



BIOLOGICAL LABORATORY REGULATIONS
IMPLEMENTATION & ENFORCEMENT GUIDELINES

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Monica Valdes Lupi, JD, MPH, Executive Director

October 15, 2019

Date

1. AUTHORITY

The Executive Director of the Boston Public Health Commission (BPHC) has issued these Guidelines, as authorized by Section 6.00 of the BPHC's Biological Laboratory Regulations.

2. DEFINITIONS

All terms used in these Guidelines shall have the same meaning as defined in Section 1.00 of the BPHC's Biological Laboratory Regulations. Any other terms not defined in this document shall have the same meaning as is used.

- a. **“Decommission”** shall mean to take a laboratory facility off-line, out of use, or change its use. The process involves securing biological materials, decontaminating equipment (e.g., biosafety cabinets, autoclaves, centrifuges) and laboratory space; taking mechanical systems (e.g., ductwork, HVAC, HEPA filters, effluent decontamination systems) off-line before closing out or renovating an existing laboratory.
- b. **“Incident”** shall mean an event that causes or has the potential of causing injury, illness, disease, or property damage. Incidents may include spills and accidents in biological laboratories which result in potential or overt exposures to recombinant DNA materials, high-risk agents or select agents or toxins; release of infectious materials or recombinant DNA materials, power failure, fire, explosion, flood, or other natural disasters like tornados, earthquakes, or hurricanes.
- c. **“Major mechanical system”** shall mean any mechanical system found in the laboratory that is needed to safely operate the laboratory and maintain biocontainment and biosecurity systems. It includes the physical building structure (e.g., windows, doors, walls, floors, ceilings, roof, partitions); site utility piping and plumbing; electrical system; heating, ventilation, and air conditioning (HVAC) and air handling units (AHU); HEPA filtration units; building automation system; fire protection and suppression systems; physical and electronic security barriers (e.g., doors, locks, anterooms, interlocks, CCTV, biometric or card readers, etc.); effluent decontamination system (EDS); chemical showers; and pass-through autoclaves.
- d. **“Regulated Laboratory Space”** shall mean the total floor area (in square feet) of the permitted biological laboratory at a single biosafety level, including animal rooms, waste storage rooms, and other rooms directly serving the laboratory as determined by the BPHC.
- e. **“Visitor”** shall mean an individual, escorted or unescorted, who does not have authorized access to the biological laboratory facility.

3. PERMIT REQUIREMENTS

(Refer to Section 2.00 of the Biological Laboratory Regulations).

3.1 Biological Laboratory Permits

3.1.1 BSL-2/ABSL-2 (Recombinant DNA) Permit

Any Entity operating or proposing to operate a biological laboratory using recombinant DNA (rDNA) at biosafety level 2 (BSL-2) or animal biosafety level 2 (ABSL-2) shall first obtain a permit for the Regulated Laboratory Space from the BPHC before any such intended use.

3.1.2 BSL-3/ABSL-3 (Non-Select Agent) Permit

Any Entity operating or proposing to operate a biological laboratory or laboratories (including for rDNA use) at biosafety level 3 (BSL-3) or animal biosafety level 3 (ABSL-3) shall first obtain a permit for the Regulated Laboratory Space from the BPHC before any such intended use.

3.1.3 BSL-3/ABSL-3 (Select Agent) Permit

Any Entity that intends to have, use, or transfer any select agent or toxin including receipt of select agents or toxins from outside the United States, for use (including rDNA use) at BSL-3/ABSL-3 shall first obtain a permit for the Regulated Laboratory Space from the BPHC before any such intended use.

3.1.4 BSL-4/ABSL-4 Permit

Any Entity operating or proposing to operate a biological laboratory or laboratories (including rDNA use) at biosafety level 4 (BSL-4) or animal biosafety level 4 (ABSL-4) shall first obtain a permit for the Regulated Laboratory Space from the BPHC before any such intended use.

3.2 Scope of Biological Laboratory Permit

- a) *Entity as Tenant or Sharing Laboratory Space:* Any Entity operating or proposing to operate a laboratory or animal facility requiring a permit (Sections 3.1.1 to 3.1.4) in a leased or shared laboratory space or using the space under any other written or verbal agreement must apply for the required permit, even if the property owner already holds such a permit.

- b) The Entity may aggregate its BSL-2/ABSL-2 (rDNA) Regulated Laboratory Space (Section 3.1.1) across multiple buildings and physical addresses to apply for a single permit.
- c) The Entity may aggregate its BSL-3/ABSL-3 or BSL-4/ABSL-4 Regulated Laboratory Space (Sections 3.12 to 3.14) located within a single building into a single permit of the appropriate type.
- d) The Entity shall not aggregate its BSL-3/ABSL-3 or BSL-4/ABSL-4 laboratories (Sections 3.12 to 3.14) that are found in different buildings and at different physical addresses. A separate permit is required for each building.
- e) The Entity shall not aggregate laboratories of different biosafety levels or types (Sections 3.1.1 to 3.1.4) into a single permit, even if they are in the same building. A separate permit is required for each biosafety level or type.

3.3 Permit Duration and Annual Renewal Dates

- a) All Biological Laboratory Permits are valid for one (1) year from March 1 to February 28 of the following calendar year.
- b) The BPHC may issue a permit to any Entity that submits a new permit application after March 1. The permit shall be valid from the date of issue through the end of February of the following year.
- c) The Entity must submit an application for annual permit renewal by January 31 each year.

4. NEW PERMIT APPLICATION: REQUIRED DOCUMENTS

(Refer to Section 2.01b of the Biological Laboratory Regulations)

The Entity shall send permit application documents to the Director of Biological Safety, Environmental Health Office, Boston Public Health Commission, 1010 Massachusetts Avenue, 2nd Floor, Boston, MA 02118. Contact the Environmental Health Office at 617-534-5965 or biosafety@bphc.org if you have any questions of permit application.

4.1 New BSL-2/ABSL-2 (Recombinant DNA) Permit

Any Entity seeking a permit to use rDNA at BSL-2/ABSL-2 must send the following documents to the BPHC:

- a) Completed and signed Recombinant DNA Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety.
- b) Check for permit application fees, made payable to the Boston Public Health Commission.
- c) List of all physical locations (Street address, Building, Room Number), including animal care and core research facilities, where rDNA materials are used or stored.
- d) List of all current research protocols using rDNA, including the assigned biosafety levels and the category of non-exempt experiments (Section III of the NIH Guidelines). The BPHC may ask the Entity to provide copies of any research protocols.
- e) Description of large-scale rDNA activities, containment facilities, and equipment (Appendix K of the NIH Guidelines), if applicable.
- f) Biosafety Manual describing the institutional policies and procedures based on risk assessment. The Biosafety Manual must establish minimum standards and guidelines for the research activities and facility operations in BSL-2/ABSL-2 laboratories. The biosafety policies and procedures must protect laboratory personnel, public, and the environment from biohazardous materials, and ensure compliance with federal, state, and local regulations.
- g) OSHA Bloodborne Pathogens Standard Exposure Control Plan (29 CFR 1910.1030) and Chemical Hygiene Plan (29 CFR 1910.1450).
- h) Biological Waste Management Plan for disposal of infectious waste generated at the laboratory facility, in compliance with 105 CMR 480.000 (*Minimum Requirements for the Management of Medical or Biological Waste; State Sanitary Code Chapter VIII*) and other applicable federal, state, and local regulations.
- i) A brief description of the institution's Occupational Health Services Program approved by the Institutional Biosafety Committee (IBC) for all persons working with rDNA materials at the laboratory facility.
- j) Laboratory Safety Training Program for all employees, students and visitors working with recombinant DNA and biohazardous materials at the laboratory facility. The training modules must include information specific to recombinant DNA technology use and BPHC incident reporting requirements.
- k) Emergency Response Plan covering accidental spills, personnel contamination, or environmental release resulting from recombinant DNA materials.
- l) Brief description of the insect/rodent control program used at the facility.

- m) List of all IBC members (name and title), clearly showing the Chair, contact person, Biosafety Officer (if applicable), recombinant DNA expert, community members, and ad hoc consultant (if applicable).
- n) Biographical sketches of all IBC members, including community members.
- o) Copy of IBC minutes (if the IBC has already held its first meeting).
- p) Copy of Laboratory Registration Permit (Boston Fire Department).
- q) Copy of Certificate of Occupancy (Boston Inspectional Services Department).

4.2 New BSL-3/ABSL-3 (Non-Select Agent) Permit

Any Entity seeking a permit to operate a BSL-3/ABSL-3 facility the must send the following documents to the BPHC:

- a) A completed and signed BSL-3/ABSL-3 Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety.
- b) Check for permit application fees, made payable to the Boston Public Health Commission.
- c) List of all physical locations (Street address, Building, Room Number), including animal care and core research facilities, where rDNA materials or Risk Group 3 agents are used or stored.
- d) List of all current research protocols using rDNA materials approved by the Entity's IBC, and all Risk Group 3 agents used or stored in the Regulated Laboratory Space (Section III of the NIH Guidelines). The BPHC may ask the Entity to provide copies of any research protocols.
- e) Biosafety Program Management Leadership: The Entity must develop a written policy signed by senior management outlining the Entity's commitment to provide the leadership, vision, and resources needed to implement an effective biosafety program. The senior management must show commitment to continuous improvement of the biosafety program, communicate that commitment to all employees, set biosafety program expectations, and designate roles and responsibilities.
- f) Biosafety/Biocontainment Plan: The Entity must develop and implement a written biosafety/biocontainment plan, based on the BMBL (5th edition), NIH Guidelines, and other reputable national and international biosafety guidelines. The Plan must outline the hazardous characteristics of each high-risk agent or select agent or toxin listed on the Entity's permit application. The Plan must describe the safety measures implemented to protect laboratory personnel, the public, and the environment from exposure to high-risk agents, select agents or toxins, or recombinant DNA materials. The safety measures may

include elimination (physically remove the hazard), substitution (replace the hazard), engineering controls (isolate people from the hazard), administrative controls (change the way people work), and personal protective equipment (PPE) (protect the worker).

- g) Biosafety Manual describing the institutional biosafety policies, programs, and procedures based on an overarching risk assessment. The Biosafety Manual must establish acceptable standards and guidelines for the research activities and operations in the BSL-3/ABSL-3 or BSL-4/ABSL-4 facility. The biosafety policies and procedures must protect laboratory personnel, public, and the environment from biohazardous materials, and ensure compliance with federal, state, and local regulations. The Biosafety Manual may include a description of the biosafety program itself, and each of the core elements described below.
- h) Security Plan describing the security measures implemented to prevent unauthorized access, theft, loss, misuse, diversion, or intentional release of high-risk agents and select agents or toxins from the laboratory facility. The security measures must be based on site-specific security risk assessment of the facility, high-risk agents, and select agents or toxins used or stored in the BSL-3/ABSL-3 or BSL-4/ABSL-4 laboratory. The Security Plan must include mitigation strategies for the risks associated with physical security; personnel suitability and reliability; accountability for high-risk agents, select agents or toxins, and other regulated infectious material; inventory management; incident and emergency response; and information management.
- i) Hazard Evaluation or Risk Management Plan including a comprehensive review of the biological, chemical, radiologic, or physical hazards existing in the research laboratory that could cause harm to laboratory personnel, the public, or the environment. The Entity must review the facility design and operational procedures, determine if hazard control measures are adequate, and develop risk management plan to mitigate the identified hazards.
- j) Laboratory Safety Training Program based on a training needs assessment. The training program must include laboratory-specific or agent-specific training for researchers, laboratory personnel, and visitors who may work in the BSL-3/ABSL-3 or BSL-4/ABSL-4 facility. The training program must include training for emergency responders and other city agencies, as needed. The Entity must review and update the training program, as needed.
- k) Emergency Response Plan/Incident Response Plan outlining the actions to be taken in the event of a natural or man-made disaster such as biological spill, personnel exposure, release of high-risk agents, select agents or toxins, recombinant DNA materials; escape of infected animals; personnel injury or illness; security breaches; severe weather and other natural disasters (e.g., flood, earthquake, or hurricane); workplace violence; bomb threats and suspicious packages; emergencies like fire, gas leak, explosion, or power outage; or

any other natural or man-made events that may threaten the Entity. The site-specific plan must protect public health and safety, property, and the environment. The Entity must consider the impact to the laboratory, the facility and surrounding community.

- l) Disease Surveillance and Reporting Plan implemented to prevent and detect personnel illness or disease related to occupational exposure to infectious materials.
- m) Biological Waste Management Plan outlining the processes and procedures implemented to ensure proper removal, treatment, and disposal of biohazardous wastes from the BSL-3/ABSL-3 or BSL-4/ABSL-4, in compliance with 105 CMR 480.000 (*Minimum Requirements for the Management of Medical or Biological Waste; State Sanitary Code Chapter VIII*) and other applicable federal, state, and local regulations.
- n) Decontamination Plan describing the validated standard operating procedures for disinfection, inactivation, or sterilization of contaminated biological materials such as cultures of high-risk agents or select agents or toxins, personal protective equipment, animal caging systems and bedding, animal carcasses, tissues or body fluids, laboratory surfaces and equipment, and biological waste.
- o) Laboratory Facility Commissioning Plan describing the commissioning procedure of the BSL-3/ABSL-3 or BSL-4/ABSL-4 facility to ensure that the buildings design is properly constructed, compliant, and assessed so that it can be used and maintained. The Entity must hire an independent commissioning agency to offer consulting and engineering services and onsite performance testing and observations to verify that mechanical systems meet the design intent.
- p) Laboratory Facility Decommissioning Plan describing decommissioning procedures of the BSL-3/ABSL-3 or BSL-4/ABSL-4 facility to ensure the building has been properly decontaminated and made safe for future use. Before decommissioning, the facility must be decontaminated and verified according to the institution's standard operating procedures.
- q) Transportation of Biological Materials Plan outlining the policies and procedures to be followed when transporting Risk Groups 3 or 4 agents and select agents and toxins to ensure compliance with U.S. Department of Transportation's *Hazardous Materials Regulations* (49 CFR Parts 171-177); Federal Select Agent regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73); International Air Transport Association (IATA) *Dangerous Goods Regulations* (DGR); and the World Health Organization guidelines (*Guidance on Regulations for the Transport of Infectious Substances 2013–2014*).
- r) Attenuated Strain Verification Procedures for identifying attenuated organisms derived from known, virulent organisms that originally required BSL-3/ABSL-3 or BSL-4/ABSL-4 biocontainment when the attenuation results in a decreased virulence of the organism, or a reduction of required biocontainment level for possession or use. The

verification must include direct testing for the presence or absence of the virulence factors lost in attenuation by phenotypic or genetic means. The Entity must ensure it is in compliance with the Federal Select Agent Program requirements for excepted organisms.

- s) Plan for Termination of Work with Biological Agents outlining the procedures for ending research work with high-risk agents or select agents and toxins. The plan must address applicable federal regulatory requirements and standards, such as the Federal Select Agent Program regulations (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73); BMBL (5th Edition or successor); Massachusetts Department of Public Health regulation (105 CMR 480.000); and BPHC's Biological Laboratory Regulations.
- t) Brief description of the insect/rodent control program implemented at the facility.

4.3 New BSL-3/ABSL-3 (Select Agent) or BSL-4/ABSL-4 Permit

Any Entity seeking to use select agents or toxins (including rDNA uses) at BSL-3/ABSL-3 or BSL-4/ABSL-4 must submit the following documents to the BPHC:

- a) A completed and signed BSL-3/ABSL-3 or BSL-4/ABSL-4 Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety.
- b) Check for permit application fees, made payable to the Boston Public Health Commission.
- c) List of all physical locations (Street address, Building, Room Number), including animal care and core research facilities, where rDNA materials, Risk Groups 3 or 4 agents, or select agents and toxins are used or stored.
- d) List of all current research protocols using rDNA technology approved by the Entity's IBC, Risk Groups 3 or 4 agents, or select agents and toxins used or stored in the Regulated Laboratory Space (Section III of the NIH Guidelines). The BPHC may ask the Entity to provide copies of any research protocols.
- e) All the required permit application documents listed under Section 4.2(e) to 4.2 (t) above.

The Entity must submit to the BPHC the exact copies of the Security Plan, Biosafety/Biocontainment Plan, and Incident Response Plan documents the Entity submitted to the APHIS/CDC Federal Select Agent Program when applying for a select agent registration or permit.

- f) Copy of completed and signed **APHIS/CDC Form 1** (*Registration for Possession, Use, and Transfer of Select Agents and Toxins*) submitted to the Federal Select Agent Program.

- g) Copy of the permit or registration approval letter issued to the Entity by the APHIS/CDC Federal Select Agent Program.
- h) Copies of all APHIS/CDC Federal Select Agent Program facility inspection reports issued to the Entity before and after submitting a permit application to the BPHC.
- i) Copies of all **APHIS/CDC Form 2** (*Request to Transfer Select Agents and Toxins*) submitted to the APHIS/CDC Federal Select Agent Program.
- j) Copies of all **APHIS/CDC Form 3** (*Incident Notification and Reporting*) submitted to the APHIS or CDC at any time when the Entity is permitted by BPHC.
- k) The Entity must notify the BPHC if the APHIS/CDC Federal Select Agent Program declines to approve, suspends, or revokes a permit or registration.

More information is available at the Federal Select Agent Program website at <https://www.selectagents.gov/>.

5. ANNUAL PERMIT RENEWAL: REQUIRED DOCUMENTS

5.1 Renewal of BSL-2/ABSL-2 (Recombinant DNA) Permit

- a) Completed and signed Recombinant DNA Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety.
- b) Check for permit renewal fees, made payable to the Boston Public Health Commission.
- c) List of any original permit application documents (Section 4.1) with a brief description of the changes made to each document. The BPHC may ask the Entity to provide any other information.
- d) IBC annual report (Section 7.3).

5.2 Renewal of BSL-3/ABSL-3 (Non-Select Agent) Permit

- a) Completed and signed BSL-3/ABSL-3 Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety.
- b) Check for permit renewal fees, made payable to the Boston Public Health Commission.
- c) List of any original permit application documents (Section 4.2) with a brief description of the changes made to each document. The BPHC may ask the Entity to provide any other information.

- d) IBC annual report (Section 7.3).

5.3 Renewal of BSL-3/ABSL-3 (Select Agent) or BSL-4/ABSL-4 Permit

- a) A completed and signed BSL-3/ABSL-3 or BSL-4/ABSL-4 Permit Application Form. The form is available on the BPHC Biosafety Program website at www.bphc.org/biosafety
- b) Check for permit renewal fees, made payable to the Boston Public Health Commission.
- c) List of any original permit application documents (Section 4.3) with a brief description of the changes made to each document. The BPHC may ask the Entity to provide any other information.
- d) IBC annual report (Section 7.3).

5.4 Permit Amendment

The Entity shall apply for a permit amendment:

- a) Before changing the biosafety level designation of the Regulated Laboratory Space.
- b) Before starting any new research program or project involving Risk Groups 3 or 4 agents (Section 9).
- c) Before starting large-scale recombinant DNA activities in the Regulated Laboratory Space (Section 2.05 of BPHC's Biological Laboratory Regulations).
- d) After completing major modifications to the Regulated Laboratory Space during decommissioning (Section 12).

6. PERMIT APPLICATION REVIEW PROCESS

(Refer to Section 2.02 of the Biological Laboratory Regulations).

6.1 Review of Permit Application

- a) The BPHC will review the Entity's permit conditions and any past violations by the Entity of the Biological Laboratory Regulations and Guidelines, BPHC's Disease Surveillance and Reporting Regulation and Guidelines, or any other applicable federal, state, or local regulations.
- b) The BPHC may request evidence of approval for other permits, licenses or registrations issued by federal, state, or local regulatory agencies.

- c) The BPHC may decline to issue a permit, or revoke a permit issued under the Biological Laboratory Regulations if the Entity does not get approval for a permit, license or registration required by other regulatory agencies.

6.2 Approval of Permit Application

1. The Entity must pay the permit application fee and any outstanding fines before the BPHC approves the permit application.
2. The BPHC may grant approval after reviewing the permit application, inspecting the laboratory, and if no significant deficiencies, regulatory violations, or public health risks are found.
3. The BPHC may grant administrative approval if minor deficiencies are found but the Commission determines that a follow-up laboratory inspection is not needed. The BPHC shall grant formal approval after receiving a letter or email from the Entity, confirming that the Entity has corrected the minor deficiencies.
4. If the BPHC finds major deficiencies after reviewing the permit application documents or inspecting the laboratory facility, the BPHC may schedule a follow-up inspection to verify that the Entity has corrected all the deficiencies.
5. The BPHC may issue an Entity a provisional permit if the Entity's application is complete and follows the provisions of the regulation. A provisional permit shall not exceed one hundred twenty (120) days and shall not be renewed or extended.
6. The BPHC may issue a full permit to the Entity after determining that the permit application satisfies the criteria outlined in these Guidelines and the Biological Laboratory Regulations.
7. The BPHC may issue permits with conditions or restrictions relative to protecting the public health.
8. The Entity and all persons conducting regulated research activities under a permit must follow the permit conditions or restrictions.
9. The Entity shall inform every person conducting regulated research activities under a permit about the permit conditions and restrictions.

6.3 Denial of a Permit

1. The BPHC may decline to issue a permit to any Entity if:
 - a) The permit application does not meet the criteria outlined in these Guidelines and the Biological Laboratory Regulations;

- b) The Commission finds major deficiencies after inspecting the Entity's Regulated Laboratory Space and reviewing permit application documents;
 - c) The Entity does not provide documented evidence of approvals, registrations permits, or licenses required by other local, state, or federal agencies; or
 - d) The Commission determines that granting such a permit may jeopardize public health and safety or the environment.
2. The BPHC will send a written notice to the Entity stating the reason(s) for the denial of the permit.
 3. The Entity may correct any deficiencies found in the permit application, or file an appeal with the BPHC Executive Director, within ten (10) days after receiving the written notice of denial.
 4. The denial of a permit may be appealed following the BPHC's Standard Hearing Procedure.

7. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

(Refer to Section 2.04 of the Biological Laboratory Regulations).

7.1 IBC Membership

- a) The IBC shall include at least one (1) representative from the Entity with expertise in recombinant DNA technology.
- b) The IBC shall include at least two (2) members who represent the interests of the surrounding community with respect to health and protection of the environment.
- c) The community members shall have no affiliation with the entity and reside in the community in which the laboratory is located or abutting communities, including the city of Boston and cities and towns abutting the city of Boston.

7.2 Approval of IBC Community Member (BSL-3 and BSL-4 Laboratories only)

The BPHC shall approve the nomination of one of the community members based on the following criteria:

- a) The person shall not be affiliated with the Entity or its parent institution (apart from membership on the IBC).
- b) The person shall have no immediate family relationship with anyone who has a professional or financial relationship with the Entity or its parent institution.

- c) The person shall reside in the community in which the laboratory is located or abutting communities, including the city of Boston and cities and towns abutting the city of Boston.
- d) An educational or work background in a scientific field is preferred.

7.3 IBC Annual Report

1. The Entity's Responsible Official, Chief Executive Officer or Institutional Official shall file an annual report with the BPHC by January 31 of the following year.
2. The IBC annual report shall include:
 - a) Copies of the minutes of all IBC meetings held since the last IBC annual report. The minutes must contain enough details to show the type of risk assessment conducted during the IBC review of the proposed work (e.g. NIH Risk Group and assigned biosafety level).
 - b) Updated list of all IBC members (names and titles), clearly showing the Chair, contact person, Biosafety Officer (if applicable), community members, recombinant DNA expert, and ad hoc consultant (if applicable).
 - c) Biographical sketches of all new IBC members, including community members.
 - d) For BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities, a summary of quality assurance and quality improvement activities completed since the last IBC annual report. Examples include facility performance and verification reports (containment barrier, HVAC, autoclaves, effluent decontamination systems); biosafety cabinet certification; laboratory safety training; emergency drills/exercises; laboratory inspections; acquisition of laboratory equipment; and facility decontamination, renovations, or commissioning/decommissioning.
 - e) Certification by the Responsible Official, Chief Executive Officer, or Institutional Official, confirming that the Entity is in compliance with the NIH Guidelines and BPHC's Biological Laboratory Regulations.

7.4 IBC Meetings: BSL2-BSL-2 (Recombinant DNA) Laboratories

Entities operating BSL-2/ABSL-2 laboratories using recombinant DNA shall hold an IBC meeting at least once during the calendar year, and at any other times as may be determined by the BPHC Executive Director and required as a condition of the permit.

7.5 Public IBC Meetings: BSL-3/ABSL-3 and BSL-4/ABSL-4 Laboratories

1. Entities operating BSL-3/ABSL-3 (Select and Non-Select Agent) or BSL-4/ABSL-4 laboratories shall hold IBC meetings at least twice during the calendar year, and at any other times as may be determined by the BPHC Executive Director and required as a condition of the permit.
2. At least one of the Entity's IBC meetings during a calendar year shall be open to the public.
3. The Entity should review the type and nature of biological research at BSL-3/ABSL-3 (Select and Non-Select Agent) and BSL-4/ABSL-4 laboratories conducted by the Entity.
4. The Entity may summarize the research projects during public IBC meetings to protect confidential information, proprietary information, or trade secrets.
5. The Entity shall hold all public IBC meetings at a location that is easily accessible to the public and persons with disabilities.
6. The Entity shall make available to the public all IBC meeting minutes, upon request. If public comments are made on IBC actions, the Entity shall send both the public comments and the IBC's response to the BPHC.
7. The Entity shall post a notice of any public IBC meeting on the Entity's website, and in a newspaper of general circulation at least fifteen (15) days before such meeting.
8. The BPHC strongly encourages the Entity to post a notice of any public IBC meeting on social media according to its institutional policy.
9. The Entity shall send a written notice of any public meeting to the BPHC's Director of Biological Safety, the BPHC Executive Director, the District City Councilor, and Mayor's Office of Neighborhood Services at least fifteen (15) days before such meeting. Such notice shall include the date, time and venue of the meeting, the purpose of the meeting, and contact information for the Entity's person responsible for the scheduling the meeting.

8. LABORATORY OVERSIGHT

(Refer to Section 3.00 of the Biological Laboratory Regulations)

8.1 Laboratory Incidents Reporting Requirements

The Entity shall report the following incidents to BPHC:

- a) Any case or suspected case of illness or disease caused by a high-risk agent. Refer to the list, “*Research Laboratories: Reportable Infectious Disease Agents and Toxins*,” which is available on the BPHC website at <http://www.bphc.org/diseasereporting>.
- b) Any accidental release, spill or accident which results in an exposure or potential exposure to recombinant DNA materials or high-risk agents.
- c) Any illness among persons caused or potentially caused by recombinant DNA material, a high-risk agent or attenuated strain of a high-risk agent present in a laboratory.
- d) Any employee who is absent from the workplace for two (2) or more consecutive workdays due to illness suspected of being related to occupational exposure to any high-risk agent used in the laboratory.
- e) Any incident, problem, accident, or other event that caused or is suspected to have caused a serious threat to the public health; death; serious illness or bodily injury to any person; or extensive property damage.
- f) Failure of any major mechanical systems occurring in the BSL-3/ABSL-3 or BSL-4/ABSL-4 laboratory, even if redundant or backup systems are available and perform as designed during the incident.
- g) Any incident, problem or accident that must be reported to the Entity’s IBC, NIH Office of Science Policy (OSP), or APHIS/CDC Federal Select Agent Program.

8.2 Laboratory Incident Reporting Procedures

8.2.1 BSL-2/ABSL-2 (rDNA) and BSL-3/ABSL-3 (Select/Non-Select Agent) Laboratories

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

- 1. Call the BPHC Infectious Disease Bureau at (617) 534-5611 **IMMEDIATELY** during regular business hours to report any illness or cases of disease/infection (suspected/confirmed) or exposures due to high-risk agents or select agents or toxins.
- 2. Fax the completed “*Biologic Research Laboratory Reporting Form: High-Risk Agents*” to BPHC Infectious Disease Bureau (fax number is 617 534-5905) within one business day after completion of the occupational health assessment. The form is available on the BPHC website at <http://www.bphc.org/diseasereporting>.

B. For ALL laboratory-related incidents:

- 1. Call the BPHC Environmental Health Office at (617) 534-5965 during regular business hours or send an email (biosafety@bphc.org) within 24 hours to report any laboratory incident.

2. All incidents involving select agents or toxins that must be reported to the CDC Federal Select Agent Program must also be reported to the BPHC. Send a copy of the APHIS/CDC Form 3 to BPHC Environmental Health Office (biosafety@bphc.org) within 7 days.
3. All incidents that occur during the conduct of research subject to the *NIH Guidelines* that must be reported to the NIH Office of Science Policy (OSP) must also be reported to the BPHC. Send a copy of the NIH Incident Report to BPHC Environmental Health Office (biosafety@bphc.org) within 30 days.

8.2.2 BSL-4/ABSL-4 Laboratories

The Entity must investigate and document any incident involving high-risk agents, select agents or toxins, recombinant DNA materials or other regulated infectious materials, infected laboratory animals, or failure of major mechanical systems occurring in BSL-4/ABSL-4 to determine the root cause(s) and implement corrective actions.

- a) Call the BPHC Office of Public Health Preparedness Medical Intelligence Center (MIC) Duty Officer at (617) 343 6920 or send email (mic@bphc.org) to report any laboratory incidents occurring in the BSL-4/ABSL-4 facility. The MIC office is open 24/7.
- b) Call the BPHC Infectious Disease Bureau at (617) 534 5611 **IMMEDIATELY** during regular business hours to report any illness or cases of disease/infection (suspected/confirmed) or exposures due to high-risk agents or select agents/toxins.
- c) Fax the completed “*Biologic Research Laboratory Reporting Form: High-Risk Agents*” to the BPHC Infectious Disease Bureau within one business day after completion of occupational health assessment. The fax number is (617) 534-5905. The form is available on the BPHC website at <http://www.bphc.org/diseasereporting>.
- d) Send a copy of the Entity’s After-Action Report to BPHC Office of Public Health Preparedness Medical Intelligence Center (MIC) send email (mic@bphc.org) within 7 days.
- e) Send a copy of the APHIS/CDC Form 3 to the BPHC Environmental Health Office (biosafety@bphc.org) within 7 days.
- f) Send a copy of the Entity’s Incident Investigation Report to the BPHC Environmental Health Office (biosafety@bphc.org) within 15 days (upon request).
- g) Send a copy of the NIH Incident Report to BPHC Environmental Health Office (biosafety@bphc.org) within 30 days.

8.3 Laboratory Incident Report Follow-up

The BPHC will investigate the incident and take proper action(s), including:

- a) Inspect the laboratory facility (unannounced), if necessary.
- b) Review the Entity's Incident Investigation Report, After-Action Report, APHIS/CDC Form 3, or NIH Incident Report.
- c) Recommend more corrective actions to promote laboratory safety to ensure compliance with the BPHC regulations.

8.4 Laboratory Inspections

(Refer to Section 3.03 of the Biological Laboratory Regulations)

1. The BPHC or its designees shall have the authority to inspect, with or without prior notice, any laboratory facility to monitor compliance with the Biological Laboratory Regulations and identify deviations from acceptable laboratory practices.
2. The BPHC will inform the Biosafety Officer/Manager, Responsible Official, Chief Executive Officer, Institutional Official or Select Agent Responsible Official at least fifteen (15) days before an announced inspection.
3. If the Entity does not allow an inspection without a reasonable justification, the BPHC may immediately suspend the Entity's permit.
4. The BPHC inspectors or consultants shall review all relevant documents and records of laboratory research activities in the Regulated Laboratory Space.
5. The Entity shall give copies of all relevant documents and records to BPHC inspectors or consultants, upon request. The BPHC may issue a citation for a fine, add permit restrictions, or suspend the permit if the Entity does not comply.

8.5 Laboratory Inspection Procedures

The BPHC inspectors will assess potential laboratory health and safety hazards and evaluate the mitigation measures. The BPHC will send an inspection report to the Entity within sixty (60) days after completing the laboratory inspection. The report will include a summary of the deficiencies found, recommended corrective actions, and a copy of the completed inspection checklist.

9. NOTIFICATION OF NEW RESEARCH PROJECTS OR PROGRAMS

(Refer to Section 2.04 of the Biological Laboratory Regulations)

1. The Entity shall notify the BPHC Director of Biological Safety of any new research project(s) involving BSL-3/ABSL-3 (Select and Non-Select Agent) or BSL-4/ABSL-4 containment at least thirty (30) days before starting such research project. Such notification must include the Entity's IBC approval letter and the approved protocol for the new research project.
2. The Entity shall send a written notice to the Boston City Council at least thirty (30) days before starting any new BSL-4/ABSL-4 research projects. The notification shall include an executive summary of the proposed research project with enough details confirming that the work will be done in compliance with the Biological Laboratory Regulations.
3. The Entity shall send a written notice to the BPHC Executive Director at least thirty (30) days before starting any new BSL-4/ABSL-4 research projects. The notification shall include an executive summary of the proposed research project with enough details confirming that the work will be done in compliance with the BPHC's Biological Laboratory Regulations.
4. The Entity shall send all BSL-3/ABSL-3 (Select and Non-Select Agent) or BSL-4/ABSL-4 new research protocols and major research protocol amendments to the BPHC for review and approval before starting any work.
5. Major research protocol amendments include significant changes to an approved research protocol involving non-exempt use of rDNA materials, high-risk agents, select agents or toxins; Dual Use Research of Concern (DURC); animal experiments; experimental procedures or techniques; standard operating procedures; host vector systems or biosafety level designation.
6. Research protocol amendments requiring non-scientific administrative actions (changes in personnel or funding sources), or minor changes to experimental procedures or techniques described in an approved research protocol may be omitted from this requirement.
7. The Entity shall send copies of the approved research protocol, the IBC approval letter, and the biographical sketch of the Principal Investigator to the BPHC.
8. The BPHC staff shall review all BSL-3/ABSL-3 new research protocols and major research protocol amendments before approval.
9. The Boston Biosafety Committee shall review all BSL-4/ABSL-4 new research protocols and major research protocol amendments before approval by the BPHC Executive Director.

10. NOTICE AND DISTRIBUTION OF REGULATIONS

(Refer to Section 5.00 of the Biological Laboratory Regulations)

10.1 Notice of Permit

The BPHC shall send a copy of the Permit to the Entity. The Entity shall post a copy of the Permit at the Regulated Laboratory Space where it is visible to all persons accessing the laboratory.

10.2 Reporting Violations

The Entity shall develop a procedure for reporting health and safety violations anonymously to the Chief Operating Officer/Institutional Official or Responsible Official, Health and Safety Officer, Biological Safety Officer, the IBC Chair, or the BPHC. The procedure shall include the following statement:

“To report a violation, call the Environmental Health Office, Boston Public Health Commission at (617) 534- 5965 or send an email to biosafety@bphc.org”.

11. COMMUNITY BENEFITS PROGRAM

(Refer to Section 7.00 of the Biological Laboratory Regulations)

1. Any Entity operating a BSL-4/ABSL-4 laboratory shall establish and maintain a Community Benefits Program to support local health and safety needs.
2. The Entity shall develop, implement, and report on its Community Benefits Program based on the principles outlined in the Community Benefits guidance issued by the Commonwealth of Massachusetts Attorney General’s Office, “***The Attorney General’s Community Benefits Guidelines for Non-Profit Acute Care Hospitals***” available at <https://www.mass.gov/service-details/community-benefits-guidelines>.
3. The Entity’s Community Benefits Program shall include specific programs that are related to the BSL-4/ABSL-4 laboratory facility, reflecting the identified community health and safety needs.
4. Broad institutional-wide community programs that are implemented as part of the Entity’s overarching corporate social responsibility may be included in the Community Benefits Program only after conducting a community health needs assessment to identify and prioritize significant health and safety needs of the communities affected by the BSL-4/ABSL-4 facility.

5. The Entity shall send the Community Benefits Program proposal to the BPHC for review and approval.
6. The Entity shall file an annual report of its Community Benefits Program with the BPHC. The annual report shall be due on January 31. It must cover the previous 12-month period of the Entity's fiscal year.

12. DECOMMISSIONING PROCEDURES (BSL-3/ABSL-3 AND BSL-4/ABSL-4 LABORATORIES)

1. The Entity shall decontaminate all BSL-3/ABSL-3 or BSL-4/ABSL-4 laboratory areas used for handling or storing biohazardous materials before terminating the Entity's permit.
2. The Entity shall hire a third-party agent with appropriate experience and expertise in the decommissioning of BSL-3/ABSL-3 or BSL-4/ABSL-4 laboratories. The BPHC may request the Entity to select another decommissioning agent if the Commission determines that the third-party agent does not have the necessary experience and expertise in decommissioning of high-containment laboratory facilities.
3. All floors, laboratory equipment (e.g., biosafety cabinets, chemical fume hoods, centrifuges, and benchtops) must be surface decontaminated using an effective disinfectant. The Entity shall perform decontamination using a validated method that is effective against the biological agents used in the BSL-3/ABSL-3 or BSL-4/ABSL-4 facility, in compliance with the NIH Guidelines, CDC guidelines, and the decommissioning and decontamination plans filed with the permit application.
4. The Entity shall document the decommissioning process and submit the record to the BPHC upon completion.

12.1 Notice of Decommissioning

1. The Entity shall notify the BPHC at least thirty (30) days before any decommissioning of BSL-3/ABSL-3 or BSL-4/ABSL-4 facility begins.
2. The notice of decommissioning shall include:
 - a) Purpose of decommissioning;
 - b) Physical locations (Street address, Building, Room Number) of the laboratory as listed in the Entity's permit application;
 - c) Timeline for proposed decommissioning activities (estimated start and completion dates);

- d) Disinfection method (chemical or heat) used for decontamination of the laboratory space and equipment;
 - e) Termination of existing research project, or starting of new project; or change of laboratory space to office area; and,
 - f) Evidence that the biological agent or rDNA is made non-infectious.
3. The Responsible Official shall certify that the Entity has created a laboratory decommissioning plan, including an estimated completion date.
 4. The Entity shall send a decommissioning plan to the BPHC when applying for a permit renewal or amendment.

12.2 Inspection of Decommissioned Laboratory Facility

The Entity shall send a written notice to the BPHC's Director of Biological Safety within forty-eight (48) hours after completing the decommissioning project. The BPHC may inspect the decommissioned laboratory facility within thirty (30) days after receiving the written notice from the Entity.

12.3 Permit Amendment

The Entity shall review and update the permit application form and supporting documents after changing the Regulated Laboratory Space during the decommissioning. The BPHC may issue an amended permit within thirty (30) days after receiving the written notice from the Entity (Section 5.4).

13. PROTECTION OF CONFIDENTIAL AND PROPRIETARY INFORMATION

(Refer to Section 2.02e of the Biological Laboratory Regulations)

The Regulation states that any information regarding the type of agent, its location or security measures, required to be submitted to the Commission, where the release of this information may jeopardize the health and safety of the public, shall be considered confidential and kept in a secure manner, separate and apart from the rest of the permit application materials. To the extent that the permit application may need the submission or review of proprietary information, the Executive Director shall develop procedures for assuring confidentiality of the proprietary information.

Those procedures are as follows:

1. In general, BPHC and Boston Biosafety Committee (BBC) members will refrain from disclosing materials sent by entities in connection with permitting and oversight responsibilities under the Regulation to the public. Access to such documents will be limited to the persons necessary to conduct permitting and oversight.
2. If an entity determines that certain information included in documents is proprietary in nature, an entity may redact proprietary information before submitting materials. If any materials are redacted or withheld, the entity must send a confidentiality log identifying each part of the materials that is redacted and a brief reason why the information needs to be designated as such. Entities may also name areas that are not redacted but contain information related to safety and security and that they believe should be exempt from disclosure if requested by a member of the public.
3. If BPHC or the BBC is unable to evaluate the permit application or a research protocol without the redacted information, the BBC will collaborate with the applicant to establish a procedure for reviewing the complete documents without taking possession of them.
4. BPHC may disclose to a city, state, or federal agency any information for official purposes as it considers necessary.
5. BPHC is subject to public records laws. Upon receipt of any request for public records under these laws, the BPHC records access officer will make a determination as to whether the requested information is exempt from disclosure for safety and security or other enumerated purposes under G. L. c. 4, § 7(26) and withhold any documents, or portions thereof, that are covered by an exemption.