

BOSTON PUBLIC HEALTH COMMISSION REGULATION

BIOLOGICAL LABORATORY REGULATIONS

Adopted September 19, 2006

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, and any High Risk Agent as defined by Section 1 (I) of the regulation.
- c. "Attenuated Strain" a debilitated, weakened or less virulent virus, bacteria, other organism or toxin.
- d. "Biological Weapon" a 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, are defined as:
 - i. Biosafety in Microbiological and Biomedical Laboratories, 4 th Edition;
 - ii. Any amendments, revisions, or substitutions subsequent to the above referenced edition; and,
 - iii. Any further amendments to (i) or (ii) above, wherever published, which are adopted by U.S. Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health and approved by the Executive Director. Amendments not acted upon by the Executive Director within sixty (60) days shall be considered approved.
- 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 or otherwise come into contact with any High Risk Agent.
- l. “High Risk Agent” any select or overlap select agent and toxins or agents in risk group RG4 as specified in the National Institute of Health’s Guidelines for Research Involving Recombinant DNA Molecules or recommended for Biosafety Level four by the Biosafety in Microbiological and Biomedical Laboratories published by the US Centers for Disease Control and Prevention and the National Institutes of Health and the amendments and rulings made relative thereto from time to time (hereinafter “NIH Guidelines/BMBL”), highly pathogenic avian influenza, SARS Co-Vor and any other agent identified by the Executive Director. This definition shall not include any select or overlap agent specifically excluded pursuant to 42 CFR 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. 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 involving more than 10 liters of culture conducted at biosafety levels three and four.
- 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/BMBL Sections V and VII or any room or rooms where vertebrate animals are contained under animal biosafety levels three and four as described in NIH Guidelines/BMBL Section IV. The term “laboratory” shall also include those rooms that directly serve a laboratory.

- p. “NIH Guidelines”, unless otherwise specified, are defined as:
- i. *National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules* as published in the Federal Register of April 2002.
 - ii. Any amendments, revisions, or substitutions subsequent to the above referenced “Guidelines;” and,
 - iii. Any further amendments to (i) or (ii) above, wherever published, which are adopted by NIH and approved by the Executive Director. Amendments not acted upon by the Executive Director within sixty (60) days shall be considered approved.
- 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 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.
- t. “Recombinant DNA molecules” and “RDNA” and “organisms and viruses containing RDNA” are those defined in the “NIH Guidelines” as defined above.
- 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 and 73.4, 42 CFR 73.5, and 9 CFR Part 121.4 and the rulings made by the United States Centers for Disease Control and United States Department of Agriculture relative thereto as amended from time to time.
- 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, shall obtain a permit from the Boston Public Health Commission. Entities operating or conducting research in such laboratories on the date of passage of this regulation must comply with the requirements as outlined in Section 11.00 of this regulation. Such permit shall be valid for a period of three (3) years, or until the end of the project if less than three years, or unless otherwise revoked pursuant to the terms of this regulation.
- b. Each permit application shall include, the following:
 - i. Name and location of the entity;
 - ii. The location and biosafety level rating or ratings for each laboratory that will operate under the permit;
 - iii. Roster, biographical information and contact information of institutional biosafety committee (IBC) indicating the Chair, Biological Safety Officer, plant expert, animal expert, community members or ad hoc consultant;
 - iv. Name, title and contact information of the entity’s Occupational Health Officer, Biological Safety Officer and Responsible Official;
 - v. Project information including but not limited to, title and brief description of the project, grant identification number or other unique institutional identifier number, Principal Investigator and the agent or agents used in the project including any high risk agent or agents for each project or program;
 - vi. Protocols, procedures and policies relating to laboratory safety, including but not limited to, training, security, laboratory inspections, transportation, waste disposal, commissioning, decommissioning, decontamination, termination of work with agents, training of all employees, visitors or students and first responder plans including evacuation and emergency response; and,

- vii. Such other information as specified in the BPHC Guidelines.

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 by 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 financial interest in 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 shall meet at least twice a year and at such times as may be specified by the BPHC Guidelines. 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 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.
- 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, shall require a separate large scale use permit.
- b. Any entity requesting a large scale use permit at biosafety levels 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 High Risk 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 High Risk 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 not 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 Use Regulation Permits

- a. All entities operating a BSL- 4 laboratory or BSL- 3 laboratory under a permit issued pursuant to the Boston Public Health Commission's Recombinant DNA Technology Use Regulation or such other permit issued under the Department of Health and Hospitals Recombinant DNA Technology Use Regulation or the City of Boston Code 17.9 must apply for and receive a permit pursuant to Section 2.01 and, if applicable, 2.05 of this regulation.
- b. Application for and approval of a permit pursuant Sections 2.01 and 2.05 of this regulation shall be deemed to meet the requirements of the Sections 1.03, 1.04, 1.05, 1.06 and 1.07 of the Recombinant DNA Technology Use Regulation.

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 good small scale and large scale microbial practices and operate in conformance with the practices, principles and standards set forth in the BMBL, NIH Guidelines, the Center for Disease Control/NIH Guidelines on Primary Containment for Biohazards, this regulation, and the permits and guidelines promulgated hereunder.

Section 3.02 Incident Reporting

- a. Any case or suspected case of disease caused by a High Risk Agent, any spill or accident which result in an overt exposure to a High Risk Agent, any illness among persons caused or potentially caused by a High Risk Agent or attenuated strain of a High Risk Agent present in a laboratory, shall be reported to the Commission in accordance with the Commission's Disease Reporting and Surveillance Regulation and Guidelines.
- 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 BLS -3 and 4. Members shall have the qualifications and abilities 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 RDNA and 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 and RDNA 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 hereby assumed and replaced by 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 anyway as a principle 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 NON-RETALIATION

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. 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 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 Programs, to support local health and safety needs in manner proscribed 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 issuances 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 - fine

- 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 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 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 90 days from the date of passage, September 19, 2006. Within 200 days from the date of passage, all entities operating a BSL-3 or BSL-4 laboratory facilities must file a permit application pursuant to Section 2.00 of this regulation. Within 260 days of the passage of the regulation all entities operating a BSL-3 or BSL-4 laboratory must have a permit or provisional permit. All entities commencing operation of a BSL-4 or BSL-3 laboratory more than 200 days after passage of this regulation, must comply with all provisions of this regulation prior to use of the laboratory for biological research.

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