



REVISED GUIDELINES:

BIOLOGICAL LABORATORY REGULATIONS

BOSTON BIOSAFETY USERS' GROUP (BBUG)

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Simon Muchohi, PhD, MPH, CIH, CSP, CHMM

Director of Biological Safety

Boston Public Health Commission

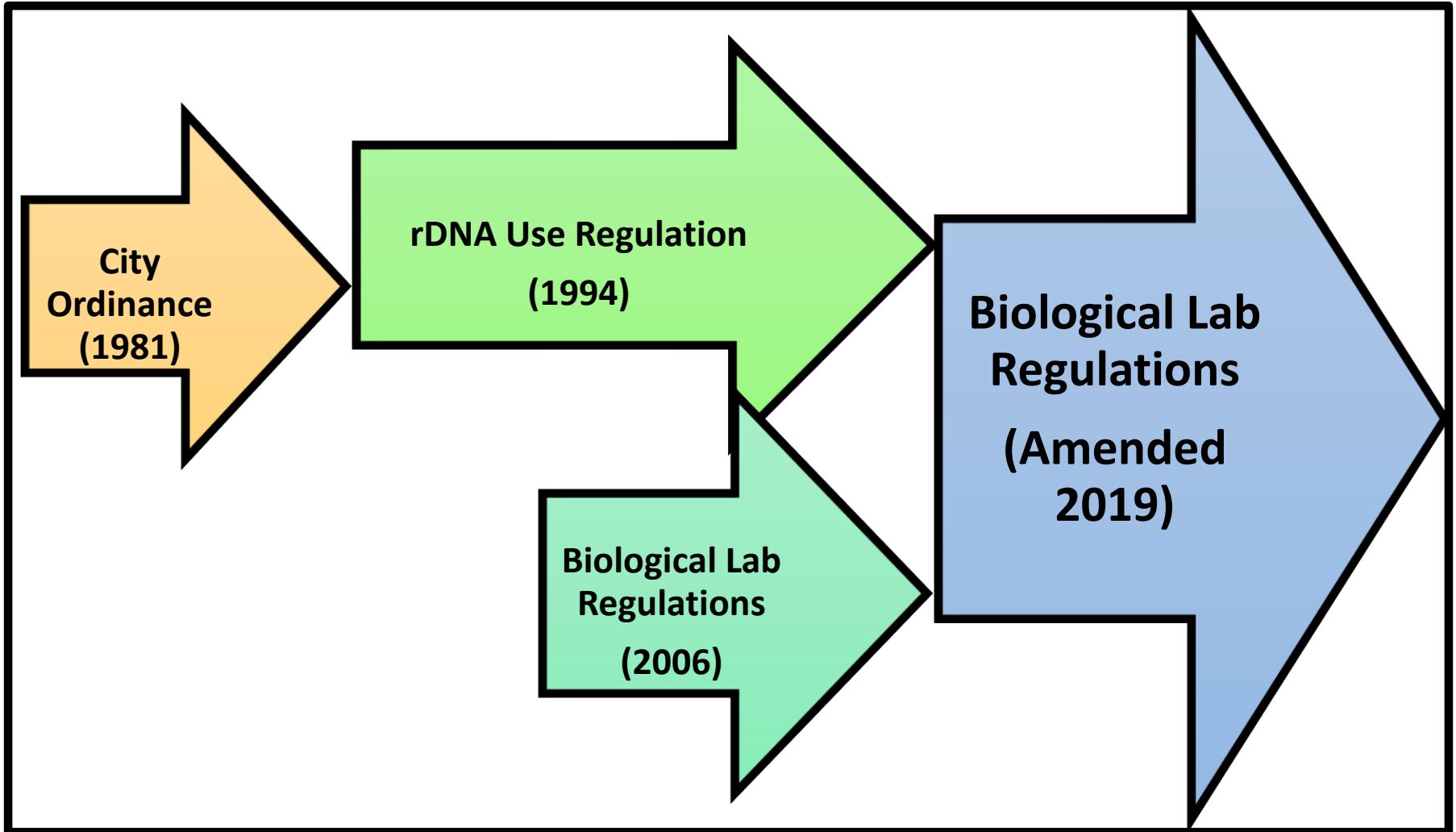


The opinions expressed in this presentation are solely those of the speaker(s) and may not entirely reflect those of the Boston Public Health Commission.

Objectives

- Discuss key changes to BPHC's Guidelines to Biological Laboratory Regulations.
- Respond to your main concerns (where possible).
- Explore opportunities for improvement.

Boston Regulatory Framework



Regulation Changes

- Rescind the Recombinant DNA Use and Technology Regulation.
- Remove the prohibition of rDNA research on BSL-4 agents in Boston.
- ***Any rDNA project must undergo rigorous approval process for BSL-4 projects.***
- Incorporate regulation of rDNA use into Biological Laboratory Regulation.
- ***Each BSL-4 research project must undergo review by Boston Biosafety Committee before approval by BPHC.***

Summary of changes to Guidelines

- Added definitions: incident, major mechanical system, regulated laboratory space, and visitor.
- Separate permit requirements: rDNA (BSL-2/ABSL-2), non-select agent (BSL-3/ABSL-3), select agent (BSL-3/ABSL-3), and BSL-4
- Separate permits required for each type of Biological Laboratory.
- Lists of required documents for permit applications.
- Revised permit fees schedule.
- All permits are valid for one year.

Summary of changes to Guidelines

- Updated section on Incident Reporting
- Incident Reporting Procedures based on lab type.
- Requirement to notify both BPHC's Biosafety Program and Infectious Disease Bureau.
- Revised list of High-Risk Agents.
- Clarified permit amendment requirements and review process.
- Updated Community Benefits Program section; specific guidance.

Biological Laboratory Permits

- Recombinant DNA Permit (BSL-2/ABSL-2)
- BSL-3/ABSL-3 (Non-Select Agent) Permit
- BSL-3/ABSL-3 (Select Agent) Permit
- BSL-4/ABSL-4 Permit

Biological Laboratory Permit: Scope

BIOLOGICAL LABORATORY	BUILDING 1 (651 Main St)	BUILDING 2 (655 Main St)	BUILDING 3 (665 Main St)	Permits Required
BSL-2/ABSL-2 (rDNA)	YES	YES	YES	Single rDNA Permit
BSL-3/ABSL-3 (Non-Select Agent)	YES	NO	NO	Single Non-SA Permit
BSL-3/ABSL-3 (Non-Select Agent)	YES	NO	YES	Non-SA Permit for each building
BSL-3/ABSL-3 (Select Agent)	NO	NO	YES	Single SA Permit
BSL-4/ABSL-4	NO	NO	YES	Single BSL-4 Permit

Permit Duration & Annual Renewals

- **All permits will be valid for 1 year**
 - ✓ March 1 to February 28 (or 29)
- Entity must submit annual permit renewal application by **January 31** each year.
- BPHC will automatically extend all current permits (Nov 1, 2019 to Feb 29, 2020)
 - ✓ No permit renewal application required
 - ✓ No payment of permit fees

New rDNA (BSL-2/ABSL-2) Permit Application: Required Documents



- ✓ Permit Application Form
- ✓ Check for permit application fees
- ✓ List of all physical locations (street address, building, room number)
- ✓ List of all current research protocols using rDNA
- ✓ Description of large-scale rDNA activities
- ✓ Biosafety Manual
- ✓ OSHA Bloodborne Pathogens Exposure Control Plan
- ✓ Chemical Hygiene Plan
- ✓ Biological Waste Management Plan
- ✓ Occupational Health Services Program
- ✓ Laboratory Safety Training Program
- ✓ Emergency Response Plan
- ✓ Insect/rodent control program
- ✓ List of all IBC members
- ✓ Biographical sketches of all IBC members
- ✓ Copy of IBC minutes
- ✓ Copy of Lab Registration Permit (BFD)
- ✓ Copy of Certificate of Occupancy (Inspectional Services Department)

New BSL-3/ABSL-3 (Non-Select Agent) Permit Application: Required Documents



- ✓ Permit Application Form
- ✓ Check for permit application fees
- ✓ List of all physical locations (address, Building, Room),
- ✓ List of all current research protocols using rDNA and all Risk Group 3 agents
- ✓ Biosafety Program Management Leadership
- ✓ Biosafety/Biocontainment Plan
- ✓ Biosafety Manual
- ✓ Security plan
- ✓ Hazard Evaluation or Risk Management Plan
- ✓ Laboratory Safety Training Program
- ✓ Emergency Response Plan/Incident Response Plan
- ✓ Disease Surveillance and Reporting Plan
- ✓ Biological Waste Management Plan
- ✓ Decontamination Plan
- ✓ Laboratory Facility Commissioning Plan
- ✓ Laboratory Facility Decommissioning Plan
- ✓ Transportation of Biological Materials Plan
- ✓ Strain Verification Procedures
- ✓ Plan for Termination of Work
- ✓ Insect/rodent control program

BSL-3/ABSL-3 (Select Agent) or BSL-4 /ABSL-4 Permit: Required Documents

Submit **ALL** documents required for BSL-3/ABSL-3
(Non-Select Agent) permit application, **AND:**

- ✓ Security, Biosafety, and Incident Response Plans
- ✓ Copy of permit/registration approval letter.
- ✓ Facility inspection reports from APHIS/CDC
- ✓ Copy of completed and signed APHIS/CDC **FORM 1**.
- ✓ Copies of all APHIS/CDC **FORM 2** (transfer document).
- ✓ Copies of all APHIS/CDC **FORM 3** (incident notification).

Annual Permit Renewal: Required Documents

- Permit Application Form.
- Check for permit renewal fees.
- List of any original permit application documents.
 - ✓ brief description of changes made to each doc
 - ✓ any other information requested by BPHC
- IBC annual report.

Proposed Permit Fees: **Under Review**

BIOLOGICAL LAB TYPE	SIZE OF REGULATED LABORATORY SPACE (Square Feet)	PERMIT FEE (\$)
BSL-2/ABSL-2 using rDNA	1-5,000	[REDACTED]
	5,001-10,000	[REDACTED]
	≥ 10,001	[REDACTED]
BSL-3/ABSL-3 (Non-Select Agent)	1-5,000	[REDACTED]
	5,001-10,000	[REDACTED]
	≥ 10,001	[REDACTED]
BSL-3/ABSL-3 (Select Agent)	Any size	[REDACTED]
BSL-4/ABSL-4	Any size	[REDACTED]

Permit Amendment

Entity shall apply for a permit amendment:

- ✓ Before changing biosafety level designation.
- ✓ Before starting any new research program or project involving Risk Groups 3 or 4 agents.
- ✓ Before starting large-scale rDNA activities.
- ✓ After completing major lab modifications.

What Lab Incidents Must be Reported?

- ✓ Illness or disease (confirmed or suspected) caused by high-risk agent/attenuated strain.
- ✓ Spill or accident release (rDNA materials or high-risk agents).
- ✓ Personnel exposure or potential exposure.
- ✓ Unexplained absenteeism from workplace.
- ✓ Failure of major mechanical system (e.g. HVAC) in BSL-3/ABSL-3 or BSL-4/ABSL-4 labs.
- ✓ Any incidents reportable to IBC, NIH or CDC.

BSL-2/ABSL-2 (rDNA) & BSL-3/ABSL-3 Labs

**For ALL illnesses, cases of disease/infection,
or occupational exposures:**

1. Call BPHC Infectious Disease Bureau at
(617) 534-5611 IMMEDIATELY.
2. Call or email BPHC Environmental Health
Office within 24 hours.
3. Fax completed form to BPHC Infectious
Disease Bureau within one business day.

BSL-2/ABSL-2 (rDNA) and BSL-3 /ABSL-3 Labs



For ALL laboratory-related incidents

1. Call or email BPHC Environmental Health Office within 24 hours.
2. Send copy of APHIS/CDC **FORM 3** to BPHC Environmental Health within 7 days.
3. Send copy of NIH Incident Report to BPHC Environmental Health within 30 days.

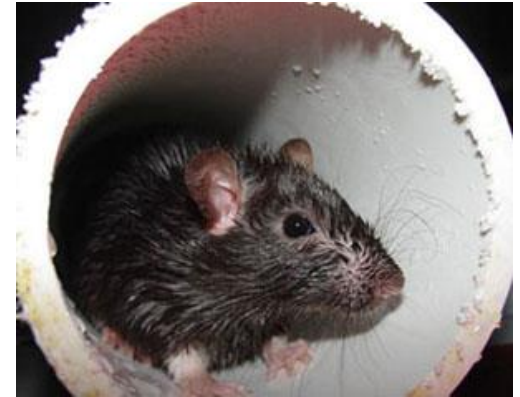
BSL-4/ABSL-4 Labs

1. Call BPHC Office of Public Health Preparedness Medical Intelligence Center (MIC).
2. Call BPHC Infectious Disease Bureau **IMMEDIATELY**.
3. Fax completed form to BPHC Infectious Disease Bureau within one business day.
4. Send copy of **After-Action Report** to BPHC MIC within 7 days.
5. Send copy of APHIS/CDC **FORM 3** to BPHC EHO within 7 days.
6. Send copy of Incident Investigation Report to BPHC.
7. Send copy of NIH Incident Report to BPHC EHO within 30 days.

Which Animal Bit or Scratched You?

Lab research Animal

Domestic/wild animal



**BIOLOGIC RESEARCH
LABORATORY REPORTING FORM**



**ANIMAL BITE
REPORTING FORM**

Animal Bites/Scratches: Use Right Form



	Boston Public Health Commission Infectious Disease Bureau 1010 Massachusetts Avenue Boston, MA 02118 Phone: 617-534-5611 Fax: 617-534-5905	Biologic Research Laboratory Reporting Form: High-Risk Agents and Other Reportable Agents
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TYPE OF LABORATORY INCIDENT : <input type="checkbox"/> Exposure (without associated illness) <input type="checkbox"/> Infection							
Case Identification	NAME, LAST		FIRST		GENDER <input type="checkbox"/> male <input type="checkbox"/> female		
	STREET ADDRESS		APT. #	CITY		STATE	ZIP
	PHONE		CELL PHONE		DOB	AGE	
	RACE <input type="checkbox"/> Black <input type="checkbox"/> White <input type="checkbox"/> Hispanic <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Other: _____						
	WAS CASE HOSPITALIZED? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes: from ___/___/___ to ___/___/___					ETHNICITY	



Boston Public Health Commission (BPHC)
Reporting Form for Animal Bites

(Use Research Laboratory Reporting Form if the animal bite was from a research lab animal. Additional reporting forms can be found at www.bphc.org.)

Patient	Last Name		First Name		Gender <input type="checkbox"/> male <input type="checkbox"/> female		
	Street Address		Apt. #	City		State	Zip
	Phone		Cell Phone		DOB	Age	
	Race <input type="checkbox"/> Black <input type="checkbox"/> White <input type="checkbox"/> Hispanic <input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Other: _____						
	Ethnicity		If a minor, Name of Parent or Guardian		Parent/Guardian Phone		
Date of Exposure		Time:	Location (address)				
___/___/___		AM PM					
Animal: <input type="checkbox"/> Wild <input type="checkbox"/> Domestic		<input type="checkbox"/> Dog <input type="checkbox"/> Cat	<input type="checkbox"/> Bat <input type="checkbox"/> Raccoon	<input type="checkbox"/> Ferret <input type="checkbox"/> Skunk	<input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____	Description (Breed, Color, Sex)	



What You Should Do ...

- 1. GET** copies of the current biological laboratory regulations and guidelines
- 2. SEND** any comments or suggestions to the BPHC Biosafety Program (biosafety@bphc.org).
- 3. SPREAD** the word (about the Guidelines)!

Contact Information



**Simon Muchohi, PhD, MPH, CIH,
CSP, CHMM**

Director of Biological Safety

Boston Public Health Commission
1010 Massachusetts Avenue
Boston, MA 02118

Phone: 617-534-2683

smuchohi@bphc.org

Julien Farland, MS, RBP, CBSP

Director of Environmental Hazards

Boston Public Health Commission
1010 Massachusetts Avenue
Boston, MA 02118

Phone: 617-534-2814

jfarland@bphc.org