

BOSTON PUBLIC HEALTH COMMISSION REGULATIONS

BIOLOGICAL LABORATORY REGULATIONS

Adopted September 19, 2006 and amended January 16, 2019

SECTION 1.00 DEFINITIONS

- a. "Abutting community" a city, town or neighborhood contiguous to or touching upon any land of the neighborhood in which the laboratory is located.
- b. "Agent" any biological agent classified as Risk Group 2 through 4 by the NIH Guidelines, biological agent requiring BSL-2 through 4 containment based on risk assessment, any High-Risk Agent as defined by Section 1 (l) of the regulation, or any agent modified using recombinant DNA unless exempted by the Boston Public Health Commission.
- c. "Attenuated Strain" a debilitated, weakened or less virulent virus, bacteria, other organism, or toxin.
- d. "Biological Weapon" microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective treatment or other peaceful purposes.
- e. "BMBL" unless otherwise specified, is defined as Biosafety in Microbiological and Biomedical Laboratories, published by the Centers for Disease Control and Prevention and National Institutes of Health, as amended;
- f. "BPHC" or "Commission" the Boston Public Health Commission.
- g. "BPHC Guidelines" the guidelines issued by the Executive Director pursuant to Section 6.00 of this regulation.
- h. "Board" the Board of the Boston Public Health Commission.
- i. "Entity" any single individual, group of individuals, corporation, partnership, hospital, academic institution, society, association, firm, sole proprietorship or any other legal entity, whether public or private.
- j. "Executive Director" the Boston Public Health Commission's Executive Director and may include his or her designee.

- k. “Expose or Exposure” any situation arising from or related to the work operation of an employer where an employee, another person present in the laboratory or a community resident may ingest, inhale, absorb through the skin or eyes, be injected percutaneously, or otherwise come into contact with any High-Risk Agent or agent otherwise requiring reporting under any BPHC regulation or guideline.
- l. “High-Risk Agent” any Select or Overlap Select Agent and toxin or agents in Risk Group 3 (RG3) or Risk Group 4 (RG4) as specified in NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules or any agents recommended for Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4) containment by the BMBL, and any other agent identified by the Executive Director. This definition shall not include any Select or Overlap Agent or toxin specifically excluded pursuant to 42 Code of Federal Regulations 73.3(d),(e) and 73.4 (d),(e) respectively, from the requirements of 42 CFR Part 73. The Executive Director shall compile and update, as necessary, a list of high-risk agents that require reporting to BPHC. The list shall be posted on the BPHC’s website.
- m. “Institutional Biosafety Committee” or “IBC” a local institutional committee established by an entity to review and oversee biological research conducted by the entity. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. (See section IV-B-2 of the NIH Guidelines.)
- n. “Large scale” any research or production activity categorized as large-scale by the NIH Guidelines.
- o. “Laboratory” a room or rooms which is or are used primarily for biological research, development, non-routine testing or experimentation activity in which any agent is used at biosafety levels three and four as described in NIH Guidelines or BMBL or where rDNA experiments covered by this Regulation are conducted, or any room or rooms where animals are contained under animal biosafety levels three and four as described in NIH Guidelines or BMBL. The term “laboratory” shall also include those rooms that directly serve a laboratory, as determined by BPHC. Clinical laboratories licensed under 105 CMR 180 or laboratories in educational institutions used exclusively for instruction and not research experiments shall be exempt from permitting under this Regulation.
- p. “NIH Guidelines”, unless otherwise specified, are defined as NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, as amended.
- q. “Occupational Health Officer” a licensed physician experienced in occupational medicine or a registered nurse experienced in occupational health nursing or a

physician's assistant experienced in occupational medicine, designated by the entity. The Occupational Health Officer may also name a designee to perform occupational health assessments or evaluations, who is also a licensed physician experienced in occupational medicine or a registered nurse experienced in occupational health nursing or a physician's assistant experienced in occupational health.

- r. "Principal Investigator" the individual designated by the entity to direct the biological research project or program conducted at biosafety levels three or four or research at biosafety level 2, 3, or 4 using rDNA and who is responsible to the entity for the scientific and technical direction of that project or program.
- s. "Project" a biological research experiment or biological research experiments or biological production activities, under a principal investigator, in which the risk assessment has designated a biosafety level of three or four, or research at biosafety level 2, 3, or 4 using rDNA.
- t. "Recombinant DNA molecules" and "rDNA" and "organisms and viruses containing rDNA" are those defined in the "NIH Guidelines" as defined above. For the purposes of this Regulation, all references to "rDNA" and "recombinant DNA" shall be read to include synthetic nucleic acid molecules.
- u. "Responsible Official" a senior management official or officials designated by the entity and approved by the BPHC with the responsibility and authority to act on behalf of the entity and ensure compliance with this regulation.
- v. "Select and Overlap Select Agent" microbial and toxic agents listed at 42 CFR 72.3, 73.4, 73.5, 73.6, 7 CFR 331.3, 9 CFR Part 121.4 and the rulings made by the United States Department of Health and Human Services and United States Department of Agriculture relative thereto as amended from time to time. Select Agent shall not include any exempt amounts of select agents or toxins that are excluded from 42 CFR 73.00.
- w. "Serious bodily injury" shall mean bodily injury that results in a permanent disfigurement, loss or impairment of a bodily function, limb or organ, death or a substantial risk of death.
- x. "Serious illness" shall mean illness that results in a permanent disfigurement, loss or impairment of a bodily function, limb or organ, death or a substantial risk of death.
- y. Any other terms, not specifically defined herein, shall have the meaning as defined in the "BPHC Guidelines". If the "BPHC Guidelines" do not define the term, it shall have the meaning as is commonly used.

SECTION 2.00 PERMIT REQUIREMENTS

Section 2.01 Permit Application

- a. Any entity operating or proposing to operate a biological laboratory or laboratories at biosafety levels 3 or 4, or any entity conducting or proposing to conduct any biological research at biosafety levels 3 or 4 or any entity operating or proposing to operate an animal facility at animal biosafety levels 3 or 4, or any entity proposing to use rDNA at biosafety levels 2, 3, or 4 shall obtain a permit from the Boston Public Health Commission.
 - i. Permits shall be valid for a period of one (1) year, or unless otherwise revoked pursuant to the terms of this regulation.
- b. Permit application requirements shall be set forth in BPHC Guidelines and permit application documents.

Section 2.02 Permit Application Process

- a. The BPHC Guidelines shall set forth the procedures, consistent with this regulation, for the submission, review and approval of permit applications and issuance and renewal of permits. Permits may be issued which contain conditions or restrictions relative to the Commission's interest in protecting the public health.
- b. Application for a permit or renewal of a permit shall be acted upon within sixty (60) days of submission of a completed application. The Commission shall have no obligation to review incomplete applications. If, at the conclusion of the sixty (60) day period, the review of the application is not complete, the Commission may issue an entity a provisional permit if the entity's application is complete and substantially complies with the provisions of the regulation. A provisional permit shall not exceed 120 days in length and shall not be renewed or extended.
- c. An entity may be required to obtain separate permits for multiple laboratories if such additional permits would enhance the enforcement of this regulation and BPHC's ability to protect the public health.
- d. All laboratory facilities permitted pursuant to this regulation shall be subject to inspection, at reasonable times and in a manner that maintains the health and safety systems of the laboratory, to monitor compliance with this regulation.
- e. 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 require the submission or review of proprietary information, the Executive Director shall develop procedures for assuring confidentiality of the proprietary information.

- f. The denial of an application for a permit may be appealed pursuant to the Boston Public Health Commission's Standard Hearing Procedure.

Section 2.03 Institutional Biosafety Committees

- a. All entities that hold a permit pursuant section 2.01 of this regulation shall have an institutional biosafety committee (IBC) to ensure the safety and conformance with this regulation of all biological research projects. The IBC shall be established and operate in accordance with the BPHC Guidelines. The composition of the IBC shall include at least two community representatives, with no affiliation with the entity, from the community in which the laboratory is located or abutting communities. The selection of one of the community representatives shall be subject to the approval of the Commission.
- b. The IBC shall report to the responsible official.
- c. The IBC for entities conducting BSL-3 and BSL-4 research shall meet at least twice a year and at such times as may be specified by the BPHC Guidelines. When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public, and at least one of its meetings during a calendar year shall be open to the public and should review the type and nature of the biological research at BSL-3 and 4 that is conducted by the entity. Notice of such public meeting shall be in a manner prescribed by the BPHC Guidelines.

Section 2.04 IBC Reports and the Reporting of New Projects or Programs

- a. All entities permitted pursuant to Section 2.01 of this regulation shall file an annual report with the Commission. Such report at a minimum shall include complete copies of all IBC minutes for the time period, certification that the entity is in compliance with this regulation and the BPHC Guidelines, a report on any quality assurance and quality improvement efforts made during the period, a complete roster of current IBC members and an update of any information provided in the permit application. To the extent IBC minutes contain information regarding the agent, its location, or security measures, where the release of the information may jeopardize the health and safety of the public or proprietary information, the Executive Director shall develop procedures for assuring confidentiality.

- b. All entities permitted to conduct BSL-3 or BSL-4 research pursuant to Section 2.01 of this regulation shall notify the Commission upon IBC approval of any new project or program. All required information regarding new projects or programs shall be filed with the Commission in the manner prescribed in Section 2.01(b), at least thirty (30) days before initiating any project experimentation activity requiring the IBC's approval. All BSL-3 projects are subject to approval by the BPHC Executive Director. All BSL-4 projects are subject to review by the Boston Biosafety Committee and approval by the BPHC Executive Director.
- c. The intended decommissioning of a laboratory facility shall be reported to the Boston Public Health Commission at least 30 days prior to decommissioning.

Section 2.05 Large-Scale Use Permit

- a. Any large-scale use or production of an agent requiring a biosafety level 3 or 4 or using rDNA at biosafety level 2, 3, or 4, shall require a separate large-scale use permit.
- b. Any entity requesting a large-scale use permit at biosafety levels 3 or 4 or using rDNA at biosafety level 2, 3, or 4 shall have a valid permit pursuant to Section 2.01 of this regulation. The application for a large-scale use permit may be filed contemporaneously with the permit application filed pursuant to Section 2.01. The term of the large-scale use permit shall run concurrently with the permit issued pursuant to section 2.01.
- c. All applications for a large-scale use permit shall contain a list of all agents being used on a large-scale basis, the content of any training provided to employees, staff or students regarding large-scale use and all policies or procedures specifically related to the care and handling of any agent used on a large-scale basis.
- d. Any entity holding a large-scale use permit shall request approval to conduct any new large-scale activity not specified in the permit from the BPHC prior to the initiation of any new large-scale related activity, which may include, but need not be limited to, construction or renovation of facilities.
- e. During the review of the entity's permit request, the BPHC may request additional information from the entity pertaining to the proposed large-scale activity.
- f. All large-scale activity must be clearly identified in the minutes of the IBC.

Section 2.06 Recombinant DNA Technology

- a. The Boston Public Health Commission's Recombinant DNA Technology Use Regulation and City of Boston Ordinance 17-9 are superseded by this Regulation pursuant to section 6(d) of the Boston Public Health Act of 1995.
- b. Research projects using rDNA in BSL-4 laboratories are subject to review by the Boston Biosafety Committee and approval by the Executive Director.

SECTION 3.00 LABORATORY OVERSIGHT

Section 3.01 Standards of Operation

All entities permitted and required to be permitted pursuant to this regulation shall employ standard microbiological practices and operate in conformance with the practices, principles and standards set forth in the BMBL, NIH Guidelines, this Regulation, permitting documents, and any guidelines promulgated hereunder.

Section 3.02 Incident Reporting

- a. Any case or suspected case of disease caused by a High-Risk Agent, any accidental release, spill or accident which result in an exposure to rDNA material, a High-Risk Agent, or any illness among persons caused or potentially caused by rDNA material, a High-Risk Agent or attenuated strain of a High-Risk Agent present in a laboratory, as well as any case or suspected case of disease or exposure otherwise specified by the Commission's Disease Reporting and Surveillance Regulation and Guidelines, shall be reported to the Commission in accordance with the Commission's Disease Reporting and Surveillance Regulation and Guidelines unless otherwise specified.
- b. An entity shall immediately report to the BPHC 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 serious bodily injury to any person; serious property damage; or, the failure of any major mechanical system in the laboratory. Any incident, problem or accident that must be reported to the IBC, the National Institute of Health or the Centers for Disease Control and Prevention shall be reported to the Commission in a like manner.

Section 3.03 Inspections

The Commission shall have the authority to review all documentation relating to the operations of the laboratory and conduct a physical inspection of any laboratory, with or without prior notice; so long as such inspections are conducted

at reasonable times and in a manner that maintains the health and safety systems of the laboratory. Failure to provide any requested documentation or access to a laboratory may result in a fine or the immediate suspension or restriction of an entity's permit.

Section 3.04 Boston Biosafety Committee (BBC)

- a. The Executive Director shall appoint a Boston Biosafety Committee (BBC) composed of both scientific and community representatives to assist in regulating biological laboratories at BSL-3 and 4. Members shall have the qualifications and expertise as specified in the BPHC Guidelines.
- b. The BBC shall be composed of at least seven (7) members, one of whom shall be the Executive Director or his/her designee who shall serve as chairperson. Members shall be appointed for a two-year term and shall only be removed for cause. Members appointed to fill vacancies shall serve for a full two-year term. Any member of the Committee may be eligible for reappointment.
- c. The BBC shall periodically provide technical assistance and review of the effectiveness of the Biological Laboratory regulation and advise and/or deliberate as needed about technical issues arising out of permits and applications under the regulation.
- d. The BBC shall consider policy changes or possible amendments to the regulations to improve the system of laboratory regulations, the safe handling and transportation of high-risk agents and advise and/or deliberate as needed.
- e. The BBC shall meet with sufficient frequency to assure its ability to carry out its duties and responsibilities.
- f. The Duties and Responsibilities of the Boston rDNA Advisory Committee (BRAC) as defined in the Recombinant DNA Technology: Use Regulations Section 2.00 are assumed by the provisions of this section.

SECTION 4.00 PROHIBITIONS – WEAPONIZATION AND CLASSIFIED RESEARCH

Section 4.01 Weaponization

Any research that has the potential to enable the use of a High-Risk Agent to serve in any way as a principal component of a biological weapon, or significantly aid in the construction of a biological weapon or any research that

has the potential to increase a High-Risk Agent's pathogenicity, reduce a High-Risk Agent's resistance to treatments by antibiotic, anti-viral or other anti-microbial agent, alter the High-Risk Agents' vector of transmission, that is conducted for no prophylactic, protective, treatment or other peaceful purposes, is forbidden in the City of Boston.

Section 4.02 Classified Research on High-Risk Agents

All research on High-Risk Agents, designated by Presidential Executive Order 12958 or any other federal rule, regulation or law, as "Top Secret," "Secret," "Confidential," or any other classification or requirement including by contract, grant or funding requirement, that would prohibit the Boston Public Health Commission's complete knowledge of the research, shall be prohibited in the City of Boston. Any Entity that denies the Commission access to any facility or fails to provide any information due to it being "classified" or otherwise secret or confidential, or because the research is being done by another person in the facility who will not provide the access or information, shall have its permit revoked and all laboratory facilities operating under the permit shall be closed.

SECTION 5.00 NOTICE, VIOLATION REPORTING AND NONRETALIATION

Section 5.01 Posting and Distribution of Regulation

- a. A copy of this regulation shall be distributed to all employees, students and any other person who has regular access to any portion of a laboratory permitted pursuant to section 2.01, within sixty (60) days of the effective date of this regulation or before the commencement of regulated project operations or at the start of employment or access to the laboratory.
- b. A copy of this regulation or a notice of the regulation as approved by the Executive Director shall be conspicuously posted in each laboratory permitted pursuant to section 2.01 of this regulation. Such notice shall contain the statement that any violation of the regulation may be reported to the Commission with a telephone number and e-mail address to report such violations.

Section 5.02 Reporting of Violations

All entities, permitted pursuant to section 2.01, shall have a system for reporting health and safety violations in an anonymous manner to the Health and Safety Officer, Biological Safety Officer, or the IBC.

Section 5.03 Non-retaliation

- a. No person shall be required to conduct scientific research, experimentation, study or take other action in a laboratory that violates any provision of this regulation or permit issued hereunder or has reasonable potential to adversely affect public or employee health and safety.
- b. No person or employer shall discharge, refuse to hire, discipline or in any manner retaliate or take any adverse action against any employee, applicant, or other person because such employee, applicant or person:
 - i. Discloses or threatens to disclose to a supervisor or a governmental agency an activity, policy or practice that the person reasonably believes is in violation of this regulation; or
 - ii. Objects to or refuses to participate in any activity, policy or practice that the person reasonably believes is in violation of this regulation.
- c. The protection against retaliatory action shall not apply to the public disclosure of confidential or proprietary information, trade secrets or other confidential materials, unless such confidential disclosure is made by the person directly to a state, local or federal governmental law enforcement or public health agency.

SECTION 6.00 GUIDELINES

The Executive Director of the Boston Public Health Commission shall issue guidelines for the implementation of this regulation, including but not limited to definitions of terms as used in these regulations and in the guidelines. In the event of a conflict between these regulations and the guidelines, as either may be amended, the regulation shall control.

SECTION 7.00 COMMUNITY BENEFITS PROGRAM

All entities permitted pursuant to Section 2.01 for the operation of a BSL-4 laboratory shall establish and maintain a Community Benefits Program, to support local health and safety needs in manner prescribed in the BPHC Guidelines. The entity shall file with the Commission an annual report detailing the operations of the program.

SECTION 8.00 PERMIT FEES

The Executive Director is hereby authorized to establish fee scales for the issuance and renewal of permits which may vary according to the type of use and scale of activity being conducted. All fees shall be directly related to the costs incurred by the Commission in the issuance of permits, the inspection of laboratories and any other costs associated with the implementation of this regulation. Such fee scales shall be approved

by the Board of the Boston Public Health Commission. Payment of such fee or fees shall be a condition of the granting or renewal of any permit.

SECTION 9.00 PENALTIES

Section 9.01 Violation of Regulation - Fines

- a. A violation of any condition or restriction of a permit or any provision of this regulation shall subject the violator to a fine of one thousand (\$1000.00) dollars per day per violation. Each such violation shall constitute a separate and distinct offense.
- b. A violation of any provision of the Boston Public Health Commission's Disease Surveillance Reporting Regulation by an entity covered by this regulation shall be considered a violation of this regulation.

Section 9.02 Revocation, Suspension, Modification or Non-renewal

- a. Once a permit has been issued it may be revoked, suspended, modified or not renewed only upon a determination, after due notice and hearing, that the entity has materially failed to comply with these regulations, the BPHC guidelines or the permit requirements, conditions, or restrictions.
- b. All decisions of the Executive Director regarding the issuance, suspension or revocation of a permit shall be the final decision of the Boston Public Health Commission.

Section 9.03 Immediate Threat to the Public Health

Notwithstanding the provisions of Section 9.02, the Executive Director, upon a determination that any violation constitutes an immediate threat to the public health and safety, may order any necessary corrective action including but not limited to the immediate closure of any laboratory engaging in or contributing to such threat, without prior notice and hearing but with subsequent notice and hearing.

SECTION 10.00 SEVERABILITY OF SECTIONS

If any section, subsection, sentence, clause, or portion of this regulation is for any reason held invalid or unconstitutional by any court of competent jurisdiction, such portion shall be deemed a separate, distinct and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

SECTION 11.00 IMPLEMENTATION

The regulation, except as provided for in this section, shall become effective upon passage.

On September 19, 2006 the Board voted unanimously in favor of the foregoing regulation.

On January 16, 2019 the Board voted unanimously in favor of amendments to the foregoing regulation.