# Board of Health



## ARTICLE 11 BIOSAFETY REGULATION

### SECTION 11.1 AUTHORITY

The Needham Board of Health (the "Board"), pursuant to the authority granted under Massachusetts General Laws Chapter 111 section 31 hereby adopts the following regulation to protect the-public health of the community**.**

### SECTION 11.2 PURPOSE

In order to safeguard the health and welfare of the residents of the Town of Needham (the "Town"), the Board hereby promulgates this regulation governing the use of all biological agents within the Town. The use of biological agents requiring Biosafety Laboratory 3 containment shall not be permitted within the Town without a variance from the Board and the Biosafety Committee. Biosafety Laboratory 4 containment shall not be permitted in Needham.

### SECTION 11.3 DEFINITIONS

***Board:*** The Board of Health or its agent or designee.

***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 is identified as part of any defined risk group as defined by the National Institutes of Health (NIH) Guidelines (as defined below); or requires a BSL 3 containment as determined by an Institutional Biosafety Committee (as defined below); or is identified by the United States Department of Health and Human Services ("DHHS") or the United States Department of Agriculture ("USDA") as a "Select Agent" (as defined below).

***Biotechnology:*** The use of modern biological techniques for industrial or research purposes. The term Biotechnology shall include any industrial or research activities which use recombinant DNA molecules (rDNA) or organisms and viruses containing rDNA.

***Needham Biosafety Committee (the Committee):*** The Needham Biosafety Committee shall be composed of the Chairman of the Board or his/her designee, the Town's Director of Health and Human Services or her/his designee, and a up to three other members to be appointed by the Board of Health. Members are selected through an application process based on their professional experience or advanced graduate level studies in biotechnology, rDNA technology, public health, or another related scientific field.

***Director:*** The Town Director of Health and Human Services.

***Guidelines:***

**(1)** National Institutes of Health (NIH) Guidelines for Research involving Recombinant DNA 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.

**(2)** Biosafety in Microbiology and Biomedical Laboratories (BMBL), newest edition as provided by the Centers for Disease Control and Prevention (CDC).

**(3)** Any amendments, revisions or substitutions enacted subsequent to the above-referenced guidelines. In the event that there is a conflict between the NIH Guidelines and the BMBL, the Needham Biosafety Committee will review and opine on the appropriateness of next steps. It is incumbent on the IBC, however, to seek the appropriate legal advice from federal authorities concerning the conflict and present such advice to the Board.

***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.

***Select Agent***: shall mean any microbial and toxic agents listed at 42 CFR §73, 7 CFR § 331 and 9 CFR §121, 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 shall not include any de minimis amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

***Recombinant DNA Molecules (rDNA):*** As defined in the NIH guidelines, as defined above.

***Substantive Change:*** Any change in hazard designation as identified in the NIH guidelines.

## SECTION 11.4 NEEDHAM BIOSAFETY COMMITTEE

***11.4.1*** The Needham Biosafety Committee shall establish policies, procedures, and criteria to aid in the implementation of this regulation.

***11.4.2*** The Needham Biosafety Committee shall review reports, applications, and recommendations by the IBC and approving them where appropriate. This includes reviewing of all submissions required in this regulation and any special determinations as it deems necessary.

## SECTION 11.5 LABORATORY REGISTRATION REQUIREMENTS

***11.5.1*** The use of biological agents requiring Biosafety Laboratory 3 containment shall not be permitted within the Town without a variance from the Board and the Biosafety Committee. BSL 4 containment shall not be permitted in Town.

***11.5.2*** All permitted institutions proposing any use of biotechnology or rDNA technology, as defined in and not exempted by the NIH Guidelines, which seeks to operate in the Town must first register with the Board before engaging in any biotechnology or rDNA activity, and the Board must be notified prior to construction or renovation of facilities for those use(s).

***11.5.3*** The institution shall:

**(1)** Submit an initial registration to the Needham Public Health Department before engaging in any activity that requires a biosafety level.
**(2)** Renew and update the registration annually by May 30th of each calendar year.
**(3)** Submit all the following documentation for new registrations and renewals:

A. Names and contact information for site-based personnel who may be contacted in the event of a facility emergency
B. Name and emergency contact information for site-based personnel who are familiar with the work involving recombinant DNA and biological agents and the institution's biosafety program
C. Plot plan showing the proposed location of the facility and floor plan showing internal layout
D. A listing of all organisms, containment levels, and decontamination procedures to be employed
E. The screening process to ensure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process
F. A plan for systematic monitoring of waste to assure that viable rDNA organisms will not be released into the environment
G. A description of the training program of safeguards and procedures for personnel using rDNA and a copy of the training manual
H. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building
I. A plan for systematic security of the premises
J. A plan for orienting representatives of the Needham health, fire, and police departments to the physical plant and to procedures to be utilized in the event of an emergency
K. The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC and in accordance with NIH guidelines for all persons engaged in the use of rDNA. This includes:
    a. Immediate reporting of any employee exposure of illness, facility spill, or release that could potentially be related to the use of rDNA or biological agents used on site from an approved IBC protocol.
    b. A description of the training program of safeguards and procedures for personnel using rDNA and biological agents, and a copy of the training manual
L. Institutional Biosafety Committee (IBC):
    a. List of members with titles, including at least one community representative from the Town of Needham
    b. All minutes of the IBC meetings must be forwarded to the Needham Biosafety Committee
    c. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying the experiments conform with all applicable regulations, shall be filed with the Needham Biosafety Committee
M. Evidence of an effective compliance program to detect and prevent wrongdoing, in accordance with guidance from the U.S. Department of Health and Human Services' Office of the Inspector General (OIG).
N. An annual report summarizing the work performed over the past year and addressing any ongoing work, as well as a current list of IBC members, copies of the previous year's IBC minutes, and a summary of the changes in research in the past year.

O. If applicable, sharps permit as required by Needham Public Health.

**(4)** Allow inspections, at reasonable times, of both the institution's facilities and records, as related to this regulation.

**(5)** Submit any major modifications to the plans (including without limitation building modifications, changes in work that would require a new registration with the institutions' IBC, or changes in any of the above plans) for a required updated registration with the Town Public Health Department. All new paperwork would need to be submitted and reviewed by the Needham Biosafety Committee 60 days before modifications or changes are made.

***11.5.4*** The Needham Biosafety Committee will have 60 days from the filing of an initial registration or renewal to review all documentation and requirements as laid out in this regulation and submit it approval or denial of the registration to the Public Health Department.

***11.5.5*** Pre-existing Institutions shall have 90 days from adoption of this regulation to register with the Board.

***11.5.6*** Clinical laboratories located within licensed healthcare facilities, professional analytical services that directly support clinical or healthcare 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 this regulation unless these facilities are also engaged in research or production of biological agents. 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 this regulation.

***11.5.7 Fees:***

**(1)** Registration and renewal fees are $500.00

**(2)** Modification to plans and reinspection fees are $250.00

**SECTION 11.6 CONFIDENTIALITY**

***11.6.1*** Information submitted to the Board or its agents may be subject to G.L. c.66. The Board will make good faith effort to withhold from release all maps, layout plans, security schematics and other information that may fall within the confines of G.L. c.4, §7(26)(n). Any institution seeking to qualify any record as confidential shall mark such record as "Confidential" so that the Board may inform the institution if the record is subject to a public records request and give the institution an opportunity to seek judicial relief within the 10-business day response period required by G.L. c.66.

**SECTION 11.7 ANIMALS**

All research institutions planning to conduct experiments on animals must first obtain an animal permit. All activities must comply with federal and state ordinances, including:

a. Public Health Service Policy "Guide for Care and Use of Laboratory Animals"
b. Public Health Service "US Government Principals for the Utilization and Care of Vertebrate Animals used in Testing Research and Training"
c. Public Health Service "Animal Welfare Regulations"
d. Public Health Service "AVMA Guidelines on Euthanasia"
e. Punic Health Service "Program on Animal Care and Use"
f. The Health Research Extension Act of 1985

Each institution that performs research, experiments, or biotechnical procedures using animals shall maintain or establish an Animal Care and Use Committee, which, according to federal and state ordinances, shall have a member who is not and has not been affiliated with the institution. In addition to previously listed Biosafety Permit Requirements, institutions using animals for research are required to submit:

A. Name and contact information of a person in the organization familiar with the animals to be housed on the property and the experiments performed
B. Names and contact information of members of Animal Care and Use Committee and dates of meetings of the Animal Care and Use Committee held the previous year
C. The results of all federal and state inspections concerning animal care and use in the previous year

**SECTION 11.8 ENFORCEMENT AND PENALTIES**

***11.8.1*** Any institution that violates the terms of this regulation shall be subject to a fine of five hundred dollars $500 per offense. Each day shall constitute a separate offense.

***11.8.2*** Violations of this regulation and penalties listed in Section 11.8.1 may be subject to non-criminal disposition, M.G.L. Chapter 40, Section 21D, and Town of Needham, General By-Laws, July 1996 compilation, Section 9.2.2.6, Board Regulations, and as amended. Each day that the offense continues shall constitute a separate offense.

***11.8.3*** This regulation may be enforced by the Board and/or by the Town's Director of Health and Human Services or his/her designee, the Fire Chief or his/her designee, or by the Building Commissioner or his/her designee. If the enforcing official determines that an institution has violated this regulation, the official may issue a written order to the institution to correct violations within a reasonable specified time. The institution may request a hearing before the Board by filing a written request for a hearing with the Board within seven (7) days of being served with the order. Upon receipt of the request, the Board will schedule a hearing to occur no later than fourteen (14) days of receiving the request.

***11.8.4*** The Board may suspend or revoke a registration if it determines that the institution has failed to comply with the terms of this regulation or other permit condition. Suspension or revocation shall follow a written notice and hearing procedure as described above.

**11.8.5** If the Board or its agent determines that there is an imminent threat to public health or safety, it may immediately suspend a registration without prior notice. In this instance, the Board shall schedule a hearing within five (5) days of the suspension. After the hearing, the Board may affirm, modify, or rescind the suspension or take other action it deems appropriate.

**11.8.6** The Board retains the authority to designate independent consultants to review applications, perform inspections, conduct testing and investigate incidents at the institutions. The frequency of inspections will be determined by the Board. Such consultants shall act as agents of the Board.

**SECTION 11.9 VARIANCE**

The Board may take requests for varying the application of any provision of this regulation with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board is not in conflict with the spirit of these standards. Any request for a variance, including a change of biosafety level, must be made in writing, set forth the specific variance sought, and explain the reasons for the variance. The request for a variance will be made available for public comment and a public hearing before it is considered by the Board of Health and Biosafety Committee. Any variance granted by the Board must be in writing with a copy available to the public at all reasonable hours in the Office of the Town Clerk and in the Office of the Board. The Board may establish additional conditions in connection with the granting of such a variance when the interest of public health so requires.

**SECTION 11.10 SEVERABILITY**

In the event any section, subsection or provision of the regulation is held to be invalid or unenforceable, the remainder of this regulation shall remain in full force and effect.

**SECTION 11.11 EFFECTIVE DATE**

Substantial revisions to Article 11 were discussed by the Board of Health at its public meetings in November and December 2022, and again at its meetings in January, February, March, and April 2023. Public Hearings on the proposed revisions were conducted on February 16, 2023 and March 17, 2023. The revisions to Article 11 were formally adopted by the

Needham Board of Health at its meeting on April 14, 2023 following a unanimous vote. The revised regulation shall take effect on 6/15/2023.

The original Article 11, Biotechnology Registration Regulation, took effect following public hearings and a Board of Health vote on July 20, 1993.