

REGULATIONS FOR USE OF RECOMBINANT DNA MOLECULE TECHNOLOGY

The Board of Health, Town of Bedford, Massachusetts, acting under the authority of Section 31, Chapter 111 of the General Laws and amendments and additions thereto, and by any other power thereto enabling, adopt the following rules and regulations in the interest of and for the preservation of the public health.

1. APPLICABILITY

All activities associated with constructing and handling: a) recombinant DNA (RDNA) molecules and b) organisms and viruses containing RDNA molecules within the Town of Bedford shall be performed in strict accordance with these regulations and with the National Institutes of Health Guidelines. These regulations shall govern in addition to the Guidelines. These regulations do not apply to finished products which contain RDNA molecules and which have been approved by other government regulatory agencies for medical or other purposes.

2. DEFINITIONS

For the purpose of these regulations, the following definitions are adopted:

- a) Guidelines mean: National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register of November 23, 1984, and any subsequent Federal amendments thereto.

In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect as to all activities within the Town of Bedford.

- b) Institution means: Any public or private entity including Federal, State, and local governmental agencies.
- c) Institutional Biosafety Committee (IBC) means: A committee that (i) meets the requirements for membership specified in the Guidelines (Section IV- B-2) and (ii) reviews, approves, and oversees projects in accordance with the responsibilities defined in the Guidelines (Section IV-B-2 and IV-B-3).
- d) Large-scale means: The use of more than ten liters but less than 5000 liters of RDNA culture.
- e) Recombinant DNA Molecules mean: (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above.
- f) Significant deviation means: Any deviation that might have an adverse affect on personal or public health.

3. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- a) The Institutional Biosafety Committee (IBC), established by the Guidelines, shall include as members the Director of Public Health of the Town of Bedford or his/her designee, plus one additional community representative appointed by the Board of Health.
- b) The IBC shall meet no less than once a year. All minutes of the IBC meetings shall be forwarded to the Board of Health.
- c) The community member of the IBC and the Director of Public Health, or his/her designee, shall have no financial interest in any institution involved in the use of RDNA, or any other institution in competition therewith, and such representatives shall be bound to the same provisions as to non-disclosure and non-use of proprietary information and trade secrets as all other members of IBC, except to the extent necessary to alleviate any public health hazard. As used in these regulations proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.

- d) In accordance with the Guidelines, the IBC, acting on behalf of an institution, reviews all RDNA use for compliance with the Guidelines and approves those projects that conform with the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the Board of Health.
- e) All information sent to the Board of Health shall have any proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC.

4. PERMITS

- a) All institutions planning to use RDNA must obtain a permit from the Board of Health before commencing said technology. All permits are issued for one year and may be revoked for cause.
- b) Institutions seeking such a permit from the Board of Health shall submit the following:
 - (1) A plot plan showing the proposed location of the facility and a floor plan shown in the internal layout of the facility.
 - (2) A listing of all organisms, containment levels, and decontamination procedures to be employed.
 - (3) A plan for a screening process to insure 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.
 - (4) A plan for systematic monitoring of waste to assure that surviving RDNA organisms will not be released into the environment.
 - (5) A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in any and all segregated buildings.
 - (6) A plan for systematic security of the premises.
 - (7) 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 for all persons engaged in the use of RDNA. Such programs shall include, but shall not necessarily be limited to:
 - A pre-employment medical examination for employees.
 - Prompt reporting to the IBC of employee illnesses that are potentially related to RDNA use.
 - Retention of medical and health records for ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.
 - A training program of safeguards and safety procedures for personnel.
 - (8) The name(s) of the Principal Investigator(s) who shall be responsible for enforcing the guidelines.
 - (9) A plan for orienting representatives of the Bedford Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
 - (10) Written authorization to allow inspection of facilities and pertinent records by the Board of Health.
- c) The Board of Health shall review the institution's application for a permit and supporting documents. Copies of the application and supporting documents, shall be filed with the Planning Board within 45 days after the application is reviewed. The Board of Health shall take final action on the permit application within 75 days after the application is filed. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and the applicant.

d) The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be \$500.00

5. INSPECTION AND REVIEW

- a) All institutions involved in the use of RDNA shall allow inspection of their facilities, procedures and practices in order to confirm compliance with this ordinance.
- b) The Board of Health will require an independent representative, professionally competent, paid for by the company, to perform inspections and reviews. The results shall be reported to the Board of Health, and the institution involved.
- c) The Board of Health, its employees, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information release to them by reason of these regulations.

6. RESTRICTIONS

- a) RDNA use requiring BL3 and BL4 containment shall not be permitted.
- b) Experiments for which containment levels are not prescribed in the guidelines, shall be approved by the Board of Health before the experiment is initiated.
- c) Large scale RDNA use shall not be permitted without prior review and approval by the Board of Health. Use of more than 5,000 liters of RDNA culture shall not be permitted.
- d) Precautions shall be adhered to, to preclude release into the environment, that is to sewers, drains or the air, of any live organisms containing RDNA or active antibiotics.
- e) The institution shall report within 24 hours to the Director of Health, followed by a written report within 15 days to the Board of Health, any significant accidents or illnesses or releases related to the use of RDNA. An additional inspection of facilities and procedures may be deemed necessary by the Board of Health based upon its judgment of the nature and extent of the problem.

7. PENALTIES

- a) Violation of these regulations shall subject the violator to a fine of Five Hundred Dollars (\$500.00) per day, and in addition, the facility in which the violation occurs may be closed by the Board of Health. Each day of violation shall constitute a separate and distinct offense.
- b) If in the opinion of the Board of Health, the RDNA use causes a nuisance or adversely affects the public health, safety and welfare in Bedford, the permit may be revoked. Once a permit has been issued it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements or the guidelines.

8. ASSESSMENTS

The salaries and expense paid by the Town for inspections, reviews, staff and consultants for work directly related to carrying out the requirements of these regulations shall be assessed to the institutions requesting and holding permits under these regulations. An accounting of these costs will be furnished annually to each institution.

9. SEPARABILITY

Each part of these regulations is construed as separate to the end that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

10. VARIANCE

Variances from these specific requirements of these Regulations may be authorized by the Board of Health after notice and public hearing if the Board reasonably determines that the relief sought will be detrimental or injurious to the public health.

The Bedford Board of Health adopt these Regulations effective on April 1, 1986, at a duly called and held meeting on March 19, 1986.

Daniel W. Oblas, Clerk

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