Natick Board of Health Regulation

Chapter 30

Biological Safety Regulation

Section 1. AUTHORITY

This regulation is adopted pursuant to its authority granted under Massachusetts General Laws Chapter 111, Section 31.

Section 2. PURPOSE AND INTENT

In order to safeguard the health and welfare of the citizens and visitors of the Town of Natick (the "Town"), the Natick Board of Health hereby promulgates this regulation governing the use of all regulated biological agents (as defined herein) in the Town.

Section 3. DEFINITIONS

AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care International

Animals: Warm-blooded animals as defined in the Animal Welfare Regulations as listed under Title 9 Code of Federal Regulations (CFR) 1.1 – Definition of Terms

Animal Research Components: Animals used in research that are not covered under the definition as set under 9 CFR 1.1. This includes, but is not limited to birds, rats of the genus Rattus or mice of the genus Mus that are bred for use in research, reptiles, amphibians, fish, and invertebrates.

Biological Agent: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance (including, but not limited to, biologically produced toxins and prions), or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance.

Biological Risk Group: Equivalent to the risk group for any biological pathogen as defined in *Risk Groups* (Subsection II-A-1) of the latest amendment of the NIH Guidelines (defined below), and as specified in the latest edition of the BMBL (defined below). Risk Group designation describes the natural risk to human health and the likelihood of transmission associated with the unaltered form of each biological agent.

Biosafety Level: Physical containment as defined in Physical Containment Levels (Appendix G-II) of the latest amendment of the NIH Guidelines (defined below) and the latest edition of BMBL (defined below).

Biosafety Manual: A document that provides information, guidelines, policies, and procedures that will enable and encourage those working in the Institution's environment to work safely and reduce or eliminate the potential for exposure to biological hazards.

Biosafety Officer (BSO): Individual assigned by the Institution responsible for developing, implementing, and maintaining a comprehensive biosafety, biocontainment, and biosecurity management program for an Institution. The BSO is responsible for managing the Institution's biological safety program, and conducts periodic inspections to ensure compliance with developed programs and this Regulation.

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."

Board of Health: The Natick Board of Health

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

Healthcare Facility: Places that provide healthcare including, but not limited to hospitals, clinics, outpatient care centers and specialized care centers, such as birthing centers and psychiatric care centers.

Institution: Any public or private entity (including but not limited to: individual person or group, corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization) 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 of the NIH Guidelines (defined below) and any applicable requirements of this regulation. The IBC shall be the party responsible within an institution with regard to the implementation of this regulation, with oversight by the Board of Health as described.

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 (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:

1. Are 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 above), or

2. Are classified as a Risk Group 3 or 4 agent in the NIH Guidelines or above by the BMBL (as defined above), or

3. Are identified as a "Select Agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), under 7 CFR Part 331, 9 CFR 121, and 42 CFR Part 73. Excluded from this Regulation are *de minimis* amounts of agents or toxins which are excluded from 42 CFR 73.00 et seq.

Veterinary Facility: Places that provide clinical care and/or laboratory support for healthcare of animals including hospitals, clinics, outpatient care centers, and specialized care centers such as dental or surgical facilities.

SECTION 4. GENERAL REQUIREMENTS

A. All Institutions proposing to use Regulated Biological Agents, unless specifically exempt herein, shall obtain a permit from the Board of Health before commencing or continuing research, manufacturing, or other use of regulated biological agents.

B. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit, as supported by the supporting documents as filed with said application.

C. The use of regulated biological agents requiring Biosafety Level (BSL)-3 or above containment as described in the NIH Guidelines and the BMBL shall not be permitted in Natick.

D. All Institutions working with BSL-2 biological agents shall designate a biosafety officer. The biosafety officer shall be responsible for facilitating compliance with this Regulation on behalf of the Institution. In the event the BSO is replaced, the Institution shall notify the Board of Health within seventy-two (72) hours of appointment.

E. Each Institution applying for a permit under these regulations shall establish and operate an Institutional Biosafety Committee (IBC) in accordance with NIH Guidelines and this Regulation unless specifically exempted by the Board of Health.

F. The IBC must consist of:

1. Institution's Biosafety Officer

2. Researcher with subject matter expertise

3. At least one staff member of the laboratory

4. Person(s) familiar with Institution technology and research and its risks.

5. If animal research components, plants or recombinant DNA work is conducted, a committee member who is an expert in that field.

6. Other applicable staff or representatives as determined necessary by the Board of Health in order to safeguard the public health

G. Each Institution seeking permit approval shall certify and attest in its application that it will comply with the NIH Guidelines, the biosafety standards established in the BMBL, and all other conditions set forth in this Regulation. 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, is required by the Board of Health as a condition of permit approval.

H. Institutions shall provide a written summary of any incidents or adverse event involving biological agents, toxins, or other hazardous materials that may have resulted in an exposure within the facility, or in the release from the facility involving groundwater, wastewater, direct airborne release, or any 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 (7) days from the date of the incident. This requirement does not supersede or replace notification required by any other federal, state, or local regulation

I. In the event of an incident or adverse event, as described in Section 4. H. of this Regulation, testing as requested by the Board of Health shall be followed in order to prevent the release of any viable biological organisms into the environment, of particular concern are contamination of the local aquifer or aerosol releases, and to comply with all provisions of 105 CMR 480.000, Minimum Requirements for the Management of Medical or Biological Waste.

SECTION 5. PERMITTING REQUIREMENTS

All Institutions that are subject to these Regulations shall obtain a permit from the Board of Health. Permit applications will be provided by the Board of Health. Application for a permit must be accompanied by a nonrefundable permit application fee. The application must be submitted electronically and shall include the following information:

A. Institution name and address, both physical and corporate.

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.

C. Name and emergency contact information of the Institution's designated official responsible for compliance with this Regulation. Including the designated Biosafety Officer.

D. 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:

1. The location of the Institution on a local map.

2. A plot plan showing the location of the permitted facility with all points of entry clearly Indicated.

3. A floor plan showing the internal layout of the facility with specific biological containment, laboratories, non-biological laboratory areas, biological waste storage areas, chemical storage areas, and biological waste removal routes clearly indicated.

4. Ventilation system plan insuring air and substances are not entering common areas, residences, shopping areas or areas of high population density.

5. Updated floor plans to reflect any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal. Any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal to be considered and approved by the Board of Health.

E. 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.

F. Description of all biological agents in use, and all protocols reviewed and approved by the IBC in the past year, in sufficient detail to allow the Board of Health and its Agents or professional consultants to understand the risk assessment and risk assignment process by which the IBC determined biosafety level and corresponding safety practices. Documentation must include, at a minimum:

1. A listing of all biological agents utilized (e.g., host cell lines, biological vectors)

2. Any inserted gene sequences that would elevate risk (e.g., oncogenes)

3. The BSLs assigned after IBC review, with the rationale or guidance document upon which the selected BSL was based.

G. Copy of a completed biosafety manual.

H. An evaluation of the public health and environmental risks associated with all biotechnology- byproduct effluents generated by the facility and a determination of the applicability of conditions, including appropriate effluent treatment requirements for waste disposal, consistent with 105 CMR 480.000.

I. A treatment and/or monitoring plan and signed vendor agreement for systematic pest control management in laboratories, contiguous facilities and food service establishments (separately permitted by the Board of Health) in any and all facility buildings.

J. The Institution's health monitoring and surveillance plan for an appropriate medical surveillance program including oversight by an occupational health physician, or documentation of a signed medical surveillance agreement with a qualified provider. Plan must include consideration of workers from susceptible populations such as pregnant or immunocompromised.

K. Institutions shall notify the Board of Health of any proposed changes in assigned biosafety level, use of Biological Agent(s) and change or expansion of laboratory areas. Board of Health approval shall be granted prior to any implementation of changes in the Institution's operation. Failure to do so may result in suspension or revocation of permit

L. Upon submission of a permit application to operate a BSL-2 Institution and dependent on proximity to residential buildings or high density population areas for the proposed location of the Institution, the Board may require additional action from the applicant. This action includes, but is not limited to enhanced Institution ventilation systems, prevention of cross ventilation conditions, physical barriers, or additional containment structures.

M. Institutions permitted pursuant to these regulations shall file a report to the Board of Health annually, and for each permit renewal cycle. This report, at a minimum, shall include:

1. Copies of updated biosafety manual(s) with training records for all current employees.

2. Copies of all IBC minutes for the preceding calendar year

3. Certification that the entity is in compliance with this Regulation and the NIH Guidelines and BMBL.

4. A report on any quality assurance and quality improvement efforts made during the previous year.

5. A complete roster of current IBC members.

SECTION 6. PERMITS AND FEES

A. The application fee for a permit or annual renewal by the Board of Health shall be determined by the Board of Health

B. 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.

C. Acceptance of this permit is acknowledgement that it is the responsibility of the Institution to properly decommission the facility at end of use. Upon moving or closing a facility permitted by the Board of Health under these regulations, the institution shall submit a report to the Board of Health and Natick Fire Department indicating that the facility was properly decommissioned; including, but not limited to, cleaning and sanitizing drain lines and tanks, removal of all hazardous materials and wastes and removal of all biological material and wastes. Upon receipt of this documentation, the Board of Health may conduct a final inspection of the facility.

SECTION 7. PROHIBITIONS

A. The use of biological agents requiring Biosafety Level 3 (BSL-3) containment (as defined herein) or above, 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 of Natick.

B. The use of warm-blooded “animals”, as defined in the USDA Animal Welfare Regulations, 9 CFR 1.1, shall be prohibited in Institutions operating in the Town of Natick

C. The use of Animal Research Components shall only be allowed provided the Institution meets the requirements of Section 5., F (5), and applies for AAALAC accreditation and receives this accreditation within a time determined sufficient by the Board of Health through the accreditation process established by AAALAC.

SECTION 8. EXEMPTIONS

A. Clinical laboratories located within health care facilities, professional analytical services that directly support clinical or health care services, professional analytical laboratories conducting routine air, water or food quality tests, or veterinary facilities shall not be required to obtain a permit or comply with any permit requirements as stated herein unless these facilities are also engaged in research or production of biological agents.

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.

SECTION 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..

SECTION 10. ENFORCEMENT

A. The enforcement of this Regulation shall be the responsibility of the Board of Health and its approved agents.

B. The Board of Health retains all final responsibility for enforcement of this regulation, The Board of Health shall retain the authority to designate an independent consultant, professionally competent, paid for by the Institution, to review applications, perform inspections, conduct testing, and investigate incidents.

C. Frequency of inspections will be reasonably determined by the Board of Health in accordance with the risk associated with the regulated activity. The results shall be reported to the Board of Health, and the Institution involved.

D. Any Institution currently engaged in these regulated activities at the time of passage of these Regulations, shall initiate the permit application process within 6 months and apply for and receive a permit on or before 1 year from the passage hereof and then annually in accordance with the permit procedures set forth herein.

SECTION 11. 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 and shall set forth the specific variance sought and the reasons therefore.

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.

SECTION 12. VIOLATION

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

A. If a designated agent of the Board determines that a party has violated this regulation, such agent may issue a written order ("Order") to the Institution (permit holder) and/or its designated agent to correct violations within a reasonable specified time.

B. Violation of any provision of this regulation may subject the violator to a fine of $500 per day. Each day of violation shall constitute a separate and distinct offense.

C. An Institution to whom an order has been served pursuant to this Regulation may request a hearing before the Board of Health by filing a written petition requesting a hearing with the Board of Health within seven (7) days after the day the order was served. Upon receipt of such petition, the Board of Health will set a time and place for such hearing not later than 30 days after the day on which the order was served. The Board of Health may postpone the date of a hearing for a reasonable time beyond such 30- day period, if in the judgment of the Board of Health the petitioner has submitted sufficient reason for such postponement.

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.

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 request a hearing process to appeal a suspension. After a hearing, the Board may affirm, modify or rescind said Order, or take any other action it deems warranted and appropriate.

SECTION 13. SEVERABILITY

If any provision of this Regulation is declared invalid or unenforceable, the other provisions shall not be affected thereby but shall continue in full force and effect.

SECTION 14. EFFECTIVE DATE

This Regulation shall be effective as of May 1, 2023

Karla H. Sangrey, PE, Chair

Peter A. Delli Colli, DMD, Vice Chair

Donald J. Breda, PE, Clerk