Requires whistleblower provisions for anonymous reporting of health and safety violations
- Strengthens community involvement and awareness
- Establish permitting and penalty procedures

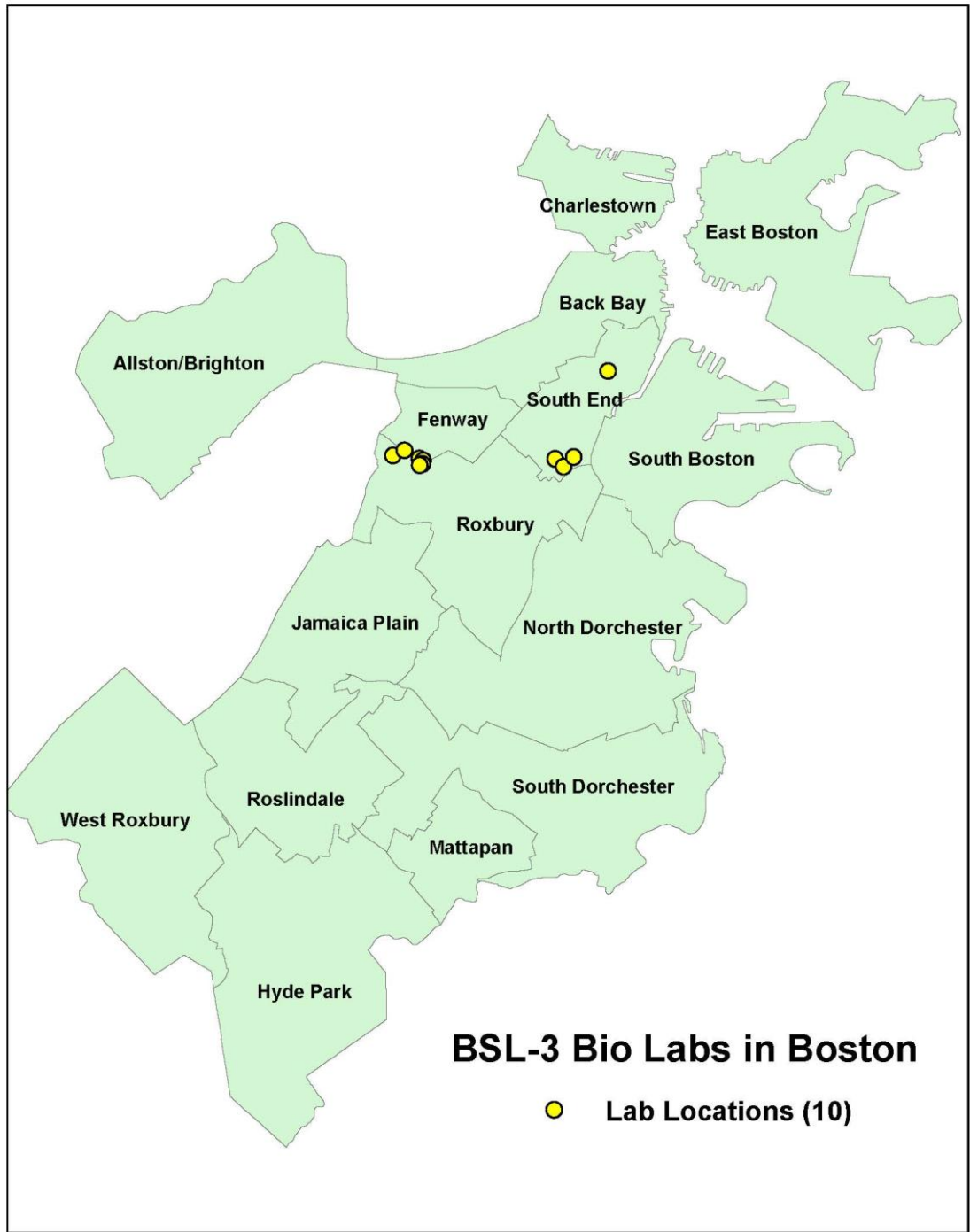


Restrictions

- 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

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





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 covers
 - 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 QA/QI. Facility Verification, HEPA Certification, Training, Drills, Inspections, Equipment purchases, Facility Maintenance.
- Responsible Official's signature on statement
- Annual Public IBC Meeting



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



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



National Emerging Infectious Disease Laboratory (NEIDL)

- BSL2 work is currently occurring at the NEIDL
- BPHC has worked with city agencies to prepare for emergency responses at the NEIDL.
- Tabletop exercises and drills, classroom exercises, and tours of the facility have occurred and are an ongoing obligation of Boston University (BU).
- Online Training on biosafety and the NEIDL is under development.

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



Contact Information

Julien Farland

Director of Biological Safety

Boston Public Health Commission

Office: 617-534-2814

Email: jfarland@bphc.org

Website: www.bphc.org/biosafety