

## Chapter 8.20 RECOMBINANT DNA TECHNOLOGY

### 8.20.10 Purpose.

All use of recombinant DNA (RDNA) in the City shall be undertaken only in strict conformity with the guidelines set out in Section 8.20.020, the other requirements of this chapter and health regulations promulgated by the Cambridge Commissioner of Health and Hospitals (the Commissioner). (Ord. 1148 (part), 1993)

### 8.20.020 Definitions.

A. "Guidelines" means:

1. National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register of May 7, 1986.

2. Any amendments, revisions or substitutions subsequent to the above-referenced guidelines, including, but not limited to:

Notices of action under NIH Guidelines for Research Involving Recombinant DNA Molecule on August 24, 1987, July 29, 1988, October 26, 1988, March 13, 1989, March 1, 1990, September 12, 1990, July 18, 1991, October 15, 1991, November 21, 1991, January 28, 1992, and April 22, 1992.

3. Such amendments to subsections (A)(1) and (A)(2) above which are adopted by the National Institutes of Health (NIH) and approved by the Commissioner. Amendments not acted upon by the Commissioner within sixty days shall be considered approved. In the event that the NIH shall discontinue or abolish its guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in Cambridge.

B. "Person" means an institution, corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization and any other group acting as a unit, as well as a natural person.

C. "Recombinant DNA molecules" and "organisms and viruses containing RDNA" are those defined in the guidelines referred to in subsection (A)(1) above, and such amendments as may be approved by the Commissioner. Amendments not acted upon by the Commissioner within sixty days shall be considered approved. (Ord. 1148 (part), 1993)

### 8.20.030 Cambridge Biosafety Committee--Membership--Staff.

A. The Cambridge Biosafety Committee (CBC) (formerly known as the Cambridge Biohazards Committee) shall be composed of the Commissioner or his/her designee, the chairperson of the Cambridge Health Policy Board, or a board members designated by the chairperson, and a minimum of three other members to be appointed by the City Manager.

The City Manager is authorized to provide for the adequate staffing of the CBC. Members of the CBC shall be special municipal employees.

B. The CBC and the Commissioner are authorized to retain competent professional assistance in carrying out their duties under this chapter.

C. The salaries and expenses of the staff and consultants of the CBC under this chapter shall be apportioned to the persons holding permits under Section 8.20.050. (Ord. 1148 (part), 1993)

#### 8.20.040 Cambridge Biosafety Committee--Duties and responsibilities.

The responsibilities of the CBC shall include:

A. Establishing policies, procedures and criteria to aid in the implementation of this chapter;

B. Determining the manner in which permit holders make reports or applications to the CBC, and the type of information required in such reports or applications. Reviewing reports, applications and recommendations by the Institutional Biosafety Committees (IBC) and approving them where appropriate. Carrying out site visits to permitted facilities;

C. Reviewing manuals and worker training programs, approving health-safety programs and monitoring the procedures required by this chapter;

D. Developing a procedure for persons to report to the CBC violations of this chapter, the guidelines or any health regulation. (Ord. 1148 (part), 1993)

#### 8.20.050 Permit requirements.

A. All persons proposing to use RDNA must obtain a permit from the Commissioner with the approval of the CBC. Permit requirements shall, at a minimum, include written agreement to:

1. Follow the guidelines as defined in this chapter;
2. Follow other conditions set forth in this chapter;
3. Allow reasonable inspections of facilities and pertinent records by the CBC;
4. Prepare a health and safety manual which contains all procedures relevant to the use of RDNA at all levels of containment in use at the facility, and a program for waste disposal in compliance with all applicable federal, state and local laws. The manual shall be submitted to the CBC for review;

5. Establish a training program of safeguards and procedures for personnel using RDNA;

B. Permits shall be issued and renewed on an annual basis. The Commissioner may establish fees for the issuance and renewal of permits.

#### 8.20.060 Institutional Biosafety Committees.

The Institutional Biosafety Committees (IBC) shall be established in accordance with the guidelines, except that the required composition of each IBC shall include at least one representative from the surrounding community approved by the Health Policy Board. The IBC shall be the final arbiter within an institution with regard to the implementation of this chapter and the guidelines. (Ord. 1148 (part), 1993)

#### 8.20.070 Reports.

Each holder of a permit shall file regular reports with the CBC, in a manner to be determined by the CBC. All minutes of IBC meetings must be sent to the Commissioner and the CBC. (Ord. 1148 (part), 1993)

#### 8.20.080 Medical surveillance program.

Each permit holder must provide an appropriate medical surveillance program as determined by its IBC and consistent with the guidelines. Such programs must be approved by the CBC. (Ord. 1148 (part), 1993)

#### 8.20.090 Violation of guidelines--Notification.

The permit holder shall report, within thirty days, to the Commissioner and the CBC any significant problems with or violations of the guidelines and any significant RDNA-related accidents or illnesses. (Ord. 1148 (part), 1993)

#### 8.20.100 Protection against rodents and insects.

Effective rodent and insect control programs must be in place on premises where RDNA use under this chapter takes place. (Ord. 1148 (part), 1993)

#### 8.20.110 Restrictions.

A. RDNA use requiring containment defined by the guidelines as "BL4" shall not be permitted in Cambridge.

B. Any accidental release which represents a significant potential hazard to employees or the public shall be reported to the Commissioner immediately, and in no case more than twenty-four hours after the release. (Ord. 1148 (part), 1993)

#### 8.20.120 Enforcement--Violation--Penalty.

A. Any person who violates any provision of this Chapter shall be subject to a fine of three hundred dollars per violation. Each day of violation shall constitute a separate and distinct offense.

B. Once a permit has been issued, it may be revoked, suspended, modified or not renewed by the Commissioner only upon a determination by the Commissioner and the CBC, after due notice and hearing, that the permit holder has materially failed to comply with this chapter, the permit agreements or the guidelines.

C. Notwithstanding the above, the Commissioner, 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. (Ord. 1148 (part), 1993)