

BOSTON PUBLIC HEALTH COMMISSION BOARD
CITY OF BOSTON

RECOMBINANT DNA TECHNOLOGY: USE REGULATIONS

**SECTION 1.00 GUIDELINES FOR THE REGULATION OF RECOMBINANT
DNA USE.**

1.01. APPLICABILITY

These regulations apply to all use of Recombinant DNA Molecules by institutions in the City of Boston, which shall be undertaken only in strict conformity with the "Guidelines," as defined, and in conformity with such other health regulations as the Boston Public Health Commission Board may from time to time to time promulgate or administrative practices which the Boston Public Health Commission Executive Director may from time to time require.

1.02. DEFINITIONS

- a. "Board" shall mean the Boston Public Health Commission Board.
- b. "Boston RDNA Advisory Committee" (BRAC) shall mean an advisory committee appointed by the Executive Director to advise the Board and the Executive Director in carrying out the duties and responsibilities of the Board and the Executive Director in regulating RDNA research, production, and technology in the City of Boston.
- c. "Executive Director" shall mean the Boston Public Health Commission Executive Director and may include his or her designee.
- d. "Guidelines", unless otherwise specified, are defined as:
 - (i) *National Institutes of Health (NIH) Guidelines for Research Involving recombinant DNA molecules* as published in the Federal Register of April 2002.

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

(iii) Any further amendments to (i) or (ii) above, wherever published, which are adopted by NIH and approved by the Executive Director. Amendments not acted upon by the Executive Director within sixty (60) days shall be considered approved.

e. "Institution" shall mean any single individual, group of individuals, or organization, whether public or private.

f. "Institutional Biosafety Committee" (IBC) shall be a committee established by an institution in accordance with the "Guidelines" and the terms set forth in these regulations.

g. "Recombinant DNA molecules" (RDNA) and "organisms and viruses containing RDNA" are those defined in the "Guidelines", as defined above.

h. Any other terms, not specifically defined herein, shall have the meaning as defined in the "Guidelines". If the "Guidelines" do not define the term, it shall have the meaning as is commonly used.

1.03. PERMIT REQUIREMENTS

a. All institutions proposing any use of RDNA technology, as defined in and not exempted by the November 21, 1980 NIH Guidelines, must obtain an RDNA use permit from the Board before engaging in any RDNA activity, including construction or renovation of facilities for RDNA use(s).

b. Permit requirements shall, at minimum, include written agreement and evidence to demonstrate the capacity to:

(i) Follow the Guidelines as defined in these regulations.

(ii) Adhere to any other conditions as set forth in these regulations.

(iii) Allow inspections, at reasonable times, of both the institution's facilities and records, as related to these regulations.

(iv) Adhere to a Health and Safety Manual, prepared by the institution, which contains all procedures relevant to the use of RDNA at all levels of containment at use at the institution. The manual shall also include a plan for waste disposal in compliance with all applicable federal, state, and local regulations.

(v) Establish and implement a training program of safeguards and procedures for personnel using RDNA.

c. The Executive Director may establish such procedures as deemed appropriate for the submission and review of permit applications and issuance of permits so long as they are consistent with these regulations. Permits may be issued which contain conditions or restrictions relative to the Board's interest in protecting the public health.

d. Applications for permits shall be acted upon within sixty (60) days. The Commission shall have no obligation to review incomplete applications. Failure to act within such time period shall constitute an approval unless the applicant has been notified within the sixty (60) day period of a delay.

e. A permit issued prior to the enactment of these regulations under the City of Boston Code 17.9 shall be valid, on the condition the permit holder complies with all aspects of these regulations.

1.04. INSTITUTIONAL BIOSAFETY COMMITTEES

The Institutional Biosafety Committees (IBCs) shall be established in accordance with the Guidelines. However, the composition of the IBC shall include at least one representative from the surrounding community, who shall be approved by the Executive Director. Institutions are also strongly encouraged to include a non-doctoral person from the laboratory technical staff, if available, on the IBC.

Institutions which are using RDNA technology solely in a manner which is currently exempt under the NIH Guidelines and which are not required by NIH to establish an IBC, may establish a biosafety review system, such as a biosafety officer or internal committee, to oversee and review all RDNA uses within the institution in lieu of an IBC in order to satisfy these regulations and permit requirements.

1.05. ANNUAL REPORTS

The Executive Director shall require the filing of an annual report from each permitted institution in a manner to be determined by the Executive Director. Such reports at a minimum shall include copies of IBC minutes, certification that the institution is in compliance with the Guidelines and these regulations, and a complete roster of current IBC members. To the extent IBC minutes may contain proprietary information, the Executive Director and the institution shall develop procedures for assuring confidentiality.

1.06. LARGE SCALE USE

All institutions intending to use RDNA on a "Large Scale" (as defined in the Guidelines) require a RDNA use permit as well as specific approval to conduct large scale activity.

Any currently permitted institution shall request approval to conduct large scale activity from the Executive Director at least thirty (30) days prior to the initiation of any large scale-related activity, which may include, but not be limited to, construction or renovation of facilities. The Executive Director shall act and make a decision on the request within a thirty (30) day period from receipt of the request. Failure to act within such time period shall constitute an approval unless the institution has been notified within the thirty (30) day period of a delay.

Institutions which do not have a current permit shall request approval to conduct large scale activity as part of their application for an RDNA use permit.

During the review of the institution's request, the Executive Director/Board may request additional information from the institution pertaining to the proposed large scale activity.

All large-scale activity must be clearly identified in the minutes of the IBC.

1.07. MISCELLANEOUS

- a. All institutions shall provide an appropriate medical surveillance program as determined by their IBC and consistent with the Guidelines. Each institution shall submit a description of its medical surveillance program and documentation regarding its implementation as part of its annual report.
- b. All areas in which RDNA is utilized shall be free of rodent and insect infestation.
- c. Within thirty (30) days an institution shall report any significant problems with or violations of the Guidelines and any significant RDNA related accidents or illnesses to the Executive Director and the Boston RDNA Advisory Committee. Any such problems, accidents, or illnesses which have a potential impact on the public health and safety shall be reported immediately.
- d. The Executive Director may establish a process for renewal or continuance of permits.
- e. The Commission shall have the authority to conduct inspections of institutions, with or without prior notice, so long as such inspections are conducted at reasonable times.

SECTION 2.00 BOSTON RDNA ADVISORY COMMITTEE (BRAC)

2.01. COMPOSITION

The BRAC shall be composed of at least seven (7) members, one of whom shall be the Executive Director or her/his designate who shall serve as Chairperson; two (2) of whom shall be residents of neighborhoods which are or may be impacted by RDNA research or technology; one (1) of whom shall be a scientist knowledgeable in the field of RDNA technology; and three (3) of whom shall assure representation from any of the following fields; public health, occupational health, infectious diseases, process engineering, and environmental quality. If additional members beyond seven are appointed by the Executive Director, those appointees shall have qualifications which the Executive Director determines are necessary for the functioning of the BRAC. The members shall serve at the pleasure of the Executive Director and shall be appointed by the Executive Director to serve for terms of two (2) years. Persons appointed by the Executive Director to fill vacancies shall serve for the unexpired term of said vacancy. Members of the BRAC shall be Special Municipal Employees. The BRAC shall be established within sixty (60) days of passage of this ordinance.

2.02. STAFFING

The Executive Director shall make available competent professional staff support to assist the BRAC in carrying out its duties under these regulations.

2.03. DUTIES AND RESPONSIBILITIES

Recognizing the need for community and scientific input to assist the Board and the Executive Director in carrying out the duties and responsibilities in regulating Recombinant DNA research, production, and technology, the BRAC shall have the following duties and responsibilities.

- a. The BRAC shall continually review literature in the area of Recombinant DNA research, production, and technology and shall continually review the effectiveness of the regulatory system established by these regulations and, in light of such review, shall advise and make recommendations to the Executive Director and the Board as to the manner in which the system may be improved. Included within such responsibilities, the BRAC shall review and make recommendations to the Executive Director on all amendments to the Guidelines.
- b. The BRAC shall review and make recommendations to the Executive Director on all applications for permits.
- c. The BRAC shall review, comment and make recommendations to the Executive Director on policies, procedures, and manuals and programs adopted by individual institutions for the purpose of determining conformity with the requirements of these regulations or an individual institution's permit.

- d. A member of the BRAC, other than the Executive Director, shall participate in site inspections carried out under these regulations.
- e. The BRAC shall review and make recommendations to the Executive Director and the Board in regard to appropriate administrative actions to be taken for violations of these regulations.
- f. The BRAC shall meet with sufficient frequency to assure prompt and effective response to its duties and responsibilities.

SECTION 3.00 RESTRICTIONS

3.01. RDNA use requiring containment defined by the Guidelines as "BL4" shall not be permitted in the City of Boston.

3.02. Any deliberate release into the environment of any surviving organism containing recombinant DNA shall be made in full compliance with NIH regulations and rules and regulations of the Commonwealth of Massachusetts. Any accidental release shall be reported to the Executive Director immediately and in no case longer than twenty-four (24) hours.

SECTION 4.00 PERMIT FEES

The Executive Director is hereby authorized to establish fees for the issuance and continuance of permits. Further the Executive Director is authorized to establish fee scales which may vary according to the type of use and scale of activity being conducted. Payment of such fee or fees shall be a further condition of the granting or continuance of any permit.

SECTION 5.00 PENALTIES

5.01. A violation of any condition or restriction of a permit or provision of these regulations shall subject the violator to a fine or civil penalty of three hundred (\$300.00) dollars per day per violation. Each such violation shall constitute a separate and distinct offense.

5.02. Once a permit has been issued it may be revoked, suspended, or modified, by the Executive Director, or not renewed only upon a determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations or the permit requirements, conditions, or restrictions, including adherence to the Guidelines. Notice and hearing procedures shall be those established by the Executive Director.

5.03. Notwithstanding the above, the Executive Director, upon a determination that any violation constitutes an immediate and severe threat to the public health and safety, may order the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice and hearing but with subsequent notice and hearing.

SECTION 6.00 SEVERABILITY OF SECTIONS

If any section, subsection, sentence, clause, or portion of this section is for any reason held invalid or unconstitutional by any court of competent jurisdiction, such portion shall be deemed a separate, distinct and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

SECTION 7.00 EFFECTIVE DATE

These regulations shall become effective as of the date of passage, March 22, 1994.