City of Beverly, MA
Friday, January 8, 2021

Chapter 400. Board of Health Regulations

Article XII. Regulation of Biological Safety

[Adopted effective 1-1-2014]

§ 400-12.1. Purpose.

A. In order to safeguard the health and welfare of the citizens of the City of Beverly (the "City"), the City of Beverly Board of Health (the "Board of Health") hereby promulgates this regulation governing the use of all regulated biological agents (as defined herein) in the City. The use of regulated biological agents requiring Biosafety Level 4 (BSL-4) containment (as defined herein) shall not be permitted in the City of Beverly.

B. Unless specifically exempted under this regulation, all research or manufacturing involving regulated biological agents, as defined below, in the City shall be undertaken only in strict conformity with the National Institutes of Health Guidelines for Research ("NIH Guidelines"), the current edition of the Department of Health and Human Services' Centers for Disease Control (CDC) publication entitled "Biosafety in Microbiological and Biomedical Laboratories" (BMBL), and all other health regulations as the Board of Health may from time to time promulgate.

§ 400-12.2. Definitions.

As used in this regulation, the following terms shall have the meanings indicated:

BEVERLY BIOSAFETY COMMITTEE or BBC
A committee established by the Board of Health for the purpose of assisting the Board of Health in carrying out its responsibilities under this regulation.

BIOLOGICAL RISK GROUP
Equivalent to the risk group for any biological pathogen as defined in Subsection II-A-1 (Risk Groups) of the latest amendment of the NIH Guidelines for Research Involving Recombinant DNA Molecules and as specified in the latest edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL). This designation pertains to the natural risk to human health and the likelihood of transmission associated with the unaltered form of that biological agent.

BIOSAFETY LEVEL or BSL
Physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the NIH Guidelines for Research Involving Recombinant DNA Molecules (published by the National Institutes of Health, Recombinant DNA Advisory Committee) and the latest edition of Biosafety in Microbiological and Biomedical Laboratories (published by the Centers for Disease Control and Prevention).

BMBL
The current edition of the Department of Health and Human Services' Centers for Disease Control (CDC) Publication No. 21-1112, entitled "Biosafety in Microbiological and Biomedical

Laboratories."

INSTITUTION

An individual person or a group of persons, and/or a corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization and any other group acting as a unit responsible for compliance with the requirements set forth in this regulation.

INSTITUTIONAL BIOSAFETY COMMITTEE or IBC

A committee established in accordance with Subsection IV-B-2 (institutional biosafety committee or IBC) of the NIH Guidelines and any applicable requirements of this regulation. The IBC shall be the final arbiter within an institution with regard to the implementation of this regulation, with oversight by the Board of Health as described herein.

NIH GUIDELINES

The National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register of June 1, 1983, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee (RAC) within the National Institutes of Health (NIH).

REGULATED BIOLOGICAL AGENTS

Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that:

A. Is identified as a "Recombinant DNA Molecule" in Section I-B (Definition of Recombinant DNA Molecules) of the most recent revision of the NIH Guidelines (as defined herein); or

B. Is classified as a Risk Group 3 or Risk Group 4 Agent in the NIH Guidelines or the BMBL (as both are defined herein); or

C. Is identified as a "select agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 CFR 73.3, 73.4, 73.5, 73.6, 7 CFR 331.3 and 9 CFR 121.4, and the rulings made by the CDC and the USDA relative thereto, as such regulations and rulings may be amended from time to time. However, "select agent" as herein defined shall not include any de minimus amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

§ 400-12.3. Biosafety committee or professional advisory assistance.

A. The Board of Health retains all final responsibility for enforcement of this regulation. Notwithstanding the foregoing, the Board of Health, whenever the facts and circumstances deem necessary, shall be authorized to:

(1) Convene a municipal biosafety committee (known as the "Beverly Biosafety Committee" or "BBC") with three appointed members or any number of members deemed appropriate by the Board.

(2) Retain assistance from a professional consultant with appropriate professional and academic experience and training to support review of applications and required documentation.

(3) Engage the services of the Beverly Health Department for site inspection or review of compliance with documentation requirements.

B. Costs incurred by the Board of Health in utilizing any one or combination of the resources set forth in Subsection **A** may be assessed to a BSL-3 permit holder/applicant according to the time

required to inspect facilities and to review documentation for said permit holder/applicant. This cost assessment is in addition to any established permit fee(s).

C. The BBC, if established by the Board of Health as authorized in Subsection **A(1)**, will serve as an advisory committee to the Board of Health on general biosafety matters that fall within the provisions of this regulation. All appointees will be approved by the Board of Health and will have no direct conflict of interest with companies holding or requesting a permit under this regulation. All members will be subject to all ethics requirements and documents required by the City or the Board of Health. The Board of Health shall retain final authority on all matters relative to research or manufacturing of regulated biological agents performed within the City.

D. Responsibilities of the BBC, if established by the Board of Health, shall include:

(1) Recommending policies, procedures and criteria to aid in the implementation of this regulation, including recommendations related to permit application requirements, reporting requirements and inspection requirements;

(2) Reviewing biosafety permit applications and indicating support for or opposition to all such permit applications;

(3) Reviewing reports and other required documentation submitted by institutions subject to this regulation, and providing recommendations to the Board of Health regarding approval, where appropriate;

(4) Carrying out site visits to permitted facilities or facilities requesting a permit, where appropriate; and

(5) Performing other functions as may be specified by the Board of Health, to assist the Board in carrying out its duties under this regulation.

§ 400-12.4. Permit requirements.

A. All institutions proposing to use or continue the use of regulated biological agents at BSL-1, BSL-2 or BSL-3 containment levels must obtain a permit from the Board of Health before commencing or continuing said research, manufacturing, or other use of regulated biological agents and annually thereafter. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit applications, and supporting documents filed with such application. The use of regulated biological agents requiring BSL-4 containment shall not be permitted in the City.

B. Permit holder's responsibilities.

(1) Each institution seeking permit approval in the City shall certify and attest to its understanding that it shall:

(a) Conform with the NIH Guidelines.

(b) Conform with the biosafety standards established in the BMBL.

(c) Conform with other conditions set forth in this regulation.

(d) Conform with any special or specific requirements prescribed by the City as a condition of permit approval.

(e) Allow access for site inspection of facilities and pertinent records by the Board of Health or its designees upon reasonable notice, should it be deemed necessary by the Board of Health.

(f) Submit (with permit application and renewal) a copy of all minutes from IBC meetings held during the previous year. These minutes should provide sufficient detail to allow the Board of Health and its staff, members of the BBC, or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined that all work approved by the committee would be conducted safely at the assigned biosafety level using corresponding safety practices and any additional special safety practices as specified by the IBC.

(g) Submit (with permit application and renewal) a detailed table of all protocols reviewed and approved by the IBC within the previous year, including, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), the BSLs assigned after IBC review and the rationale or guidance document upon which the selected BSL was based, and the name(s) of the principal investigator(s) who shall be responsible for each protocol.

(h) Submit (with permit application and renewal) a protocol for strain verification of all known human pathogens that are considered to be attenuated or noninfectious approved by the IBC within the previous year for use within the permitted facility, if any, or sufficient documentation to demonstrate that such a screening process has been completed by another laboratory, in order to ensure the proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.

(2) Laboratories permitted to operate at BSL-3 containment will additionally be required to submit a summary of protocols approved for BSL-3 containment that identifies the specific regulated biological agents and describes the nature of the associated research, manufacturing and/or use to be conducted in the City. This summary may conform to the NIH project registration format or may follow any other format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project. Any IBC approval of a protocol or experiment that is deemed to require BSL-3 containment must be reported to the Board of Health within 30 days of that decision.

C. Requirement for an institutional biosafety committee.

(1) Institutions seeking such a permit from the Board of Health shall establish an IBC. The IBC shall be composed as described in the NIH Guidelines. In addition, in order to ensure that all facilities engaged in research or manufacturing involving regulated biological agents are conforming to the NIH Guidelines and the BMBL, the Board of Health will appoint to each IBC one member, who shall be the Chairman of the Board of Health or its designee. In addition, each IBC will also be required to identify a second noninstitutional member, as required by the NIH Guidelines. The IBC is required to meet no less than once a year, and all minutes of the institutional biosafety committee meetings must be forwarded to the Board of Health or the BBC as instructed.

(2) A complete roster of all IBC members, including names, home addresses, phone numbers, e-mail addresses and resumes or curriculum vitae (CVs), including institutional and community members, shall be maintained and submitted upon initial application or within 30 days after submission of a completed application. An updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC since the previous roster submission shall be provided with IBC minutes and other required annual documentation.

D. Permit application requirements. Institutions seeking a permit from the Board of Health must submit a completed application form obtained from the Board of Health, accompanied by a nonrefundable permit application fee, that will include the following information:

(1) Company name and address.

(2) Name(s) of corporate officer(s) authorized to sign the application and full contact information for those individuals signing on behalf of the institution.

(3) State of incorporation.

(4) Name of the institution's designated official responsible for compliance with this regulation. This is most often the designated biosafety officer, as defined in the NIH Guidelines.

(5) Designation of the appropriate biosafety levels (as defined in this regulation) for all laboratory areas, which are consistent with the NIH Guidelines or BMBL for all IBC-approved protocols. This designation should be reflected in the IBC minutes before work commences in the permitted facility or, at latest, no more than 30 days after that work commences.

(6) Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal.

(7) Floor plans showing laboratory areas. All biosafety containment, biosafety levels, and designated waste storage areas should be indicated. Updated floor plans to reflect any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal.

(8) An emergency response plan for the purpose of orienting City representatives, including, but not limited to, the Board of Health, Fire and Police Departments, to the physical plant and to procedures to be utilized in the event of an emergency. This documentation must include a floor plan showing the internal layout of the facility with specific biological containment and nonbiological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated. Amendments to this plan must be submitted as they are incorporated.

(9) Medical surveillance agreement. This service may be provided through the institution's internal clinical resources or through an independent third-party provider. A letter indicating the completion of a contractual agreement for provision of occupational medicine and medical surveillance services shall be submitted upon application and whenever the clinical provider of these services has changed thereafter.

E. Reporting of releases or adverse events. In addition to the aforementioned requirements, each institution shall provide a written summary of any incidents or adverse event involving regulated biological agents that may have resulted in an exposure to a human pathogen within the facility or in the release of a human pathogen from the facility through wastewater or direct airborne release or through improper disposal of potentially contaminated solid waste. This report shall be sent to the Board of Health as soon as it is feasible, but not more than seven days from the date of the incident. Animal bites will be considered to represent potential human exposures, unless the animal was known to be free of infection and this can be documented upon request.

F. Annual renewal fee. Permits granted by the Board of Health shall be renewed annually, subject to submission of the annual renewal fee and required documentation as described in this section. The fee for a permit granted by the Board of Health or annual renewal thereof shall be determined by the Board of Health.

§ 400-12.5. Exemptions.

A. For the purposes of this regulation, research or manufacturing will not include clinical or health-care services or professional analytical services that directly support clinical or health-care services.

B. Educational institutions utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at Biosafety Level 1 shall not be required to

obtain a permit or comply with any permit requirements stated herein.

§ 400-12.6. Violations and penalties.

A. Violation of any provision of this regulation may subject the violator to a fine of $200 per day. Each day of violation shall constitute a separate and distinct offense. The Board of Health shall be empowered to enforce this regulation in any court of competent jurisdiction as well as the noncriminal method of disposition provided in MGL c. 40, § 21D. In addition to a fine, an institution which violates any provisions of this regulation or for which continued conduct or recombinant DNA technology or other activity covered under this regulation poses an immediate threat to the public health or environment may be closed by the Board of Health.

B. Any penalty assessed pursuant to this section shall be in addition to the actual costs, losses, expenses, damages, fees or other assessments incurred by the City as a result of a violation of this regulation.

C. Revocation of permit. The Board of Health may revoke a permit if it determines that the institution has materially failed to comply with this regulation, or other applicable permit conditions. Unless there is a threat to human health, safety or the environment, no revocation shall take place until the institution has been afforded the procedural requirements set forth in § **400-12.7** of this regulation.

§ 400-12.7. Procedure for requesting and holding hearing.

Any institution, person or entity aggrieved by the decision of the Board of Health in connection with the Board of Health's enforcement of this regulation may request a hearing by filing a written petition with the Board of Health within 10 days of such action. Upon receipt of such petition, the Board of Health shall set a time and place for such hearing and not later than 30 days upon written request, and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing, the petitioner shall be given an opportunity to be heard and to show cause why the Board of Health's decision was inconsistent with the requirements set forth in this regulation. The Board of Health, upon presentation of all evidence, shall issue a final decision in connection with the relief sought.

§ 400-12.8. Appeals.

Any institution or person aggrieved by the final decision of the Board of Health shall seek relief from any court of competent jurisdiction located in the County of Essex, Commonwealth of Massachusetts.

§ 400-12.9. Confidentiality of information.

A. Information submitted to the Board of Health may be subject to the Commonwealth of Massachusetts' Public Records Law. Any institution seeking to qualify any particular document or submission as confidential shall:

   (1) Submit said information as "Confidential Information"; and

   (2) Provide the applicable statutory citation warranting the exclusion of such information from disclosure under the Commonwealth of Massachusetts' Public Records Law (MGL Chapter 66).

B. Notwithstanding this designation by the institution, any documents that are referred to during a public meeting may be subject to public review. The exchange of information pertaining to

compliance with the permit may take place in an executive session, if the information shared in a public meeting would pose a security threat or compromise proprietary information.

§ 400-12.10. Variances.

A. The Board of Health may vary the application of any provision of this regulation with respect to any particular case when the Board of Health finds the enforcement thereof would do manifest injustice and the applicant has provided that the same degree of protection required by this regulation can be achieved without strict application of the particular provision.

B. Every request for a variance shall be submitted in writing to the Board of Health and shall set forth the specific variance sought and the reasons therefor.

C. The Board of Health may establish additional conditions in connection with the granting of a variance where the interest of public health so requires.

D. No determination with respect to a variance shall be binding unless issued in writing by the Board of Health. Copies of said determination shall be available to the public at all reasonable hours in the office of the Board of Health.

E. The institution shall post any variance granted by the Board of Health at the permitted facilities in a prominent location for the duration that the variance is in effect.