

# Cambridge Biosafety Regulation

## Section 1.00 Purpose.

In order to safeguard the health and welfare of the citizens of the City of Cambridge (the “City”), the City of Cambridge Commissioner of Health and Hospitals (the “Commissioner”) hereby promulgates this Regulation governing the use of all Biological Agents, (as defined herein) in the City. The use of Biological Agents requiring Biosafety Laboratory 4 (“BSL-4”) containment (as defined herein) shall not be permitted in the City.

All other use of Biological Agents in the City shall be undertaken only in strict conformity with this Regulation and other health regulations promulgated by the Commissioner. The requirements of this Regulation are in addition to those set forth in Chapter 8.20 of the Cambridge Municipal Code regarding the use of recombinant DNA (“RDNA”), (attached hereto as Appendix “A”).

## Section 2.00 Definitions.

**A.** “Biological Agents” shall mean any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that:

1. is classified as a Risk Group 3 through 4 Agent by the National Institutes of Health (“NIH”) Guidelines (as defined below); or
2. requires BSL-3 through BSL-4 containment as determined by an Institutional Biosafety Committee (as defined below); or
3. is identified by the United States Department of Health and Human Services (“DHHS”) or the United States Department of Agriculture (“USDA”) as a “Select Agent” (as defined below).

**B.** “Cambridge Biosafety Committee” -- shall mean the Cambridge Biosafety Committee (“CBC”) created and defined by Chapter 8.20.030 of the Cambridge Municipal Code, and shall in addition to its duties and responsibilities set forth therein, also have the duties and responsibilities set forth in this Regulation.

**C.** “Guidelines” shall mean:

1. “*NIH Guidelines*” -- NIH Guidelines for Research Involving Recombinant DNA Molecules, which are adopted by the NIH.
2. “*BMBL*” -- Biosafety in Microbiological and Biomedical Laboratories 5th edition.

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3. Any amendments, revisions, new editions or substitutions to the NIH Guidelines or the BMBL which are adopted by the DHHS, Centers for Disease Control and Prevention (“CDC”) and NIH and approved by the Commissioner. Amendments not acted upon by the Commissioner within sixty days shall be considered approved. In the event that NIH Guidelines or BMBL are discontinued or abolished, those Guidelines in effect at the time of such discontinuance shall remain in effect in Cambridge.
4. In the event that there is a conflict between the NIH Guidelines and the BMBL, the BMBL shall control.

**D.** “Institutional Biosafety Committee” – shall mean a committee established in accordance with the Guidelines and any applicable requirements of Chapter 8.20.060 of the Cambridge Municipal Code. The IBC shall be the final arbiter within an institution with regard to the implementation of this Regulation and the Guidelines as well as any applicable requirements of Chapter 8.20 of the Cambridge Municipal Code regarding the use of RDNA.

**E.** “Person” shall mean 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.

**F.** “Select Agent” shall mean any microbial and toxic agents listed at 42 CFR § 73.3, 42 CFR § 73.4, 42 CFR § 73.5, 42 CFR § 73.6, 7 CFR § 331.3 and 9 CFR § 121.4, and the rulings made by the CDC and the USDA relative thereto, as such regulations and rulings may be amended from time to time. However, Select Agent shall not include any de minimus amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

## **Section 3.00 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 Regulation;

**B.** Determining the manner in which permit holders, pursuant to this Regulation, make reports or applications to the CBC, and the type of information required in such reports or applications.

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C. Reviewing reports, applications and recommendations by the IBC and approving them where appropriate.

D. Carrying out site visits to permitted facilities.

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

F. Developing a procedure for Persons to report to the CBC violations of this Regulation, the Guidelines or any health regulation.

## **Section 4.00 Permit requirements.**

A. All Persons proposing to use Biological Agents 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 Regulation.
2. Follow other conditions set forth in this Regulation.
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 Biological Agents 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 Biological Agents.

B. Confidentiality of Documents. Proprietary documents as designated by the Person proposing to use Biological Agents will be separated from the documents available to the public in accordance with the Public Records Law. The Commissioner shall develop procedures to protect the confidentiality of any information which, if released, could jeopardize the health and safety of the public (including, without limitation, lab locations and security measures

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

## **Section 5.00 Reports.**

Each permit holder 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 or his or her designee.

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## **Section 6.00 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.

## **Section 7.00 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 Regulation.

## **Section 8.00 Protection against rodents and insects.**

Effective rodent and insect control programs must be in place on premises where Biological Agent use under this Regulation takes place.

## **Section 9.00 Reports of Accidental Releases.**

Any accidental release or exposure which represents a significant potential hazard to employees or the public or any significant Biological Agent-related accident or illness shall be reported to the Commissioner immediately and in no case more than twenty-four hours after the release, exposure, accident or illness.

## **Section 10.00 Enforcement--Violation--Penalty.**

**A.** Any person who violates any provision of this Regulation 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 Regulation, 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.