



## Board of Health

Edward Cosgrove, PhD  
Chair

Stephen Epstein, MD, MPP  
Member

Jane Fogg, MD, MPH  
Vice Chair

### **ARTICLE 11**      **BIOTECHNOLOGY REGISTRATION REGULATION**

#### **SECTION 11.1**      **AUTHORITY**

The Needham Board of Health, 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**

The Needham Board of Health recognizes that the use of modern biological techniques for industrial purposes do not pose unique risks to public health or the environment when the activities are conducted in accordance with accepted best scientific practice. However, following the recommendations of the Needham Biotechnology Committee, it is the opinion of the Board of Health that the existing regulatory structure in the Town of Needham is not sufficient to ensure that Town officials would be alerted to the presence of biotechnology companies in the Town.

The assessment of potential health risks is one of the primary roles and responsibilities of a public health agency.

Accordingly, the Board of Health declares that the purpose of this regulation is to require registration of biotechnology companies, to enable the Board of Health and other town officials to better assess and monitor potential fire and other hazards posed by flammable chemicals and hazardous materials.

#### **SECTION 11.3**      **DEFINITIONS**

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

**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.

**Director:** The Director for the Needham Board of Health or designee.

**Guidelines:**

(1) National Institutes of Health (NIH) Guidelines for Research involving Recombinant DNA molecules as published in the Federal Register of April 27, 1995.

(2) Any amendments, revisions or substitutions enacted subsequent to the above-referenced "Guidelines".

**Institution:** A single individual, group of individuals, association, organization, corporation educational institution, or medical facility conducting rDNA research, rDNA development, rDNA production, or biological material therapies or diagnostics.

**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      LABORATORY REGISTRATION REQUIRED**

**11.4.1** All institutions proposing any use of rDNA technology, as defined in and not exempted by the NIH Guidelines, which seeks to operate in the Town of Needham must first register with the Needham Board of Health before engaging in any rDNA activity, including construction or renovation of facilities for rDNA use(s).

**11.4.2** The institution shall:

- (1) Register using a form approved by the Board of Health.
- (2) Renew and update the registration annually.
- (3) Submit copies of all registration materials to the Building Department, Fire Department, Emergency Management Department and the Planning Board.
- (4) Allow inspections, at reasonable times, of both the institution's facilities and records, as related to these regulations.

**11.4.3** Pre-existing Institutions shall have 90 days from adoption of these regulations to register with the Board.

## **SECTION 11.5      REGISTRATION**

**11.5.1** In order to register, the following information must be submitted, using an application form approved by the board, to the Board of Health:

- (1) Name of institution.
- (2) Address, telephone, and fax number.
- (3) Names and telephone numbers of persons designated to be contacted on a 24-hour a day basis in case of an emergency.
- (4) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility(s).
- (5) General statement of the company's intended area of research.
- (6) General statement of the types of hazardous, bio hazardous, infectious or radioactive materials expected to be used in the facility.
- (7) Evidence of certification, as necessary, from the Massachusetts Department of Environmental Protection and the Massachusetts Department of Public Health.

**11.5.2** In order to register, the following information must be submitted to the Board of Health, on a form which is approved by the Board of Health:

- (1) The chief executive officer must certify that the company adheres to the NIH Guidelines for recombinant DNA Research.

### **11.5.3 Fees:**

The fee for registration shall be as designated in Article 17 of the Board of Health Regulations, Permit, License and other Fees.

**SECTION 11.6            RENEWAL OF REGISTRATION**

*11.6.1* The registration shall be valid for one year.

*11.6.2* All companies registered with the Board of Health must renew their registration within thirty (30) days of the expiration of the registration.

*11.6.3* The Board of Health must be notified of any substantive changes in operation at least thirty (30) prior to the change.

**SECTION 11.7            VARIANCES**

*11.7.1* The Board may vary the application of any provision of these regulations, with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice or conflict with the spirit of any minimum standard established by these regulations. Any variance shall, while it is in effect, be available to the public at all reasonable hours in the office of the Town Clerk, or in the office of the Board of Health.

**SECTION 11.8            ENFORCEMENT AND PENALTIES**

*11.8.1* Any person who violates the terms of these regulations 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 8.a. 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 of Health Regulations, and as amended. Each day that the offense continues shall constitute a separate offense.

*11.8.3* These regulations may be enforced by the Town of Needham: Board of Health director or his designee, the Fire Chief or his designee, or by the Building Inspector or his designee.

**SECTION 11.9            SEVERABILITY**

In the event any section, subsection or provision of the regulations are held to be invalid, it shall not effect the validity of any other section, subsection or provision thereof.

**SECTION 11.10          EFFECTIVE DATE**

This regulation shall take effect after publication of a summary of the regulation in a newspaper published in the Town of Needham. As required by Massachusetts General Laws, Chapter 111, Section 31, an attested copy has been filed with the Department of Environmental Protection. A public hearing regarding this regulation was held on 07/20/93. This regulation was voted by a majority of the board on 07/20/93.