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# City of Peabody
# Board of Health

# RULES AND REGULATIONS RELATIVE TO BIOLOGICAL SAFETY WITHIN THE CITY OF PEABODY

**These regulations are adopted in accordance with the authority granted by the General Laws of the Commonwealth of Massachusetts, Chapter 111, Section 31**

# CITY OF PEABODY, MA
# BOARD OF HEALTH

## RULES AND REGULATIONS RELATIVE TO BIOLOGICAL SAFETY WITHIN THE CITY OF PEABODY

The following Rules and Regulations, adopted by the Peabody Board of Health, shall govern the manufacture of, experimentation with, storage and/or distribution of, or use for any purpose of, Regulated Biological Agents, as defined herein, within the City of Peabody.

## SECTION 1. DEFINITIONS

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**"Regulated 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 or Risk Group 4 Agent in the National Institutes of Health ("NIH") Guidelines or the "BMBL" (as both are defined below) or;
2. is identified as a "Select Agent" by the United States Department of Health and Human Services ("DHHS") or the United States Department of Agriculture ("USDA"), which 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 here defined shall not include any de minimus amount of agents or toxins which are excluded from 42 CFR 73.00 et seq., or;
3. is identified as a "Recombinant DNA Molecule" in Section I-B (*Definition of Recombinant DNA Molecules*) of the most recently revision of the "NIH Guidelines" (as defined below)

**"Biosafety Level" or "BL"** means physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (published by the National Institutes of Health, Recombinant DNA Advisory Committee) and the latest edition of *Biosafety in Microbiological and Biomedical Laboratories* (published by the Centers for Disease Control and Prevention).

**"Biological Risk Group"** is equivalent to the Risk Group for any biological pathogen as defined in subsection II-A-1 (Risk Groups) of the latest amendment of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and as specified in the latest edition of *Biosafety in Microbiological and Biomedical Laboratories (BMBL).* This designation pertains to the natural risk to human health and the likelihood of transmission associated with the unaltered form of that biological agent.

**"BMBL"** means the current edition of Department of Health and Human Services Center for Disease Control (CDC) Publication No. 21-1112, entitled *Biosafety in Microbiological and Biomedical Laboratories.*

**"Institution"** means an individual person or a group of persons, and /or a corporation, firm, partnership, association, executor, administrator, guardian, trustee, agent, organization and any other group acting as a unit.

**"Institutional Biosafety Committee," or "IBC**" shall mean a committee established in accordance with subsection IV-B-2 (Institutional Biosafety Committee - IBC) of the NIH Guidelines and any applicable requirements of this regulation. The IBC shall be the final arbiter within an Institution with regard to the implementation of this Regulation, with oversight by the Peabody Board of Health as described herein.

**"NIH Guidelines"** means the most recently amended version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, which are adopted by the NIH.

## SECTION 2. REGISTRATION

A. All Institutions (including all persons meeting the definition of an Institution for the purposes of these Rules and Regulations) engaged in research, manufacture, or storage and/or distribution of, Regulated Biological Agents or toxins within the City of Peabody must be registered with the Peabody Board of Health. Excluded from this registration requirement are clinical activities conducted by patient health care facilities and institutions within Peabody for which such activities do not involve any further research or manufacture within Peabody using Regulated Biological Agents.

B. Application for registration must be accompanied by a nonrefundable application processing fee (to be established by the Peabody Board of Health), and include the following information:

1. Company name and address
2. Names of corporate officers and addresses
3. Name of the Institution's designated official responsible for compliance with this plan.
4. Summary of the type of recombinant DNA technology and/or biological agents and the nature of associated research or other use to be conducted in the City of Peabody.
5. Designation of the appropriate Biosafety Level (defined above) by the Institutional Biosafety Committee (IBC), which is consistent with the NIH Guidelines or BMBL and has been determined through an appropriate risk assessment review by that committee.
6. Copy of a completed Biosafety Manual
7. Copy of Emergency Plan for the facility containing biological activity regulated herein
8. Names and addresses of Institutional Biosafety Committee (IBC)
9. Description of planned implementation of an adequate Medical Surveillance Plan, either through engagement of the Institution's internal resources or an independent third party.

C. No manufacturing and/or research and/or storage and/or distribution involving Regulated Biological Agents may be initiated in the City of Peabody until registration has been approved, in writing, by the Peabody Board of Health.

## SECTION 3. RESTRICTIONS

A. Manufacture of, experimentation with, storage and/or distribution of, or use of Regulated Biological Agents, as defined above, within the City of Peabody shall only be allowed for uses requiring Biosafety Level 1 (BL-1) or Biosafety Level 2 (BL-2) as defined above.

Any use of Regulated Biological Agents that have been determined through a biosafety risk assessment performed under the direction of an IBC authorized under this regulation, which have been identified by the NIH Guidelines or the BMBL, to require BSL-3 and/or BSL-4 containment level shall not be permitted in the City of Peabody under any circumstances.

## SECTION 4. INSTITUTIONAL GOVERNANCE

A. The Institution shall establish an Institutional Biosafety Committee (IBC) to govern that Institution's use of Regulated Biological agents in the City of Peabody. The IBC's organization, structure, and functions shall be fully in accordance with the recommendations of subsection IV-B-2 of the NIH Guidelines. The IBC membership must be broad-based in its composition, and shall include at least two community representatives who shall be appointed by the Peabody Board of Health, one of whom shall be the Director of the Peabody Health Department, and neither of whom shall have any financial interest in the institution. Such two representatives shall be bound to the same provisions of non-disclosure and non-use of proprietary information and trade secrets as all other members of the IBC, except to the extent necessary to alleviate any public health hazard. As used in this ordinance proprietary information and trade secrets shall be defined as set forth under the law of the Commonwealth of Massachusetts.

B. Institutions proposing to manufacture, experiment with, store and/or distribute, or use Regulated Biological Agents, as defined above, shall prepare a biosafety manual (hereinafter "the Manual") which contains procedures fully in conformance with the recommendations of the NIH Guidelines to regulate said use at all levels of containment in use at the Institution. The Manual shall fully address any and all environmental monitoring requirements deemed necessary to ensure fully effective containment at the designated Biosafety Level of activity at the Institution. Training in appropriate safeguards and procedures for minimizing potential accidents shall be mandatory for all Institution personnel; the Manual shall fully document all such training requirements and procedures. The Manual shall also contain a full description of the process to be implemented and executed for the decommissioning of laboratories or other space by registered Institutions once the registered activity is completed. The Manual shall be approved by the IBC and then submitted for review to the Board of Health.

C. The Manual must be approved, in writing, by the Peabody Board of Health before any Regulated Biological Agent experimentation, manufacturing, storage and/or distribution, or use may take place.

D. In addition to the Manual, Institutions must prepare an Emergency Plan which describes procedures to be followed if an exposure or potential exposure contaminates personnel, laboratory, or the environment, as well as procedures for notification of the emergency situation to appropriate governmental agencies. The Emergency Plan must mandate a procedure for notifying first responders of the existence of hazards associated with operation of BSL-1 and/or BSL-2 laboratory operations, to include at a minimum, proper posting at all entrances of the notice "Restricted Area. Use of Standard Precautions Required." This Plan must also be submitted to the Peabody Board of Health for review, and no Regulated Biological Agent experimentation, manufacturing, storage and/or distribution, or use may occur prior to issuance of written approval by the Board of Health.

E. The Peabody Board of Health reserves the right to conduct scheduled or unannounced inspections of the Institution at its discretion to assess the compliance status of the Institution with respect to these Rules and Regulations.

F. In the event of a necessity for the Board of Health to acquire the opinions, analysis, inspectional services, and/or recommendations of Subject Matter Experts to fulfill its obligations under these Rules and Regulations, including with respect to environmental monitoring to ensure effective containment, the costs associated with obtaining that expertise shall be borne by the pertinent Institution or Institutions.

## SECTION 5. MEDICAL SURVEILLANCE

A. All Institutions involved in the use of Regulated Biological Agents in the City of Peabody are to engage a reputable clinical organization with demonstrated successful experience in monitoring and managing comparable work environments, wherein the possibility of laboratory acquired infections exists, to establish an appropriate Medical Surveillance Program, as determined by the IBC. The Medical Surveillance Program shall be created, implemented, and managed by the clinical organization, and fully described in the Institution's Manual. Solely at the discretion of the Board of Health, the Medical Surveillance Program shall be subject to review for adequacy and effectiveness by an independent third party, with any such review paid for by the registered Institution.

B. The Institution's Medical Surveillance Program shall include, at a minimum, the implementation of the following measures:

1. All cases of illness occurring in persons involved in research with, manufacturing, storage and/or distribution of, or use of, Regulated Biological Agents, as defined above, wherein those persons have become ill with symptoms that are consistent with any infectious or potentially infectious biological agents handled by that Institution, shall be reported to the laboratory or site supervisor. Similarly, any animal bites which occur in association with an Institution's research or use shall be reported to the laboratory or site supervisor. The laboratory or site supervisor shall immediately file a report of such illnesses and animal bites with the IBC and Institutional medical officer, and the Board of Health. Such report shall include the name and address of the person and the date, nature and length of the incident and/or illness involved. Those impacted persons' medical condition shall be monitored according to the recommendations of the occupational health professional associated with the clinical organization referred to above (paragraph A), and documented until such time that they are released from medical care.

   Said records shall be maintained for a period of time recommended by the clinical organization providing Medical Surveillance, and periodically reviewed by the IBC under the supervision of the Institutional medical officer. The results of such investigations shall be forwarded to the Director of the Peabody Health Department.

   All such reports shall be maintained in a confidential manner and in accordance with all applicable laws, including but not limited to Health Insurance Portability and Accountability Act (HIPAA) requirements.

2. All persons involved in research with, manufacturing, storage and/or distribution of, or use of, Regulated Biological Agents, who are absent from work or laboratory due to illness for more than five (5) consecutive days, must report to a clinician identified by the Medical Surveillance Program before being allowed to return to work or to the laboratory.

## SECTION 6: REPORTING REQUIREMENTS

A. The Institution must have adequate protocols for establishing safe practices and a safe work environment to ensure that there are no significant releases that could result in an exposure to the Regulated Biological Agents being handled in that area. All breaches in containment that could result in the release of potentially infectious material are to be recorded and reported immediately to the Biological Safety Officer, as defined in the NIH Guidelines, and to the full membership of the IBC as soon as reasonably possible, for appropriate action. These actions may include monitoring for the development of any illness as described in Section 5 (Medical Surveillance) of this regulation. In addition, any significant releases that pose a potential for human or animal infection must be reported to the Peabody Board of Health within forty-eight (48) hours.

B. The minutes of all meetings of the IBC shall be recorded and maintained in accordance with the document "Minutes of Institutional Biosafety Committee Meetings" issued by the National Institutes of Health and shall be delivered to the Peabody Board of Health ("the Board") within thirty (30) days of the meeting. If redaction of proprietary information, trade secrets or any information withheld to ensure security prevents the Board from making an assessment of safety considerations, an executive session of the Board will be convened to review such documentation without a requirement to treat this information as a public document under Commonwealth of Massachusetts law. The full text of submitted IBC minutes shall remain on file in the records of the Institution for inspection at all reasonable times by any member of the public.

C. The Institution must provide a written summary of each IBC-approved protocol or experiment, as well as any changes thereto, as well as changes to any information provided by the Institution upon which the Board of Health approval of the application for registration was based, to the Peabody Board of Health within thirty (30) days of its approval.

## SECTION 7. PENALTIES

A. A violation of any of the provisions of this ordinance shall subject the violator to a fine of up to One Thousand Dollars ($1,000.00) per day per offense and in addition the specific laboratory or Institution in which the violation occurs may be issued a cease and desist order by the Peabody Board of Health for all or part of its operations or facility. Each day of violation shall constitute a separate and distinct offense provided, however, that no monetary fine shall be imposed for any violation which occurred at any time before the day of written notice of the violation by the City of Peabody.

## SECTION 8. SEVERABILITY OF SECTIONS

A. If any section, sub-section, sentence, clause, phrase or portion of this regulation 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.