

## **Biotechnology and the use of Recombinant DNA Molecule Technology**

### **1. APPLICABILITY.**

All activities associated with constructing and/or propagating: a) recombinant DNA (rDNA) molecules b) organisms and viruses containing rDNA molecules within the Town of Watertown and (c) biological organisms having a containment of Biosafety Level Three (BSL-3) or attenuated organisms derived from a BSL-3 shall be performed in strict accordance with these regulations and with the NIH Guidelines as defined in Section 2-c below. The regulations shall govern where they differ from 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. Large-scale: The use of more than ten liters but less than 5000 liters of rDNA culture.
- b. Significant deviation: Any deviation that might have an adverse effect on personal or public health
- c. Guidelines:
  1. The most recent version and any additional approvals of the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register.
  2. In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect and approved by the Board of Health at the time of such discontinuance shall remain in effect.
- d. Biosafety Level Three organisms  
Classification of the level of biological containment required for certain organisms categorized as “BSL-3.” These organisms typically contain a risk by aerosol transmission and the diseases produced by these agents are serious but treatable. Additional facility requirements – as well as administrative and engineering controls are required for their safe use. The most recent version of the CDC/NIH Publication: “Biosafety in Microbiological and Biomedical Laboratories (BMBL)” will be followed for detailed guidance on BSL-3 organisms.
- e. Attenuated organism: A bacteria, virus, or other biological organism that has a wild-type counterpart. The attenuated strain is a weakened strain that can be safely worked on at a lower level of biosafety.
- a. Recombinant DNA :Molecules that are constructed outside living cells by joining natural or [synthetic DNA](#) segments to DNA molecules that can replicate in a living cell, or Molecules that result from the replication of those described above

### **3. WATERTOWN BIOSAFETY COMMITTEE (WBSC).**

- A. Watertown Biosafety Committee (WBSC) shall be established for the purpose of overseeing all uses of rDNA in Watertown and advising the Board of Health.
- B. Specific responsibilities of the WBSC are as follows:
  1. Establishing policies, procedures and criteria to aid in the implementation of this ordinance.

2. Reviewing all amendments to the Guidelines before submitting more stringent recommendations to the Board of Health for approval as appropriate to Watertown.
  3. Reviewing all applications for permits for the use of rDNA and biological materials in Watertown for compliance with the Guidelines and conformity with such other regulations as the Board of Health may from time to time promulgate.
  4. Reviewing institutions' manuals, annual worker training programs, health-safety programs and monitoring procedures.
  5. Determining the manner in which institutions and institutional biosafety committees make reports, applications or recommendations to the WBSC and the type of information required. Reviewing such reports, applications and recommendations and approving where appropriate. Carrying out site visits to institutional facilities. Approving the community members of the Institutional Biosafety Committees (IBCs) who are appointed by the IBC chairperson at each respective institution.
  6. Developing a procedure for members of institutions to report to the WBSC violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.
- C. The WBSC shall be composed of the Chairman of the Board of Health or his/her designee who has relevant expertise in the field, the Director of Public Health and his/her designee who is an employee of the Health Department and a minimum of one other member to be appointed from the general public nominated by the Town Manager and shall serve three-year terms.

#### **4. REGISTRATION.**

- A. rDNA users in the following categories: Both (1) and (2) are required to register proposed work with the WBSC through the Director of Public Health.
1. Users whose experiments are all exempt from the NIH Guidelines under Section III-E;
  2. Users not constructing rDNA organisms but merely propagating them;
- B. Written registration is required prior to commencement of work and includes:
1. Name and cv. of a person in the organization familiar with the proposed rDNA work and the NIH Guidelines.
  2. A brief summary from the above-named person describing the proposed work and giving:
    - a. Name and type of organisms (host/donor [foreign DNA]/vector) being used.
    - b. Reference to the section of the NIH Guidelines where the work falls.
    - c. If recombinant molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
    - d. The scale (in liters) on which the organisms will be grown.
    - e. An assurance that all work will be carried out following the NIH Guidelines, where applicable, at the appropriate BL level and that exempt work will be done at BL1.
    - f. Name of biological waste handler (if any) and written assurance that all waste will be handled and disposed of according to all applicable federal, state, and local codes.
    - g. Description of annual safety training and refresher training provided to laboratory staff.
  3. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in 2 above.

- C. Upon receiving and reviewing the submitted information, the WBSC may require additional information to be submitted, and it may recommend to the Board of Health other procedures or safeguards as it deems appropriate up to and including full permit application under the existing Board of Health Regulation.
- D. Immediate reporting to the IBC Chairman of any employee exposure or illness, facility spill, release or explosion that could be potentially related to the use of rDNA or biologicals or chemicals used on site from an approved IBC protocol. The IBC Chairman should consult with the administrative officials at the permitted facility and provide a verbal report to the Town of Watertown, Director of Public Health, within 24 hours of the potential exposure or release. A formal accident report containing details of the accident, laboratory decontamination and follow-up of the potentially exposed personnel should be submitted to the Town of Watertown Director of Public Health the next business day following the verbal report. A determination as to whether there was a release of rDNA material as described in Section 3) D. should also be addressed to the Town of Watertown.

#### **4. PERMITS.**

- A. All institutions planning to use rDNA or non-rDNA biological research and manufacturing that requires Biosafety Level Three or higher containment or attenuated strains requiring lower Biosafety Level must obtain a permit from the Board of Health.
- B. All institutions planning to use rDNA in any way must obtain a permit from the Board of Health with the prior approval of the WBSC before commencing said technology. All permits are issued for one year and may be revoked for cause.
- C. Institutions seeking such a permit from the Board of Health must first submit the following to the WBSC:
  - 1. A plot plan showing the proposed location of the facility and a floor plan showing 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 under their control in the same building. All waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.
  - 6. A plan for systematic security of the premises.
  - 7. Institutional Biosafety Committee (IBC)
    - a. The Institutional Biosafety Committee (IBC), established by the Guidelines, shall have as members, in addition to the corporate representatives, one community representative of the Town of Watertown, who shall report back to the Director of Public Health, or his/her designee. The community representative shall be appointed by the facility holding the rDNA permit and notification of the community

- appointment should be sent to the Director of Public Health, who shall report to the WBSC (see section c. Below).
- b. The IBC shall meet a minimum of at least once per year. All minutes of the IBC meetings must be forwarded to the Board of Health and the WBSC.
  - c. The community member of the IBC shall have no financial interest in the institution 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 this regulation, proprietary information and trade secrets shall be defined as set forth under the laws of the Commonwealth of Massachusetts.
  - d. In accordance with the Guidelines the IBC, acting on behalf of the 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 the experiment conforms with the Guidelines, shall be filed with the WBSC and the Board of Health.
  - e. All information sent to the Board of Health and the WBSC shall have any proprietary information 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.
  - f. The IBC must develop a policy for the verification of attenuated pathogens. These pathogens are biological agents that in the wild-type strain, are virulent pathogens, typically requiring lab containment biosafety level of three or four. The policy should contain steps to ensure the IBC approves the method and verifies the data prior to the laboratory reducing the biocontainment and/or handling requirements of an attenuated agent. Typical methods for distinguishing wild type from attenuated strains include restriction analysis or related methods.
8. 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. Retention of medical and health records for at least ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.
  - b. Immediate reporting to the IBC Chairman of any employee exposure or illness, facility spill, release or explosion that could be potentially related to the use of rDNA or biologicals or chemicals used on site from an approved IBC protocol. The IBC Chairman should consult with the administrative officials at the permitted facility and provide a verbal report to the Town of Watertown, Director of Public Health, within 24 hours of the potential exposure or release. A formal accident report containing details of the accident, laboratory decontamination and follow-up of the potentially exposed personnel should be submitted to the Town of Watertown Director of Public Health the next business day following the verbal report. A determination as to whether there was a release of rDNA material as described in Section 3) D. should also be addressed to the Town of Watertown.

- c. An annual training program of safeguards and safety procedures for personnel.
- 9. The name(s) of the Principal Investigator(s) responsible for enforcing the Policies of the IBC.
- 10. A plan for orienting representatives of the Watertown Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
- 11. Written agreement to allow inspection of facilities and pertinent records by the WBSC.
- 12. For Biosafety Level Three (BSL3) laboratories, evidence that the facility has been designed according to the latest standards for BSL-3, including the CDC/NIH Guidelines: Biosafety in Microbiological and Biomedical Laboratories.” In addition, documentation of a maintenance schedule and annual commissioning by a 3<sup>rd</sup> party agent is required to be produced during the annual inspection by Town of Watertown.
- D. The WBSC shall review the institution’s application for a permit and supporting documents and make its recommendation of the same to the Board of Health. Copies of the application, supporting documents and the WBSC recommendation shall be filed with the Board of Health within 90 days after the application is filed with the WBSC. The Board of Health shall take final action on the permit application within 45 days after receiving the recommendations of the WBSC . 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.
- E. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be \$500.00.
- F. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in Section 4 (Registration) # 2. and in addition the following:
  - 1. Current list of IBC members
  - 2. Copies of the previous year’s IBC minutes
  - 3. Summary of the research and any changes in the past year
- F. Annual report deadline will vary by company. Deadline is based on the rDNA permit renewal date.
  - 1. A permit will not be renewed if the *permit holder* has failed to pay all fines issued and the time period to appeal the fines has expired.

## **2. INSPECTION AND REVIEW.**

- A. All institutions involved in the use of rDNA and biological materials as described in Section 5) a. permits, shall allow annual inspection of their facilities, procedures and practices in order to confirm compliance with this ordinance.
- B. The Board of Health shall retain a professionally competent person, agency or institution to perform inspections and reviews. The results shall be reported to the Board of Health, the WBSC and the institution involved.
- C. The Board of Health, its employees, all members of the WBSC, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of this ordinance.

D. Consistent with the laws of the Commonwealth, issuance of a permit shall be conditioned on an applicant's consent to unannounced, periodic inspections of his/her *establishment* to ensure compliance with this Regulation.

**3. RESTRICTIONS.**

- A. rDNA use classified by the guidelines as requiring any BL4 physical containment measures as prescribed in Appendix G of the guidelines under Standard Microbiological Practices, Special Practice Containment Practices, Containment Equipment or Laboratory Facilities shall not be permitted.
- B. Biological agents that are classified as requiring Biosafety Level four containment shall not be permitted in the Town of Watertown.

**4. 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.

Effective Date

This Regulation shall take effect on.....