Regulatory Policy Homework Exercise

The City of Boston, MA has recently promulgated a Laboratory Regulation that will regulate all labs in the city that are classified at Biosafety Level 2. This would include labs working with human pathogens, human cells, recombinant DNA experiments, toxins classed at BL2 or higher, and any other lab with a BL2 or higher rating. The State of CT has had an existing human pathogen registration regulation since 1989 and CT has augmented this regulation with the 1996 State of CT BL3 Law.

Read the City of Boston, MA Laboratory Regulation and the State of CT pathogen regulations. Compare and contrast the regulations from each state and write a brief (not more than one page) report highlighting your findings. You may want to include the potential strengths, weaknesses, scope or magnitude. Which regulation do you believe will have a greater impact on public health? Or protection of the researcher? Why?

CT Human Pathogen Regulations

(h) Birds not of the psittacine family are to be regarded as dangerous when they have been exposed to psittacosis and, after such exposure, shall be quarantined for three weeks and killed and burned by the owner or other person in charge of such birds if they develop or appear to develop symptoms of the disease.

(i) No indemnity will be paid the owner or other person in charge of such birds for destroyed birds.

(j) Any shipment of psittacine birds into Connecticut for sale in Connecticut shall be accompanied by a certificate signed by a veterinarian certifying that the birds have been treated with chlortetracycline, or other approved medication, prepared and administered in accordance with procedures approved by the surgeon general of the United States Public Health Service for psittacine control.

(Effective October 25, 1989)

Sec. 19a-36-A24. Distribution and use of microbial agents for control of animal life

Microbial agents capable of producing disease in man shall not be sold, distributed or used for the control or destruction of any form of animal life.

(Effective October 25, 1989)

Sec. 19a-36-A25. Laboratories to register

Any person, firm or corporation, or the duly authorized agent thereof, operating or maintaining a laboratory in which there is made any examination, determination or test specified in section 19a-36-A26, shall register such laboratory with the state department of health before any such examination, determination or test is made. The carrying on of any of the examinations, determinations or tests specified in said section shall be deemed the operating or maintaining of a laboratory.

(Effective October 25, 1989)

Sec. 19a-36-A26. Registration required when. Exemptions

(a) Except for laboratory work of the types hereinafter exempted, registration is required for any of the following laboratory procedures:

(1) Those which utilize any living agent capable of causing human infections or reportable disease of man, or which are used to secure evidence bearing upon the presence or absence of such living agents or the illnesses caused;

(2) those used to determine the sanitary quality of water or the amount of pollution therein or to control and evaluate the effectiveness of water treatment;

(3) those performed on sewage, sewage effluent or sewage sludge in connection with investigation of sources of pollution, problems of sewage disposal or effectiveness of sewage treatment;

(4) any examination, determination or test performed on any sample of milk, cream, frozen dessert, milk product or milk beverage or of any container or package used or intended to be used for holding any such product;

(5) those used to determine the sanitary quality of any substance used as a food, or as an ingredient of food or as a container for food, or to determine whether or not such substance may be harmful to health;

(6) those performed on any material or substance for the purpose of determining the effectiveness of sanitation in the establishment serving food or beverages to the public;

(7) those performed on air or materials contributing substances to the air which may be prejudicial to health, except those performed for routine operational control or maintenance purposes.

(b) Laboratories performing any of the work specified above shall be exempt from the requirements of this section only when all such work is done under one or more of the following conditions:

(1) When laboratory findings are obtained in a laboratory facility and service maintained by a licensed practitioner of a healing art exclusively for the examination of his own patients within the scope of his license to practice;

(2) when the laboratory has been established as an agency of the state or federal government for the purpose of providing data for state or federal officials in the enforcement of the dairy and pure food and drug laws;

(3) when laboratory work is confined to butter fat tests on milk and cream for use in determining payment to producers of such products under provisions of the general statutes;

(4) repealed, March 23, 1976;

(5) when laboratory findings are obtained on materials derived from animals in a laboratory facility and service maintained by a veterinarian licensed to practice in Connecticut performing laboratory examinations exclusively on animals under his or her care and treatment.

(c) When the laboratory work consists solely of those tests necessary to control the operation of water treatment plants under the supervision of operators whose qualifications have been approved by the state department of health or of sewage treatment plants under the supervision of operators whose qualifications have been approved by the state department of environmental protection, upon recommendation of the division of environmental health services in the former case or the state department of environmental protection in the latter case, the department shall grant registration without approval as provided in section 19a-36-A33 solely for the purpose of allowing such operators to perform those tests as shall be required for the control of treatment. Such granting of limited registration or renewal thereof may be made by the department without prior inspection or investigation of facilities, personnel, equipment and proficiency.

(Effective October 25, 1989)

Sec. 19a-36-A27. Application for registration or reregistration

(a) Application for registration shall be made on forms provided for the purpose by the state department of health and shall set forth clearly essential information concerning the laboratory, including its name, its location, the name of the person, firm or corporation owning or operating it, and such additional information as the state department of health may at any time deem necessary regarding the tests to be made, the housing, equipment and personnel of the laboratory. As part of the application for registration, the owner of the laboratory, or his duly authorized agent, shall designate a person to be in charge of the laboratory and shall agree to notify the state department of health in writing before any change in status of the person in charge or removal of the laboratory to new quarters is made.

(b) In a similar manner, application for reregistration of such laboratory shall be made (1) biennially within thirty calendar days prior to expiration of the registration then current, (2) before the laboratory is moved to new

quarters, (3) whenever a change in status of the person designated to be in charge is about to be made or (4) whenever registration has lapsed for any cause.

(Effective October 25, 1989)

Sec. 19a-36-A28. Conditional permission to operate laboratory

The state department of health may extend conditional permission to operate an unregistered laboratory for a period not to exceed thirty days pending completion of investigation or carrying out of conditions imposed prior to registration or reregistration.

(Effective October 25, 1989)

Sec. 19a-36-A29. Granting of registration

Registration or reregistration of a laboratory will be granted only after the state department of health has determined by inspection and investigation that no condition or circumstance exists which would, in the opinion of the state department of health, cause the laboratory to be operated in a manner prejudicial to the health of the public.

(Effective October 25, 1989)

Sec. 19a-36-A30. Suspension or revocation of registration

Registration of a laboratory may be suspended at any time when investigation has shown that the registration agreement has been violated or that the laboratory is being operated in a manner which may be prejudicial to the health of the public. Registration may be revoked for such cause after notice to and hearing of the parties interested.

(Effective October 25, 1989)

Sec. 19a-36-A31. Inspections and investigation by state department of health

Representatives of the state department of health shall be granted reasonable access to laboratory quarters and records for inspection and investigation. Whenever necessary to evaluate the accuracy of any type of laboratory work done in a laboratory which is registered or has applied for registration, said department will require technical reviews of procedures used or submit a reasonable number of suitable specimens or samples and require reports thereon.

(Effective October 25, 1989)

Sec. 19a-36-A32. Prohibition of transmission of material to unregistered laboratory

No person, firm or corporation shall, without approval in writing from the state department of health, maintain, conduct or operate a station or office for the reception from the public of materials to be transmitted to a laboratory for the making of any clinical, medical, or sanitary laboratory examination, determination or test except when the laboratory in which the work is to be done is currently registered with the state department of health or is exempt from registration requirements, as provided for in section 19a-36-A26.

(Effective October 25, 1989)

13.5 State of Connecticut BL3 Law

Substitute House Bill No. 5521

PUBLIC ACT NO. 96-149

AN ACT CONCERNING BIOLEVEL-THREE LABORATORIES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

(NEW) (a) For purposes of this section, (1) a "biolevel-three laboratory" or "laboratory" means a laboratory which is operated by an institution of higher education and is designed and equipped under guidelines issued by the National Institutes of Health and the National Centers for Disease Control as a biolevel-three laboratory, and (2) "biolevel-three agent" means an agent classified as a biolevel-three agent by the National Institutes of Health and the National Centers for Disease Control.

(b) If an institution which operates a biolevel-three laboratory establishes a biosafety committee pursuant to the National Institutes of Health or the National Centers for Disease Control guidelines, such committee shall (1) forward the minutes of its meetings to the Department of Public Health and (2) meet at least annually with a representative of the Department of Public Health to review safety procedures and discuss health issues relating to the operation of the laboratory.

(c) Each such institution shall report to the Department of Public Health any infection or injury relating to work at the laboratory with biolevel-three agents and any incidents relating to such work which result in a recommendation by the institution that employees or members of the public be tested or monitored for potential health problems because of the possibility of infection or injury or incidents which pose a threat to public health.

(d) Each such institution shall report to the Department of Public Health any sanctions imposed on the laboratory or on the institution for incidents occurring at the laboratory by the National Institutes of Health, the National Centers for Disease Control, the United States Department of Defense or any other government agency.

Approved May 31, 1996. Effective October 1, 1996.

BOSTON PUBLIC HEALTH COMMISSION
REGULATION

BIOLOGICAL LABORATORY REGULATIONS

Whereas; Numerous research laboratories in the City of Boston work on a regular basis with biological agents that if released could pose a significant threat to the public health.

Whereas; Strict adherence to standard microbiological practices and techniques are necessary to ensure proper containment of biological agents.

Whereas; A uniform set of biosafety requirements for all biological research laboratories in the City of Boston, regardless of how the research is funded, is necessary to protect the public health.

Whereas; Several of these laboratories are located in residential areas of the City of Boston and all of the laboratories may require the services of emergency first responders from Boston EMS, Boston Fire Department and the Boston Police Department.

Whereas; The provisions of this regulation will create a centralized information resource for emergency response planning.

Therefore; The Boston Public Health Commission enacts the following regulation to ensure that biological research laboratories in the City of Boston develop, adopt and implement appropriate biosafety practices in order to protect the public health.

Section 1.00 DEFINITIONS

a. "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.

b. "BMBL" Biosafety in Microbiological and Biomedical Laboratories, 4 th Edition as it may be amended from time to time.

c. "BPHC" or "Commission" the Boston Public Health Commission.

d. "BPHC Guidelines" the guidelines issued by the Executive Director pursuant to Section 5.00 of this regulation.

e. "Board" the Board of the Boston Public Health Commission.

f. "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.

g. "Executive Director" the Boston Public Health Commission's Executive Director and may include his or her designee.

h. "Expose or Exposure" any situation arising from or related to the work operation of an employer where an employee or a community resident may ingest, inhale, absorb through the skin or eyes or otherwise come into contact with any reportable agent.

i. "High Risk Agent" any select or overlap select agent and toxins or agents in risk group RG-4 as specified in the National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules and 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 any other agent identified by the Executive Director. 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.

j. "Institutional Biosafety Committee" or "IBC" a committee established by an entity in accordance with the "NIH Guidelines" Section IV-B-2. The IBC's responsibilities shall encompass all biological research projects at the entity and its responsibilities shall not be restricted to rDNA projects.

k. "Large scale" any research or production activity involving more than 10 liters of culture conducted at biosafety levels two, three or four.

l. "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 2, 3 or 4 as described in NIH Guidelines/BMBL Sections V and VII or any room or rooms where vertebrate animals are contained under animal biosafety levels 2, 3 or 4 as described in NIH Guidelines/BMBL Section IV. The term "laboratory" shall also include those rooms that directly serve a laboratory including, but not limited to; projection rooms, telecommunications control booths, coat rooms, preparation rooms, closets, material storage, balance rooms, cold rooms, stock rooms, dark rooms, equipment issue rooms, temporary hazardous materials storage areas, and similar facilities The term "agent" in addition to the agents listed in BMBL Sections V and VII shall include any highly pathogenic avian influenza, SARS Co-V, select agent, overlap agent or any other toxin, substance or agent designated by the Executive Director as a potential threat to the public health. The Commission

shall compile and update, as necessary, a list of agents. The list shall be posted on the Commission's website. Any clinical laboratory licensed by the Massachusetts Department of Public Health pursuant to c.111 section 51 or c.111D section 5 is exempt from this regulation.

m. "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."

(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.

n. "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.

o. "Principal Investigator" the one individual who is designated by the entity to direct the biological research project or program conducted at biosafety levels two, three or four and who is responsible to the entity for the scientific and technical direction of that project or program.

p. "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 two, three or four.

q. "Recombinant DNA molecules" and "RDNA" and "organisms and viruses containing RDNA" are those defined in the "NIH Guidelines", as defined above.

r. "Responsible Official" a senior management official or officials designated by the entity with the authority and control to legally bind the entity and ensure compliance with this regulation.

s. "Select and Overlap Select Agent" microbial and toxic agents listed at 42 CFR 73.4, 42 CFR 73.5, and 9 CFR 121.2 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.

t. 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 2, 3 or 4, or any entity conducting or proposing to conduct any biological research at biosafety levels 2, 3 or 4 shall obtain a permit from the Boston Public Health Commission. Entities operating such laboratories on the date of passage of this regulation must comply with the requirements as outlined in Section 9.00 of this regulation. Those initiating biological research requiring a laboratory facility for the first time after the passage date of this regulation must obtain a permit before engaging in any research activity. Such permit shall be valid for a period of three (3) years, unless otherwise revoked pursuant to the terms of this regulation.

b. Application for a permit shall be in a form prescribed by the Executive Director.

c. Each application shall include, for the entity requesting the permit, the following:

i. The location and biosafety level rating or ratings for each laboratory that will operate under the permit;
ii. Roster of institutional biosafety committee indicating the Chair, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable) or ad hoc consultant (if applicable);
iii. Biographical sketches of all IBC members including community members;
iv. Contact information of the institutional biosafety committee (IBC) for the entity;
v. Name, address and contact information of the entity's Occupational Health Officer and Biological Safety Officer;
vi. Name, title and contact information of the entity's responsible official;
vii. Protocols, procedures and policies relating to laboratory safety, training, security, laboratory inspections, evacuation and emergency response, as specified and approved by the Executive Director; and,

viii. Such other information as the Executive Directors deems appropriate.

d. For each laboratory facility identified in section 2.01(c)(i) the entity shall provide the following information;
   i. The name and locations of any high risk agent or high risk agents used or stored at the laboratory;
   ii. Any policy, protocol or procedure for the laboratory that substantially differs for the policy, protocol or procedure that was submitted pursuant to Section 2.01(c);
   iii. Grant identification number or other unique institutional identifier number for each project or program; and,
   iv. Such other information as the Executive Directors deems appropriate.

e. Each project identified in Section 2.01(d)(iii) shall be registered with the BPHC on a form provided by the Executive Director which shall include, but is not limited to:
   i. The title and brief description of the project;
   ii. The Principal Investigator;
   iii. The name and locations of any agent or agents used or stored at the laboratory;
   iv. Laboratory spaces and biosafety rating of those spaces used by the project; and,
   v. Such other information as the Executive Directors deems appropriate.

f. The Executive Director may establish such procedures as deemed appropriate for the submission, review and approval of permit applications and issuance and renewal of permits so long as they are consistent with this regulation. Permits may be issued which contain conditions or restrictions relative to the Commission's interest in protecting the public health.

g. 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 Executive Director 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.

h. An entity may be required to obtain separate permits for multiple laboratories if, in the determination of the Executive Director, such additional permits would

enhance the enforcement of this regulation and BPHC's ability to protect the public health.

i. All laboratory facilities 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.

j. Any information regarding the type of agent, its location or security measures, required 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.

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

Section 2.02. Institutional Biosafety Committees

a. All entities that hold a permit pursuant to this regulation shall have an institutional biosafety committee (IBC) to ensure the safety and conformance with this regulation of all of biological research projects. The IBC shall be established and operate in accordance with the guidelines issued pursuant to this regulation. The composition of the IBC shall include at least one representative from the surrounding community, who shall be approved by the Executive Director.

b. The IBC shall report to the designated responsible official.

c. The IBC shall meet at least twice a year and at such times as may be specified by the Executive Director in 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 2, 3 and 4 that is conducted by the entity. Notice of such public meeting shall be in a manner prescribed by the Executive Director.

Section 2.03. IBC Reports and the Reporting of New Projects or Programs

a. All entities shall file regular reports in a manner specified by the Executive Director in the BPHC Guidelines. Such report(s) at a minimum shall include complete copies of all IBC minutes, certification that the entity is in compliance with this regulation and any guidelines promulgated by the Executive Director, a complete roster of current IBC members and an update of any information provided in the permit application. To the extent IBC minutes may contain security sensitive or proprietary information, the Executive Director shall develop procedures for assuring confidentiality.

b. All entities shall file a report with the Commission, within sixty (60) days of funding any new project or program. All new projects or programs shall be registered, in the manner prescribed in Section 2.01(e), within thirty (30) days of IBC approval and before any experimentation activity.

c. The termination of a project or the decommissioning of a laboratory facility shall be reported the Boston Public Health Commission in a manner prescribed by the Executive Director in the BPHC Guidelines.

Section 2.04. Large Scale Use Permit

a. Any "Large Scale" use or production of an agent, requiring a biosafety level of 2, 3 or 4, shall require a separate large scale use permit.

b. Application for a large scale use permit shall be in a form prescribed by the Executive Director.

c. Any entity requesting a large scale use permit 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.

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 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.

g. Any entity conducting large scale activity or operating under a large scale permit issued pursuant to the Boston Public Health Commission's Recombinant DNA Technology Use Regulation at the time of the passage of this regulation must file for a permit in accordance with section 9.00 of this regulation.

Section 2.05 Recombinant DNA Technology Use Regulation Permits

a. All entities operating 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, 2.04 of this regulation.

b. Application for and approval of a permit pursuant to this regulation shall be deemed to meet all requirements of the Recombinant DNA Technology Use Regulation.

Section 3.00 LABORATORY OVERSIGHT

Section 3.01 Incident Reporting

a. Any case or suspected case of disease, significant exposure, or illness among persons caused or potentially caused by 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 the Guidelines issued pursuant to said regulation.

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 in the laboratory and/or caused or is suspected to have caused serious property damage that caused or is suspected to have caused 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 3.02 Inspections

The Commission shall have the authority to review all documentation relating to the operations of and conduct a physical inspection of any laboratory of an entity, 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 shall result in the immediate suspension or restriction of an entity's permit.

Section 3.03 Boston Biosafety Advisory Committee (BBAC)

a. The Executive Director shall appoint a Boston Biosafety Advisory Committee (BBAC) composed of both scientific and community representatives to assist it in regulating biological laboratories at BLS levels 2-4. Members shall have the qualifications and abilities as determined by the Executive Director.

b. The BBAC 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 serve at the pleasure of the Executive Director. 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 BBAC shall periodically provide technical assistance and review of the effectiveness of the RDNA and biological laboratory regulatory system established by the Boston Public Health Commission and advise as needed about ways the system might be improved.

d. The BBAC shall consider policy changes or possible amendments to the regulations to improve the system of RDNA and laboratory regulation and advise as needed.

e. The BBAC shall periodically review a sampling of applications for permits and related interaction with applicants and advise regarding the strengths and weaknesses of the process and changes that can be made to improve the permitting process.

f. The BBAC shall meet with sufficient frequency to assure its ability to carry out its duties and responsibilities.

g. The Duties and Responsibilities of the Boston RDNA Advisory Committee (BRAC) as defined in the Recombinant DNA Technology: Use Regulations (Section 2.03) are hereby assumed and replaced by provisions of this section.

SECTION 4.00. NOTICE, VIOLATION REPORTING AND NON-RETALIATION

Section 4.01 Posting and Distribution of Regulation

a. A copy of this regulation shall be distributed to all laboratory employees and any person who has access to any portion of the laboratory, 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. 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 4.02 Reporting of Violations

All entities shall have a system for reporting health and safety violations in an anonymous manner to the Health and Safety Officer or the IBC. Such system shall be approved by the Executive Director.

Section 4.03 Non-retaliation

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 takes any action in furtherance of the enforcement of this regulation or exercises any right conferred by this regulation.

SECTION 5.00 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 6.00 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 7.00 PENALTIES

Section 7.01. Violation of Regulation - fine

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.

Section 7.02. Revocation, Suspension, Modification or Non-renewal

a. Once a permit has been issued it may be revoked, suspended, modified or not renewed by the Executive Director only upon a determination, after due notice and hearing, that the entity has materially failed to comply with these regulations, the guidelines issued by the Executive Director 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. Notice and hearing procedures shall be those established by the Executive Director.

Section 7.03. Immediate Threat to the Public Health

Notwithstanding the above, 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 8.00 SEVERABILITY OF SECTIONS

If any section, subsection, sentence, clause, or portion of this section 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 9.00 IMPLEMENTATION

The terms and conditions of this regulation shall be implemented in the following manner:

Sections 1.00, 3.01, 4.03, 5.00, 6.00, 7.03, 8.00 of these regulations shall become effective 180 days from the date of passage.

Within 200 days from the date of passage, all entities operating laboratory facilities on the date of passage must file a notice of intent to file for a permit pursuant to Section 2.00 of this regulation, on a form provided by the Executive Director.

Within 200 days from the date of passage, all entities conducting any large scale use or production of an agent, as defined in this regulation, or operating under a large scale use permit issued pursuant to Boston Public Health Commission's Recombinant DNA Technology Use Regulation must file a notice of intent to file for a permit pursuant to Section 2.04 of this regulation, on a form provided by the Executive Director.

Within 60 days of receipt of the notice of intent to file for a permit, the Executive Director shall provide the entity with notice of the timetable for the completion of the application for all permits pursuant to Section 2.01 and Section 2.04of this regulation and the determination on the issuance of the permit.

Sections 2.01, 2.02, 2.03, 2.04, 3.02, 4.01, 4.02, 7.01, 7.02 of this regulation shall become effective 18 months from the date of passage.