

ARTICLE III: ENVIRONMENTAL HEALTH

1.0 Biological Safety Regulations

[Regulation Adopted December 13, 2022]

1.1 Purpose

To safeguard the health and welfare of the residents of the Town, the Board of Health hereby promulgates this regulation governing the use of all Regulated Biological Agents (as defined herein) in the Town. The use of biological agents requiring Biosafety Level 4 (BSL-4) containment (as defined herein), and/or classified as a Risk Group 4 Agent in the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("National Institutes of Health (NIH) Guidelines") or 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) (as both are defined herein) shall not be permitted in the Town.

1.2 Applicability

These regulations shall apply to any 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 (hereinafter collectively "Institutions") involved in or in any way undertaking any and all research or manufacturing involving Regulated Biological Agents in the Town and/or any Property Owner where any Institution is involved in or in any way undertaking any and all research or manufacturing involving Regulated Biological Agents in the Town.

1.3 Definitions

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 and as specified in the latest edition of 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: Physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the NIH Guidelines (published by the National Institutes of Health, Recombinant DNA Advisory Committee) and the latest edition of BMBL (published by the CDC and Prevention).

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

Clinical Laboratory: Healthcare facilities providing a range of laboratory procedures which aid physicians in carrying out the diagnosis, treatment, and management of patients.

Healthcare Facility: Places that provide healthcare including hospitals, clinics, outpatient care centers and specialized care centers, such as birthing centers and psychiatric care centers.

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 (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 or Synthetic Nucleic Acid Molecules published in the Federal Register of July 23, 1976, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee within the NIH.

Principal Investigator: An individual designated by an Institution to direct the biological research project or program conducted using Regulated Biological Agents (as defined herein).

Property Owner: Every person who alone or severally with others: (1) has legal title to any property or building in the Town; or (2) has care, charge or control of any property or building in the Town including but not limited to agent, executor, executrix, administrator, administratrix, trustee or guardian of the estate of the holder of legal title; or (3) is a mortgagee in possession of any such property; or (4) is an agent, trustee or other person appointed by the courts and vested with possession or control of any such property. Each such person is bound to comply with Section 6B of these regulations.

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 or Synthetic Nucleic Acid Molecules" in Section I-B (Definition of Recombinant or Synthetic Nucleic Acid Molecules) of the most recent revision of the NIH Guidelines (as defined herein);
- B. Is classified as a Risk Group 3 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 or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 C.F.R. §73.3 through 73.6, 7 C.F.R. §331.3 and 9 C.F.R. §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 minimis* amount of agents or toxins which are excluded from 42 C.F.R. §73.00 et seq.

1.4 Professional Advisory Assistance

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 retain assistance from a professional consultant with appropriate professional and academic experience and training to support review of applications and required documentation. Costs incurred by the Board of Health in utilizing a professional consultant may be assessed to a 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).

1.5 General Requirements

- A. Unless specifically exempted under this regulation, all research or manufacturing involving Regulated Biological Agents in the Town shall be undertaken only in strict conformity with the NIH Guidelines, the current edition of the BMBL, and all other health regulations of the Board of Health including those classes of experiments that are exempt the NIH Guidelines.
- B. Any Property Owner whose property will be the location of an Institution that is proposing to use Regulated Biological Agents must notify the Board of Health in writing no less than 30 days prior to occupancy that an Institution is proposing to use Regulated Biological Agents at their property. Written notification shall be submitted on a form provided by the Board of Health.
- C. 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 and/or classified as Risk Group 4 Agents in the NIH Guidelines or the BMBL shall not be permitted.
 - a. Transition Rules: Any Institution currently engaged in the regulated activities hereunder at the time of passage of these regulations, shall be required to apply for and receive a permit on or before 6 months from the passage hereof and then annually in accordance with the permit procedures set forth herein.
- D. The Board of Health may impose conditions on a permit which it finds are necessary or prudent for the protection of public health, safety, and general welfare. If, under its discretion, the Board of Health determines that a permit cannot be conditioned in a manner which will protect public health, safety and general welfare then the Board of Health may deny a permit.
- E. Institutions governed hereby shall establish and operate an IBC in accordance with NIH Guidelines unless otherwise stated herein. The IBC shall:
 - a. Include at least one member of the Board of Health or its designee.
 - b. Meet no less than once a year. All minutes of the IBC meetings must be forwarded to the Board of Health.

- c. Provide to the Board of Health a complete roster of all IBC members, including names, email addresses and resumes or curriculum vitae (CVs) with the submission of a permit application. If there is a change in IBC membership, an updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC shall be provided immediately following the new member's appointment.
- d. IBC established herein need not include a community representative unless utilizing Regulated Biological Agents identified as a "Recombinant or Synthetic Nucleic Acid Molecule" in the most recent revision of the NIH Guidelines.

F. Each Institution seeking permit approval shall certify and attest in its application that it will comply with the following requirements and 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 Board of Health 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 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 Biosafety Level (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.

- G. 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. 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.
- H. Institutions permitted pursuant to these regulations shall file an annual report with the Board of Health upon permit renewal. Such report, at a minimum, shall include complete copies of all IBC minutes for the previous year, certification that the entity is in compliance with this regulation and the NIH Guidelines and BMBL, a report on any quality assurance and quality improvement efforts made during the previous year, and a complete roster of current IBC members. 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, such information may be deemed confidential under the Massachusetts Public Records Law, however, the Board of Health cannot guarantee same.

The Board of Health may develop procedures for assuring confidentiality to the extent allowable under the Massachusetts Public Records Law.

- I. Institutions permitted pursuant to these regulations 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.

1.6 Permit Application Requirements

All Institutions which are subject to these regulations shall obtain 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 as indicated in Article I, Section 4.0 of these regulations. The application must include the following information:

- A. Institution name and address; and
- B. Name(s) of corporate officer(s) authorized to sign the application and emergency contact information for those individuals signing on behalf of the Institution; and
- C. Name and emergency contact information 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; and

- D. 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 shall be reflected in the IBC minutes before work commences in the permitted facility; and
- E. Copy of a completed biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal; and
- F. 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; and
- G. An Emergency Response Plan for the purpose of orienting Town 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 non-biological laboratory areas, biological waste storage areas, and biological waste removal routes clearly indicated. Amendments to this plan must be submitted as they are incorporated; and
- H. Documentation of a medical surveillance agreement with a qualified provider; and
- I. Upon submission of a permit application, the applicants will present an overview of the use of rDNA or Regulated Biological Agents during a regularly scheduled meeting of the Board of Health. The presentation shall include a general introduction of the Institution, its mission, its research or production plans, a timeline of the use of rDNA or Regulated Biological Agents, an overview of the applicant's biosecurity risk assessment and program, and a discussion of the facilities. A presentation is not required for permit renewals and/or additional protocols or changes in protocols unless otherwise determined to be necessary by an Agent of the Board of Health; and
- J. Permit renewal applications must be submitted by January 31 each year. Permits are valid for one year from March 1 to February 28. New permits will be issued after March 1 and the permit shall be valid from the date of issue through February 28.

1.7 Prohibitions and Exemptions

- A. The use of biological agents requiring Biosafety Level 4 (BSL-4) containment (as defined herein), and/or classified as a Risk Group 4 Agent in the NIH Guidelines or the BMBL (as both are defined herein) shall not be permitted in the Town.
- B. For the purposes of this regulation, clinical laboratories located within health care facilities or professional analytical services that directly support clinical or health care services shall not be required to obtain a permit or comply with any permit requirements stated herein.

- C. Educational institutions utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at BSL-1 shall not be required to obtain a permit or comply with any permit requirements stated herein.

1.8 Confidentiality of Information

- A. Information submitted to the Board of Health is subject to public records laws. Upon receipt of any request for public records under these laws, the Burlington Records Access Officer may consult with the Board of Health and will make a determination as to whether the requested information is exempt from disclosure for safety and security or other enumerated purposes under M.G. L. c. 4, § 7(26) and withhold any documents, or portions thereof, that are covered by an exemption.

Any Institution seeking to qualify any particular document or submission as confidential shall:

- a. Submit said information as "Confidential Information"; and
- b. Provide the applicable statutory citation warranting the exclusion of such information from disclosure under the Commonwealth of Massachusetts' Public Records Law (M.G.L. ch.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.

1.9 Penalties

Whoever violates any provision of this regulation may be subject to penalties as follows:

- A. If a designated Agent of the Board of Health determines that a party has violated this regulation, such Agent may issue a written order ("Order") to the Institution (permit holder) and its designated Agent to correct the offending deficiencies within a reasonable specified time; and/or,
- B. 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 pursuant to the authority granted in M.G.L. c. 111 § 31. Each day or portion thereof shall constitute a separate offense; and/or,
- C. 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; and/or,

- D. The Board of Health may suspend or revoke a permit if it determines that the Institution has failed to comply with this regulation, or other applicable permit conditions. Suspension or revocation shall follow written notice and a hearing in accordance with the time frame set forth in Article III, Section 1.10.
- E. In the event the Board of Health or its Agent determines there is an imminent threat to public health and safety it may suspend a permit immediately without prior notice. Any Institution thereafter may invoke the hearing process in Article III, Section 1.10 to appeal said suspension.

1.10 Hearing

Any person that has received an Order issued pursuant to Section 1.9 of this regulation may request a hearing before the Board of Health. Such request shall be in writing and shall be submitted to the office of the Board of Health in writing so as to be received by the Board of Health within ten (10) days after receipt of the Order. After said hearing, the Board of Health may affirm, modify or rescind said Order or take any other action it deems warranted and appropriate.

1.11 Variances

Upon written application and public hearing, the Board of Health may in its sole discretion vary the application of any provision of this regulation with respect to any particular case when it determines that the enforcement thereof would do manifest injustice; provided that the decision of the Board of Health shall not conflict with the spirit of this regulation or any minimum standards required by Federal or State law; and provided that the applicant demonstrates to the reasonable satisfaction of the Board of Health that a sufficiently equivalent level of protection can be achieved. Any variance granted by the Board of Health shall be in writing and shall be subject to such conditions as the Board of Health deems appropriate.