



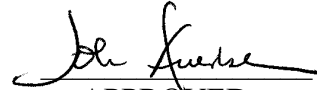
**GUIDELINES FOR THE IMPLEMENTATION AND
ENFORCEMENT OF BOSTON PUBLIC HEALTH COMMISSION'S
BIOLOGICAL LABORATORY REGULATION**

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APPROVED
John Auerbach
Executive Director

March 29, 2007
EFFECTIVE

Section 1 Authority

These guidelines are promulgated by the Executive Director of the Boston Public Health Commission, pursuant to Section 6 of the Boston Public Health Commission's Biological Laboratory Regulation (herein after "Regulation".)

Section 2 Definitions

See Section 1.00 of the Regulation for more definitions.

"Biohazardous area" shall mean any area (a complete operating complex, a single facility, a single room within a facility, etc.) in which work has been, or is being performed with biohazardous agents.

"BPHC" shall mean the Boston Public Health Commission.

"Community" shall mean one of the neighborhoods of Boston including Allston, Back Bay, Beacon Hill, Brighton, Charlestown, Chinatown, Dorchester, Downtown, East Boston, Fenway, Hyde Park, Kenmore, Jamaica Plain, Mattapan, Mission Hill, North End, Roslindale, Roxbury, South Boston, South End, West End and West Roxbury.

"Decommission" shall mean to take off-line, out of use, or change use. It is a systematic review and documentation process signifying that specified laboratory components, systems, and/or system components have been removed or changed, inspected, tested and verified to meet national and international standards. Decommissioning includes taking mechanical systems – such as HEPA, duct work, and primary and secondary barriers – off-line. If an entity converts a laboratory to or from Biosafety levels 3 or 4, the intended decommissioning shall be reported to the BPHC.

"Special Municipal Employee" shall mean an individual acting under the authority of the Boston Public Health Commission and therefore subject to the provisions of M.G.L. c.268A and c.258.

Section 3 Permits

(Corresponds to Section 2.00 of the Regulation.)

A) When a permit is required

1. **Generally:** All entities that physically operate a laboratory must have a permit.
2. **Entity as landlord:** If the entity leases the space to another entity for the purposes of operating a laboratory; acts only as the landlord pursuant to a lease agreement; and does not conduct any biological research in the laboratory, then it is the responsibility of the tenant, who is operating the laboratory, to obtain the permit.
3. **Entity as tenant or space sharing:** Any entity conducting biological research in a laboratory that it does not own or operate must obtain a separate permit, regardless of whether the entity that owns or operates the laboratory has a permit for the laboratory. This would apply to space sharing situations where an entity uses the laboratory facilities of another entity pursuant to a lease or other sort of agreement. For all permits issued to entities who do not own, operate or have a written lease or other written agreement for the use of laboratory space for a period of three or more years, the duration of the permit will be for three years or until the end of the project, whichever is shorter.
4. **Affiliated entity:** An entity conducting research in a laboratory owned or operated by a wholly owned subsidiary or affiliated entity is not required to obtain a separate permit.

B) Application submission

All documentation will only be accepted in electronic format. Contact the BPHC Director of Laboratory Safety for information on how to submit permit application electronically.

C) Application content

1. Protocols, policies and procedures attached to the application should be those documents that have been approved by the entity, distributed for use and are being used at the time of the application.
2. Protocols, policies and procedures should describe the way or manner in which the subject matter is dealt with. All logs, rosters, lists, attendance sheets or other documentation regarding adherence to a protocol, policy or procedure should not be included with the application but should be available for review during an inspection.

D) Application deadlines

1. New permits: For entities operating BSL-3 laboratories at the time of passage of the regulation (September 19, 2006), the permit application is due on Monday, April 23, 2007. For any entity proposing to operate a laboratory or laboratories at BSL-3, the permit application is due four (4) months before research can begin. For any entity proposing to operate a laboratory or laboratories at BSL-4, the permit application is due six (6) months before research can begin.
2. Permit renewal: For any entity proposing to renew its permit for a BSL-3 laboratory or laboratories, the application is due three (3) months prior to the expiration of the permit. For any entity proposing to renew its permit for a BSL-4 laboratory or laboratories, the application is due four (4) months prior to the expiration of the permit.
3. If a permit deadlines falls on a weekend or a holiday, the deadline will be extended to the following business day.

E) Application review

1. The application and required documentation will be reviewed for conformity with the standards set forth in Sections 2.01 and 3.01 of the Regulation.
2. An application will also be evaluated based on any past violations of the regulation or any other applicable law.
3. Any fine, fee or other costs, must be paid in full prior to the approval of an application.

F) Approval, multiple permits and permit issuance

1. Upon a review of the application and a determination that the application and submitted materials meet the standards set forth in the regulation, the BPHC may issue a permit.
2. If, upon examination of the permit application, it is determined that there are separate and distinct laboratories operating:
 - a. Under different operating policies and procedures; or,
 - b. Under a separate IBC; or,
 - c. In separate geographical areas; or,
 - d. With different containment levels; or,
 - e. Such other characteristics that make them separate units;

the BPHC may require such separate units to have individual permits.

3. The permit shall name the entity, the laboratories operating under the permit, any restrictions placed on the operations of the laboratory, the date issued and the expiration date of the permit.
4. Each laboratory shall post a copy of the permit on the premises visible to all employees and any other person having access to the laboratory.

G) Denial of a permit application

1. Upon the determination that an application does not meet the criteria set forth in the regulation or is otherwise unacceptable, the BPHC will immediately notify the applicant and provide a written denial setting forth the particular reasons for the denial.
2. Upon receipt of the denial, the applicant shall have ten (10) days to correct the deficiencies in the application or file an appeal of the denial.
3. All appeals shall be filed with the Executive Director. Upon receipt of an appeal the Executive Director shall appoint a hearing officer to conduct an investigation into the application. The hearing officer may conduct a hearing and take statements as may be necessary. The hearing officer may certify a technical issue for review and opinion from the BBC. During the appeal process the hearing officer may, upon application by the entity, issue a provisional permit for operations not effected by the issues on appeal. Upon completion of the investigation, the hearing officer shall issue a finding of facts and recommendations to the Executive Director. The decision of the Executive Director shall be the decision of the Boston Public Health Commission.

H) Permit fees

(Corresponds to Section 8.00 of the Regulation.)

There are no fees associated with the permit application process.

Section 4 Institutional Biosafety Committee

(Corresponds to Section 2.03 of the Regulation.)

A) Composition

All entities shall establish an Institutional Biosafety Committee that meets the requirements set forth in Section 2.03 of the Regulation and Section IV-B-2 of the NIH Guidelines.

B) Community member

1. The Boston Public Health Commission shall approve one of the two community members. Criteria for this member shall be:
 - a. Demonstrated involvement in the community;
 - b. The person cannot be employed by or have any formal or financial affiliation with the entity or its parent institutions (aside from membership in the IBC);
 - c. The person should not live in the same residence as or be closely related to any person employed by or with any formal or financial affiliation with the entity or its parent institutions;
 - d. The person should live in the surrounding community. It is recommended that this person live in the same neighborhood as the entity's laboratory operations. Consideration will be given to non-Boston residents who can demonstrate substantial commitment to Boston neighborhoods and their safety and well-being; and,
 - e. An educational or work background in a scientific discipline is preferable but not a requirement.

2. Approval process

- a. The application for approval of one of the community members, must be submitted to the BPHC at least forty-five (45) days prior to the first IBC meeting in which the member will participate and include the following:
 - b. The resume or CV of the applicant, including home address, educational background, work history and record of community involvement;
 - c. Three letters of reference attesting to general character and commitment to the community; and,
 - d. Sworn statement, signed by the applicant attesting to his or her residence in the community.

C) Public Meetings

1. All public meetings shall be held in a facility that is accessible to the public and provides handicapped facilities.

2. Notice of all public meetings shall be made no less than fifteen (15) days in advance of the meetings on the entity's website and in a newspaper of general circulation.
3. Written notice shall also be provided to the district city councilor, the BPHC Director of Laboratory Safety, and the City of Boston's Mayor's Office of Neighborhood Services.

D) Reports

All reports required by the provisions of Section IV-B-2-a-(3) and Section IV-B-2-a-(7) of the NIH Guidelines shall be filed with the BPHC.

E) Annual IBC report

(Corresponds to Section 2.04.a of the Regulation.)

1. Within thirty (30) days of permit issuance anniversary, the entity responsible official shall electronically file with the BPHC its annual report. The report shall contain the following information:
 - a. A complete set of IBC meeting minutes for the time period. These minutes shall be submitted in the format in which they are customarily kept;
 - b. A report of any quality assurance and quality improvement efforts take during the time period. This report may be either the actual institutional documentation of the efforts that are kept in the ordinary course of business or they may be submitted in summary format, giving a general description of the efforts taken, the individual responsible for the efforts, the date the efforts were implemented and the effectiveness of the efforts;
 - c. A certification by the Responsible Official stating that the entity is in compliance with regulation and these guidelines and that the information provided to the BPHC with regards to the composition of the IBC and the permit application is complete and up to date. Any exceptions to the certification shall be listed separately with references to the appropriate plans of action.
2. Contact the BPHC Director of Laboratory Safety for information on how to submit annual report information electronically.

F) IBC approval of new projects

(Corresponds to Section 2.04.b of the Regulation.)

Notification of new research projects shall be made at least thirty (30) days before initiating any project. Contact the BPHC Director of

Laboratory Safety for information on submitting information electronically.

Section 5 Laboratory Oversight: Incident Reporting, Inspections, Fines

A) Incident reporting

(Corresponds to Section 3.02 of the Regulation.)

1. All events under this section shall be immediately reported to the BPHC. “Immediately” means as soon as possible upon the discovery of the event, but in no event later than 24 hours after discovery.
2. Any laboratory employee or other individual having access to the laboratory who; has been diagnosed with; is exhibiting symptoms of; or, may have been exposed to, any high risk agent shall be reported to the BPHC in accordance with the guidelines for the Implementation and Enforcement of BPHC’s Disease Surveillance and Reporting Regulation. (See www.bphc.org/labs for copy of this regulation.)
3. Any employee absent from the work place due to illness for a period of two (2) or more consecutive work days shall be evaluated by the Occupational Health Officer or designee prior to returning to work. If the Occupational Health Officer has a reasonable suspicion that the employee’s illness may be related to an exposure to any high risk agent, the Occupational Health Officer shall immediately notify the BPHC in accordance with the guidelines for the Implementation and Enforcement of Boston Public Health Commission’s Disease Surveillance and Reporting Regulation. (See www.bphc.org/labs for copy of the guidelines.)
4. The failure, malfunction or renovation of any major mechanical or security system shall be immediately reported to the BPHC. For the purposes of this section, reporting to the BPHC shall mean the Director of Laboratory Safety or his/her designee or for any reporting outside of business hours, the emergency on call manager for the BPHC.
5. Major mechanical systems are those systems that are necessary for the operation of the laboratory and the functioning of the containment systems. These include, but are not limited to, the structure of the building including windows, doors, walls, floors, ceilings, the electrical system, heating and ventilations systems, alarm, CCTV, plumbing, any refrigeration or other storage container or facility used to store a high risk agent.

B) Inspection scheduling

1. All laboratories permitted pursuant to this regulation shall be inspected in accordance with a schedule based upon the requirements set forth below. Inspection schedules will be based upon the date the permit was issued or such other date as may be assigned by the BPHC.
2. The entity's biological safety officer will be notified at least ten (10) days in advance of a regularly scheduled inspection. An inspection may be rescheduled, based upon the operating needs of the laboratory, however, failure to conduct an inspection, due to the entity's postponements, within thirty (30) days of the initial inspection date shall be considered a violation.
3. Frequency of Inspections: Laboratories shall be inspected according to the following schedule:

BSL-4 - shall be inspected at least twice a year and as often as necessary for the enforcement of this regulation.

BSL-3 - shall be inspected at least once a year and as often as necessary for the enforcement of this regulation.

C) Inspection procedures

(Corresponds to Section 3.03 of the Regulation.)

1. The regularly scheduled inspection(s) ("inspection") shall be made up of three parts:
 - a. Review of entity and laboratory policies, procedures and on site documents;
 - b. Staff interviews; and,
 - c. Physical observation and assessment of the laboratory facilities.
2. Upon notification of an inspection, the entity shall confer with the inspector in order to facilitate access to all necessary documents, arrange suitable access to the laboratory facilities and provide the inspector with a complete list of all employees, volunteers, trainees, students and any other person who has access to the laboratory. All information shall be provided to the inspector within two (2) business days of a notice of inspection.
3. Upon receipt of the necessary information, the inspector shall provide the entity with an inspection checklist for each part of the inspection.

4. Inspection Criteria - policies, procedures and on site documents;
 - a. All policies and protocols will be evaluated for compliance with the regulation and actual laboratory operations.
 - b. All policies and procedures required by the permit application shall be reviewed as part of the inspection.
 - c. Each policy will be designated as “Satisfactory” or “Unsatisfactory.”
 - d. Each policy rated as “Unsatisfactory” shall be provided with a written corrective action plan.

5. Inspection criteria - staff interviews
 - a. Upon notification of an inspection, the entity will provide a list of all employees, volunteers, trainees, students and any other person who has access to the laboratory.
 - b. The entity shall make any individual designated by the inspector available, within a reasonable period of time, for a private interview. The entity shall provide a private meeting space for the inspector to conduct the interviews.
 - c. The interview shall cover at a minimum the following topics:
 - i. Biosafety knowledge particularly related to the agents being used in the laboratory;
 - ii. Hazards of materials in their work;
 - iii. Waste disposal practices;
 - iv. Special precautions, practices or procedures;
 - v. Personal protective equipment; and,
 - vi. Emergency response procedures.
 - d. Each interview will be designated as “Satisfactory” or “Unsatisfactory.”
 - e. For each interview rated as “Unsatisfactory” the entity shall be provided with a written corrective action plan.

6. Inspection criteria - observation and assessment of the laboratory facilities.
 - a. During the inspection, the inspector shall tour the laboratory facilities to review the condition of the facilities and equipment and observe the operations of the laboratory.

- b. The tour shall take place at a time when the inspector can view the operations of the laboratory in a manner that will minimize any disruption to the operations of the laboratory.
- c. Each laboratory will be assessed for compliance with the regulation and shall at a minimum be evaluated in the following areas:
 - i. Laboratory Signage and Postings;
 - ii. Facility cleanliness and condition;
 - iii. Equipment condition and maintenance;
 - iv. Work Place Practices;
 - v. Security Practices;
 - vi. Hazard Communication; and,
 - vii. Biohazard Waste handling.
- d. Prior to the inspector's tour, the entity shall be provided with a detailed checklist of items that will be evaluated. The assessment of laboratory operations is not limited to biosafety and may encompass chemical, electrical, fire and general safety issues.
- e. Each item will be designated as "Satisfactory," "Unsatisfactory" or "Public Health Violation."
- f. For each item rated as "Unsatisfactory" or "Public Health Violation" the entity shall be provided with a written corrective action plan.

7. Preliminary inspection report

- a. Within ten (10) business days after the completion of all parts of the inspection, the inspector shall meet with the entity's biosafety officer and the primary principal investigator for each laboratory inspected to review the preliminary inspection report and discuss any corrective action plans.
- b. The preliminary inspection report shall contain an overall assessment of the laboratory, an assessment for each part of the inspection and the completed checklists for each part of the inspection. Each assessment shall be designated as "Satisfactory," "Unsatisfactory," or "Public Health Violation."
- c. All "Unsatisfactory" or "Public Health Violations" assessments shall have a corrective action plan

8. Corrective action

- a. All items rated “Public Health Violation” shall immediately be corrected in accordance with the corrective action plan. In the event that the inspector finds that the “Public Health Violation” is an immediate threat to the public health, he/she shall immediately notify the Executive Director for further action pursuant to Section 9.03 of the Regulation.
- b. All items rated “Unsatisfactory” shall be corrected in accordance with the corrective action plan as soon as reasonably possible but in no event later than ten (10) days after the preliminary inspection report is issued.
- c. The Entity shall provide the BPHC with written documentation of compliance with all corrective actions.

9. Re-inspection

- a. If a laboratory has twenty (20) or more items marked “unsatisfactory,” or any “public health violations,” the laboratory shall be re-inspected within ten (10) business days after the Entity’s receipt of the preliminary inspection report.
- b. The re-inspection shall be limited to the parts of the inspection in which “unsatisfactory” or “public health violation” was received.

10. Citations, fines and final report

- a. If a laboratory has failed to complete the corrective action plans within the specified time period for any item rated “unsatisfactory” the inspector may issue the entity a citation for a fine of up to \$500.00 for each item rated “unsatisfactory.”
- b. If a laboratory has failed to complete the corrective action plans within the specified time period for any item rated “public health violation” the inspector shall issue the entity a citation for a fine of \$1000.00 and a hearing shall immediately be scheduled to determine what other corrective action, up to and including the closure or limitations of operations of the laboratory, should be imposed.
- c. All citations must be paid within thirty (30) days, unless a timely appeal has been filed pursuant to Section 11. Failure to pay or appeal a citation within the designated time period, will result in an additional fine of \$1000.00. Failure to pay a fine within one hundred twenty (120) days of the citation or final denial of an

appeal, will result in the automatic suspension of an entity's permit.

- d. Upon completion of the re-inspection or within ten (10) days of the preliminary report, the inspector shall issue the final inspection report.
- e. The Final report/order to correct shall include the laboratory's street and mailing addresses, permit holder's name and address, type of entity, inspection date, type of inspection and other information such as type of general nature of the biological research, status of the permit, the name of the inspector; the date and time of the inspection; the time frame for correction of each violation; any citation issued; the signature of the inspector; and the signature of the biosafety officer or the person in charge of the laboratory at the time of the inspection, or other proof of service of the order.

11. Appeals

An entity may appeal the issuance of any citation. All appeals must be in writing and filed with the Executive Director within fourteen (14) business days of issuance. The Executive Director will appoint a hearing officer to hear such appeal.

D) Public records

The final inspection report and other related enforcement documents are public records as defined in M.G.L. c.4, § 7 clause 26 and shall be made available for public disclosure. However, any portion of an inspection report, which in the determination of the BPHC's Director of Environmental Health is likely to jeopardize public safety as listed in Section 12 of these Guidelines shall be redacted.

Section 6 Boston Biosafety Committee (BBC)

(Corresponds to Section 3.04 of the Regulation.)

A) Composition

1. The BBC shall be composed of at least seven (7) members, one of whom shall be the Executive Director or her/his designate who shall serve as Chairperson; two (2) of whom shall be residents of neighborhoods in which research laboratories are located; one (1) of whom shall be a scientist knowledgeable in the field of RDNA technology; and three (3) of whom shall assure representation from any of the following fields; public health, occupational health, infectious diseases, biosafety, and environmental quality. If the

Executive Director appoints additional members beyond seven, those appointees shall have qualifications that the Executive Director determines are necessary for the functioning of the BBC.

2. All members shall serve at the pleasure of the Executive Director and shall be appointed for terms of two (2) years and shall be eligible of reappointment. Persons appointed by the Executive Director to fill vacancies shall serve for the unexpired term of said vacancy. Members of the BBC shall be Special Municipal Employees.
3. Committee members shall be reimbursed, upon submission of suitable documentation for all expenses incurred in connection with committee obligations.

B) Staffing

The staff from the Environmental Health Office and the Communicable Disease Control Division shall be available to support and assist the BBC in carrying out its duties under the regulation.

C) Duties and responsibilities

1. Recognizing the need for community and scientific input to assist the BPHC Board and the Executive Director in carrying out the duties and responsibilities in regulating biological laboratories, the BBC shall have the following duties and responsibilities.
 - a. The BBC shall continually review literature in the area of Recombinant DNA research, production, and technology and biological safety and shall continually review the effectiveness of the regulatory system established by these regulations and, in light of such review, shall advise and make recommendations to the Executive Director and the Board as to the manner in which the system may be improved. Included within such responsibilities, the BBC shall review and make recommendations to the Executive Director on all amendments to the Guidelines.
 - b. The BBC may, upon request by BPHC staff, review and make recommendations regarding: applications for permits, policies, procedures, manuals and programs adopted by individual institutions for the purpose of determining conformity with the requirements of these regulations; application of the regulation requirements to specific entity conduct; site inspections carried out under these regulations; and provide recommendations with regard to appropriate administrative actions to be taken for violations of these regulations.

- c. In submitting an issue to the Committee for consideration, BPHC staff shall provide all necessary documentation and information necessary for the Committee to make a recommendation. The identity of the entity involved in the issue shall remain confidential and redacted from all documentation submitted to the committee, unless the identity of the institution is necessary for the resolution of the issue.
- d. The BBC shall review and make recommendations regarding any issue submitted to it by a hearing officer pursuant to Section 3.G.3 of these guidelines.
- e. The BBC shall meet with sufficient frequency to assure prompt and effective response to its duties and responsibilities. All meetings of the BBC shall be open and accessible to the public.
- f. Notice of the meeting shall be posted on the website of the BPHC at least forty-eight (48) prior to the meeting. In the event of an emergency meeting, notice will be posted as soon as possible. The staff of the BPHC shall cause to be taken and maintain minutes of all BBC meetings.

Section 7 Weaponization and Classified Research

(Corresponds to Section 4.00 of the Regulation.)

An entity may request an advisory opinion on whether or not a proposed project would violate the provisions of Section 4.01. The request for an advisory opinion shall be made in writing to the BPHC Director of Laboratory Safety. A written opinion will be provided to the entity within sixty (60) days of submission.

Section 8 Notice and Distribution of Regulation

(Corresponds to Section 5.00 of the Regulation.)

A) Notice of permit

- 1. Upon issuance of a permit, the BPHC shall provide the entity with a one-page notice of permit.
- 2. Such notice shall be displayed in a location and manner so that it is visible to all persons accessing the laboratory.

B) Distribution of regulation

- 1. All persons accessing the laboratory must be provided with a copy of the Regulation as it appears on www.bphc.org/labs.

2. The entity shall keep a record of the distribution of the regulation and make such record available to the BPHC upon request.

Section 9 Community Benefits Program

(Corresponds to Section 7.00 of the Regulation.)

All applications for a BSL-4 laboratory shall include a proposal for a community benefits programs to address the impact of a BSL-4 facility on the neighborhood in which it is located. The proposal shall include a detailed outline of community benefits activities that will occur during the permit period, including specific goals of the community benefits program, budget and evidence that such program has received input from members of the neighborhood in which the facility is located. Such program shall be subject to the approval of the BPHC.

Section 10 Transportation and Transfer of Biological Agents

An entity proposing to operate a laboratory or laboratories at BSL-4 must get approval from the Police Commissioner of the City of Boston of its Transportation policies and procedures.

Section 11 Decommissioning of a Laboratory

(Corresponds to Section 2.04.c of the Regulation.)

A) Notice of decommissioning

If a laboratory or biohazardous area will be taken out of use or changed to a lower level containment or converted to a non-laboratory space, permanently or for an extended period of time, the entity shall report this activity to the Boston Public Health Commission at least thirty (30) days prior to any decommissioning.

B) Submission format

1. The format for reporting shall include, but is not limited to, the following;
 - a. purpose of decommissioning;
 - b. laboratory location as described in permit application description of work;
 - c. timeline for work (estimated start and completion times);
 - d. disinfectant method (chemical or physical) for decontamination purposes;

- e. type of disinfectant with explanation of effectiveness for agent used in laboratory;
 - f. termination of existing project or new project or change to office area; and,
 - g. proof that biological agent is rendered non-infectious.
2. This report shall include a certification by the entity's responsible official that the entity has a decommissioning plan in place for the laboratory being decommissioned and the report shall also include the date by which the decommissioning will be completed.
 3. A decommissioning plan shall be submitted at the time of the permit application in accordance with Section 2.01.b.vi of the Regulation.

C) Inspection of decommissioned facility

1. The BPHC shall be notified within 48 hours after completion of work.
2. Notification shall be in writing to the BPHC Director of Laboratory Safety. If necessary, an inspection of the decommissioned facility will occur within thirty (30) days of notification.

D) Amendment of permit

If necessary, the entity shall update the permit application to reflect the decommissioning of the laboratory. Within thirty (30) days after decommissioning of the lab, the BPHC, if necessary will issue an amended permit.

Section 12 Public Safety and Proprietary Information

(Corresponds to Section 2.02 e of the Regulation.)

This regulation is intended to ensure safe and ethical conduct of biological research in the City of Boston and facilitate public understanding of research being conducted in the neighborhood. Therefore, it is the intent of the Boston Public Health Commission to provide as open and transparent process as possible. However, the nature of the agents dealt with as well as certain proprietary property interests of the institutions require that certain safe guards be maintained.

A) Public safety

1. It is the determination of the Boston Public Health Commission that the public release of the following documents required to be submitted under

the regulations would jeopardize the public safety. Therefore the documents set forth below are not public records and are exempt from disclosure pursuant to M.G.L. c.4 § 7 (n). When submitting them to the BPHC, an entity must include a confidentiality log as outlined in Section 12.D below.

a. Security and Safety Documentation:

- i. Policies relating to laboratory security;
- ii. That portion of any document containing a blueprint, plan or other diagram of the laboratory;
- iii. That portion of any document containing any name or other identifying information regarding any person who has access to a high risk agent;
- iv. Policies regarding the transportation of any high risk agent;
- v. Operational records regarding the use of a high risk agent;
- vi. Evacuation and Emergency response plans;
- vii. That portion of any BPHC inspection report that identifies the location or security for any high risk agent; and,
- viii. That portion of any report, IBC meeting minutes or certification that identifies the location or security procedures for any high risk agent.

b. Medical Information:

- i. Information submitted to the BPHC containing personal medical information regarding employees, patients or other individuals. Such information is not a public record and exempt from disclosure pursuant to M.G.L. c.4 § 7 (d).

c. Incident Reporting:

- i. That portion of any report or findings which is personal medical information;
- ii. While an investigation is active, all records shall be kept confidential; and,
- iii. Upon completion of the investigation, the findings of the investigation shall be made public in a de-identified format.

B) Proprietary information – documents

In submitting the application, annual report or any document to the BPHC for purposes of compliance with the Regulation, an institution may redact only those items of information that the institution believes constitute trade secrets or proprietary information.

1. In the event that an institution determines that specific items of an application should be considered as proprietary or trade secret, may be redacted. A confidentiality log must be included as outlined in Section 12.D below.
2. An institution cannot claim a trade secret or proprietary information for the entire application.
3. At no time should the name of the high risk agent, any of the requested information listed in Section 2.01 b. of the Regulation or any information protected by a patent or other legal status or information that is in the public domain, be claimed as a trade secret or privileged proprietary information.
4. All redacted trade secret and proprietary information shall be available in non-redacted form for inspection by the BPHC at the laboratory facility at any time.

C) Proprietary information – Institutional Biosafety Committee meetings

1. The intent and purpose of Section 2.04 c. of the Regulation providing for public IBC meetings is to inform the public about the technical aspects of the research being conducted in their neighborhoods, the meaning and significance of the research, and significant safety, social, and ethical implications of the research. In order to achieve this purpose it is important that the institutions provide as complete information as possible.
2. In order to protect proprietary information an institution may, at any public IBC meetings, provide any of the information identified as proprietary in a summary format.
3. If an institution plans on totally excluding an item from discussion, the institution must notify and consult with the BPHC.

D) Confidentiality log - documentation required by entity

1. In submitting the application, annual report or any document to the BPHC for purposes of compliance with the Regulation, the entity may redact or designate certain portions of its annual report as confidential. Only such information that is likely to jeopardize public safety as outlined above shall be designated as confidential. Only such information that is considered proprietary or trade secret may be redacted.
2. The entire report cannot be designated as confidential or redacted.

3. Each portion of the report that is redacted or designated as confidential shall be listed in a confidentiality log, attached to the document, application or annual report. For each portion, the log shall list the name of the document, location in the document including section, page number and paragraph number if applicable, the length of the portion being marked confidential, whether it is a public safety or a trade secret exemption and a brief reason why the information needs to be designated as such.
4. All portions of the report that have been designated as confidential for public safety reasons shall be provided to the BPHC in their original format.
5. All portions of the report that have been designated as confidential for “trade secret” reasons may be redacted but shall be available to the BPHC to review at any time.

E) Data security

1. Any of the documents set forth above, that are submitted to the BPHC shall be held in a secure, limited access facility.
2. Dissemination of information shall only be made upon determination that the recipient is authorized to receive it. The criterion to determine authorization is need-to-know. Those with a need-to-know access are those who are specifically granted access for the conduct of business on behalf of the BPHC. This includes all persons or firms necessary to do work at the request of the BPHC, such as Information Technology support personnel, consultants, contractors and maintenance and repair contractors and equipment service contractors.
3. All electronic data maintained by the BPHC shall be encrypted using a 128 bit AES encryption. The decryption and use of any encrypted document shall only be done in the secure, limited access facility.
4. All computer equipment, including servers, terminals and printers, used to store or access encrypted information shall be physically secured to prevent unauthorized access. Security for the limited access facility shall be provided and monitored at all times.

Section 13 Appendices

Appendix 1: How sections in the Regulation correspond to the Guidelines

REGULATION SECTION	CORRESPONDS TO	GUIDELINES SECTION
Section 1.00 Definitions	↔	Section 2 Definitions
Section 2.00 Permit Requirements	↔	Section 3 Permits
Section 2.02 e Information	↔	Section 12 Public Safety and Proprietary Information
Section 2.03 Institutional Biosafety Committees	↔	Section 4 Institutional Biosafety Committee
Section 2.04 IBC Reports and the Reporting of New Projects or Programs	↔	Section 4 Institutional Biosafety Committee Section 11 Decommissioning of a laboratory
Section 3.02 Incident Reporting	↔	Section 5 Laboratory Oversight: Incident Reporting, Inspections, Fines (<i>Section A: Incident Reporting</i>)
Section 3.03 Inspections	↔	Section 5 Laboratory Oversight: Incident Reporting, Inspections, Fines (<i>Section B: Inspections Procedures</i>)
Section 3.04 Boston Biosafety Committee (BBC)	↔	Section 6 Boston Biosafety Committee (BBC)
Section 4.00 Prohibitions – Weaponization and Classified Research	↔	Section 7 Weaponization and Classified Research
Section 5.00 Notice, Violation Reporting and Non-retaliation	↔	Section 8 Notice and Distribution of Regulation
Section 6.00 Guidelines	↔	Section 1 Authority
Section 7.00 Community Benefits Program	↔	Section 9 Community Benefits Program
Section 8.00 Permit Fees	↔	Section 3 (H) Permits
Section 9.00 Penalties	↔	Section 5 Laboratory Oversight: Incident Reporting, Inspections, Fines

Appendix 2: Contact Information

Boston Public Health Commission

www.bphc.org/labs

Anthony Gemmellaro
Director, Laboratory Safety

Phone: (617) 534-2814
Fax: (617) 534-2406
Email: agemmellaro@bphc.org

Address:
1010 Massachusetts Avenue, 2nd Floor
Boston, MA 02118

Leon Bethune
Director, Environmental Health Office

Phone: (617) 534-5965
Fax: (617) 534-2406
Email: lbethune@bphc.org

Address:
1010 Massachusetts Avenue, 2nd Floor
Boston, MA 02118

Mayor's Office of Neighborhood Services

www.cityofboston.gov/neighborhoods

Phone: (617) 635-3485
Fax: (617) 635-3498

Address:
Room 708
1 City Hall Plaza
Boston, MA 02201

Boston City Council

For current list of councilors and their contact information, go to
www.cityofboston.gov/citycouncil

Appendix 3: Deadlines

Below is a partial list of deadlines contained in the Guidelines. Please read Guidelines completely for more information.

Permit Application

Renewal of BSL-3 permit	Three (3) months prior to the expiration of the permit
Renewal of BSL-4 permit	Four (4) months prior to the expiration of the permit
New BSL-3 permit	Four (4) months before research can begin
New BSL-4 permit	Six (6) months before research can begin
Denial of a permit application	Applicant shall have ten (10) days to correct the deficiencies in the application or file an appeal of the denial

IBC

Community member approval	Application due at least forty-five (45) days prior to the first IBC meeting in which the member will participate
Notice of public meetings	No less than fifteen (15) days in advance of meeting

Annual Report

Submission to BPHC	Within thirty (30) days of permit issuance anniversary
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Research projects

Notification of new research	At least thirty (30) days before initiating any project
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Incident Reporting

Reporting to BPHC	Immediately, but in no event later than 24 hours after discovery
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Inspections

BPHC notice of inspection	at least ten (10) days in advance of a regularly scheduled inspection
Preliminary inspection report	Within ten (10) business days after the completion of all parts of the inspection
Corrective action	Items rated “Public Health Violations:” correct immediately. Items rated “Unsatisfactory:” correct as soon as reasonably possible but no later than ten (10) days after the preliminary inspection.
Fines	Must be paid within thirty (30) days. Appeals can be made within fourteen (14) days of issue of citation.

Boston Biosafety Committee

Notice of meetings	At least forty-eight (48) prior to the meeting. In the event of an emergency meeting, notice will be posted as soon as possible.
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Decommissioning

Notice to BPHC	At least thirty (30) days prior to any decommissioning Notify BPHC within 48 hours after completion of work. If necessary, an inspection of the decommissioned facility will occur within thirty (30) days of notification.
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