

Hopkinton Biosafety Regulation

Section 1.00 Purpose.

In order to safeguard the health, safety, and welfare of the citizens of the Town of Hopkinton (the “Town”), the Town of Hopkinton Board of Health (the “BOH”) hereby promulgates this Regulation governing the use of all Biological Agents (defined herein) in the Town, pursuant to the authority granted to the BOH under G.L. c. 111, § 31.

Section 2.00 Applicability.

This Regulation shall apply to all use of Biological Agents in the Town, including but not limited to research or manufacturing. Any person currently engaged in or initiating said use at the time of adoption of this Regulation shall apply for a permit (if so required) no later than the conclusion of the sixth month following the vote to adopt this Regulation.

Section 3.00 Definitions.

“Biological Agents” shall mean all:

- (i) microorganisms;
- (ii) infectious substances (defined herein); or
- (iii) naturally occurring, bioengineered, or synthesized component of any microorganism or infectious substance that is: (a) classified as a Risk Group 3 through 4 in the NIH Guidelines (defined herein); requires BSL-3 or BSL-4 containment as determined by an Institutional Biosafety Committee (defined herein); or (c) is a Select Agent (defined herein).

“BMBL” shall mean the 5th edition of the “Biosafety in Microbiological and Biomedical Laboratories” published by the United States Department of Health and Human Services.

“BSL” shall mean biosafety level containment as defined in the BMBL.

“CDC” shall mean the Centers for Disease Control and Prevention.

“DHHS” shall mean the United States Department of Health and Human Services.

“Director” shall mean the Town of Hopkinton Board of Health Director.

“Expose or Exposure” shall mean any situation arising from or related to the work operation of an employer where any person ingests, inhales, absorbs through the skin or eyes, is injected percutaneously, or otherwise comes into contact with any Biological Agent.

“Guidelines” shall mean either or both the NIH Guidelines or BMBL, provided as follows: (i) this term shall include all amendments, revisions, new editions, or substitutions to the NIH Guidelines or the BMBL that are adopted by the DHHS, CDC, or NIH if approved by the Commissioner or not acted upon by the Commissioner within sixty days; (ii) if the NIH Guidelines or BMBL are discontinued, rescinded, or abolished, those Guidelines in effect at the time of such discontinuance shall remain in effect in Hopkinton; and (iii) if there is a conflict between the NIH Guidelines and the BMBL, the BMBL shall control.

“Hopkinton Biosafety Committee” — shall mean the Hopkinton Biosafety Committee created and defined by Section 19.6 of the Hopkinton Board of Health Regulations.

“Infectious Substances” shall mean bacteria, viruses, fungi, rickettsiae, or protozoa.

“Institutional Biosafety Committee” – shall mean a committee established in accordance with the Guidelines and any applicable requirements of Section 19.0 of the Hopkinton Board of Health Regulations.

“NIH” shall mean the National Institute of Health.

“NIH Guidelines” shall mean the NIH’s “Guidelines for Research Involving Recombinant DNA Molecules.”

“Person” shall mean any individual person as well as natural and legal entities.

“Select Agent” shall mean any microbial or toxic agent that is listed in 42 CFR §§ 73.3-73.7, § 331.3, or 9 CFR § 121.4, or in any opinions, rulings, advisories, or other authorities issued by the CDC or USDA in relation to said rules; provided, however, that the term Select Agent shall not include any *de minimus* amount of said agents or toxins.

“USDA” shall mean the United States Department of Agriculture.

Section 4.00 Prohibited Containment

The use of Biological Agents requiring BSL-4 containment (as defined herein) shall be prohibited in the Town.

Section 5.00 Permits

The use of Biological Agents requiring BSL-3 containment (as defined herein) shall be prohibited in the Town without a permit issued by the Town Health Department and approved by the HBC. A person may be required to obtain separate permits for multiple facilities or premises if such additional permits would enhance the enforcement of this Regulation or the protection of the public health, safety, or welfare.

Section 6.00 Hopkinton Biosafety Committee—Duties and responsibilities. The responsibilities of the HBC shall include:

- A. Adopting policies, procedures, and criteria to aid in the implementation of this Regulation.
- B. Creating and establishing application and report forms, procedures, and requirements.
- C. Reviewing reports, applications, and recommendations and approving the same where appropriate.
- D. Carrying out site visits at permitted facilities.
- E. Reviewing manuals and worker training programs, approving health-safety programs, and monitoring the procedures required by this Regulation.
- F. Developing a procedure for Persons to report violations of this Regulation, the

Guidelines, or any health regulation to the HBC or Town Health Department.

Section 7.00 Permit requirements.

A. Permit Compliance. All persons holding a permit under this Regulation shall:

1. Comply with the Guidelines as defined in this Regulation.
2. Comply with other requirements or conditions set forth in this Regulation.
3. Comply with all provisions and conditions contained in permits issued under this Regulation.
4. Allow reasonable inspections of facilities and records by the HBC.
5. Prepare and submit to the HBC a health and safety manual that contains all procedures relevant to the use of Biological Agents at all levels of containment in use at the facility that further includes a program for waste disposal in compliance with all applicable federal, state, and local laws.
6. Establish a training program of safeguards and procedures for personnel using Biological Agents.
7. Comply with all other permit requirements established by the Town Health Department or HBC.
8. Prevent any event, condition, or circumstance involving a Biological Agent that creates or may create a threat to the public health, safety, or welfare.
9. Comply with all orders and directives of the Director, BOH, and HBC.

It shall be a material violation of this Regulation for a person holding a permit to fail to comply with any of the items listed above.

B. Confidentiality. Any person proposing to use Biological Agents may designate documents submitted to the Town as “proprietary” and include an appropriate citation to an explanation of the basis for the document’s confidentiality and exclusion from public disclosure under the Massachusetts Public Records Law, G.L. c. 4, § 7(26).

Upon receipt of a document labeled as confidential and containing a sufficient explanation of the basis for confidentiality, the Town shall segregate the same from the Town’s publicly available file. The HBC shall develop procedures to protect the confidentiality of any information which, if released, could jeopardize the health and safety of the public (including, without limitation, lab locations and security measures).

Notwithstanding the foregoing, the Town shall not keep confidential or exempt from disclosure to the public any documents that are a public record within the meaning of the Public Records Law.

C. Issuance and Renewal. Permits shall be valid for one year, unless otherwise modified, amended, or revoked under this Regulation. Permits may be annually renewed and shall thereafter remain valid for an additional one-year period, unless otherwise modified, amended, or revoked under this Regulation. Permit issuance and renewal shall be subject to compliance with this

Regulation and all other applicable federal, state, and local law. The Director may establish fees for the issuance and renewal of permits.

Section 8.00 Professional Advisory Assistance.

The BOH retains all final responsibility for enforcement of this regulation. Notwithstanding the foregoing, the BOH, 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 or to support enforcement of this Regulation. Costs incurred by the BOH 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).

Section 9.00 Reports.

A. All permit holders shall file regular reports with the HBC, in a manner and frequency to be determined by the HBC.

B. All minutes of HBC meetings shall be sent to the Director or his or her designee within a reasonable time after an HBC vote to adopt such minutes.

Section 10.00 Medical surveillance program.

All permit holders shall provide an appropriate medical surveillance program and that is otherwise consistent with the Guidelines. All such programs shall be approved by the HBC as a condition of any permit.

Section 11.00 Notification of violations.

All permit holders are responsible to regularly monitor their own compliance with this Regulation. No later than 30 days following the discovery of any violation of this Regulation, a permit holder shall notify the HBC of any such violation.

Section 12.00 Protection against rodents and insects.

Permit holders shall develop and implement rodent and insect control programs for any premises where Biological Agents are stored or in use under this Regulation. Upon request of either the Town Health Department or HBC, a permit holder shall furnish a copy of all documentation concerning such a program and shall make said premises available to the Town for inspection. If the Town Health Department or HBC determines that any such program is not sufficiently protecting against rodents or insects to protect the public health, safety, and welfare, then the Town Health Department or HBC may issue appropriate orders to modify said program.

Section 13.00 Reports of Accidental Releases.

Any accidental (i) release of a Biological Agent, (ii) exposure, (iii) accident involving a Biological Agent, or (iv) Biological Agent related illness, any of which result in a potential hazard to any person shall be reported to the Director immediately and in no case more than twenty-four hours after the release, exposure, accident, or illness.

Section 14.00 Enforcement--Violation--Penalty.

- A.** Enforcement of this Regulation shall be by the BOH or its designated agent.
- B.** Any person who violates any provision of this Regulation or any provision or condition of a permit shall be subject to a fine of three hundred dollars per violation. Each day any violation continues shall constitute a separate and distinct offense subject to a separate fine. 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 Town as a result of a violation of this Regulation.
- C.** The BOH or its agent may require any permit holder, at any time or on a schedule set by the BOH, to comply with water, effluent or soil testing, evaluation, or other procedure to demonstrate conditions are in compliance with the health and safety needs of the Town.
- D.** The BOH or its agent may issue written orders to any person who has violated this Regulation or any provision or condition of a permit to correct the violation.
- E.** The BOH or its agent may revoke, suspend, or modify any permit issued under this Regulation for a material failure to comply with the provisions of this Regulation. Prior to any revocation, suspension, or modification for such a material failure, the Town shall provide the permit holder with notice of the violation and shall hold a hearing concerning the same.
- F.** Notwithstanding the above, the Director, upon a determination that any violation constitutes an immediate and severe threat to the public health, safety, or welfare, may order the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice or a hearing. Within a reasonable time following such an order, the Town shall provide notice and hold a hearing consistent with the requirements of paragraph E of this section.