

MEDFORD BOARD OF HEALTH BIOLOGICAL SAFETY REGULATIONS

SECTION 1: AUTHORITY

This regulation is adopted pursuant to the authority granted to local boards of health under Massachusetts General Laws, Chapter 111, Section 31.

SECTION 2: PURPOSE

To safeguard the health and welfare of the residents of the City of Medford (the "City"), the Medford Board of Health (the "Board of Health") hereby promulgates this regulation governing the use of all Regulated Biological Agents (as defined herein) in the City.

SECTION 3: APPLICABILITY

These regulations shall apply to any 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 (hereinafter collectively "Institutions") involved in or in any way undertaking any and all research or manufacturing involving Regulated Biological Agents in the City of Medford. This includes clinical laboratories located within health care facilities and professional analytical services that directly support clinical or health care services.

SECTION 4: DEFINITIONS

Biological Risk Group: 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 or Synthetic Nucleic Acid 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.

Biosafety Level: Physical containment as defined in Appendix G-II (Physical Containment Levels) of the latest amendment of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid 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).

BMBL: The current edition of the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) Publication No. 21-1112, entitled "Biosafety in Microbiological and Biomedical Laboratories."

Board: The Medford Board of Health

Clinical Laboratory: Healthcare facilities providing a range of laboratory procedures which aid physicians in carrying out the diagnosis, treatment, and management of patients.

Healthcare Facility: Places that provide healthcare including hospitals, clinics, outpatient care centers and specialized care centers, such as birthing centers and psychiatric care centers.

Institution: 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 responsible for compliance with the requirements set forth in this regulation.

Institutional Biosafety Committee (IBC): A committee established in accordance with Subsection IV-B-2 (institutional biosafety committee or 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 Board of Health as described herein.

Low Risk Facility: any Person that creates, propagates, imports or uses rDNA in any form where:

1. The experiments are all exempt from the NIH Guidelines under Section III-F of the Guidelines; or
2. Users are not constructing rDNA organisms but are merely propagating them.
3. Wildtype Microorganisms contained in BSL1 are used.

NIH Guidelines: The National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules published in the Federal Register of July 23, 1976, and any subsequent federal amendments thereto adopted by the Recombinant DNA Advisory Committee (RAC) within the National Institutes of Health (NIH).

Principal Investigator: An individual designated by an institution to direct the biological research project or program conducted using Regulated Biological Agents (as defined herein).

Regulated Biological Agents:

1. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia or protozoa) or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that:

2. Is identified as a "Recombinant or Synthetic Nucleic Acid Molecules " in Section I-B (Definition of Recombinant or Synthetic Nucleic Acid Molecules) of the most recent revision of the NIH Guidelines (as defined herein);

3. Is classified as a Risk Group 3 Agent in the NIH Guidelines or the BMBL (as both are defined herein); or

4. Is identified as a "select agent" by the United States Department of Health and Human Services (USDHHS) or the United States Department of Agriculture (USDA), which shall mean any microbial and toxic agents listed at 42 CFR 73.3, 73.4, 73.5, 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" as herein defined shall not include any de minimis amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

SECTION 5: PROFESSIONAL ADVISORY ASSISTANCE

The Board of Health retains all final responsibility for enforcement of this regulation. Notwithstanding the foregoing, the Board of Health, whenever the facts and circumstances deem necessary, shall be authorized to retain assistance from a professional consultant with appropriate professional and academic experience and training to support review of applications and required documentation. Costs incurred by the Board of Health in utilizing a professional consultant may be assessed to a permit holder/applicant according to the time required to inspect facilities and to review documentation for said permit holder/applicant. This cost assessment is in addition to any established permit fee(s).

SECTION 6: GENERAL REQUIREMENTS

A. Unless specifically exempted under this regulation, all research or manufacturing involving Regulated Biological Agents in the City of Medford shall be undertaken only in strict conformity with the NIH Guidelines, the current edition of the BMBL, the Massachusetts Minimum Requirements for the Management of Medical or Biological Waste 105 CMR 480.000, and all other health regulations of the Board of Health.

B. All Institutions proposing to use or continue the use of regulated biological agents at BSL-1 or BSL-2 containment levels must obtain a permit from the Board of Health before commencing or continuing said research, manufacturing, or other use of regulated biological agents and annually thereafter. Institutions receiving such a permit shall conduct research, manufacturing or other use only as specifically set out in their permit applications, and supporting documents filed with such application. The use of regulated biological agents

requiring BSL-3, BSL-4 containment and/or the BMBL, or identified as Select Agents by the CDC and USDA shall not be permitted.

a. Transition Rules: Any Institution currently engaged in the regulated activities hereunder at the time of passage of these Regulations, shall be required to apply for and receive a permit within one year from the passage hereof and then annually in accordance with the permit procedures set forth herein.

C. Institutions governed hereby shall establish and operate an IBC in accordance with NIH Guidelines unless otherwise stated herein. The IBC shall:

a. Meet no less than once a year. All minutes of the IBC meetings must be forwarded to the Board of Health.

b. Provide to the Board of Health a complete roster of all IBC members, including names, e-mail addresses and resumes or curriculum vitae (CVs) with the submission of a permit application. If there is a change in IBC membership, an updated roster of IBC members, with resumes or CVs of new members (community or institutional) appointed to the IBC shall be provided 10 – 14 days following the new member's appointment.

c. The IBC established shall include a community representative.

D. Each institution seeking permit approval shall certify and attest in its application that it will comply with the following requirements and that it shall:

a. Conform with the NIH Guidelines.

b. Conform with the biosafety standards established in the BMBL.

c. Conform with other conditions set forth in this regulation.

d. Conform with any special or specific requirements prescribed by the Board of Health as a condition of permit approval.

e. Allow access for site inspection of facilities and pertinent records by the Board of Health or its designees upon reasonable advance notice annually or more frequent, should it be deemed necessary by the Board of Health.

f. Submit (with permit application and renewal) a copy of all minutes from IBC meetings held during the previous year. These minutes should provide sufficient detail to allow the Board of Health and its staff or professional consultants to understand the risk assessment or risk assignment process by which the IBC determined that all work approved by the committee would be conducted safely at the assigned biosafety level using corresponding safety practices and any additional special safety practices as specified by the IBC.

g. Submit (with permit application and renewal) a detailed table of all protocols reviewed and approved by the IBC within the previous year, including, at a minimum, a listing of all biological agents utilized (e.g., host cell lines, biological vectors), any inserted gene sequences that would elevate risk (e.g., oncogenes), the BSLs and safety practices assigned after IBC review and the rationale or guidance document upon which the selected BSL and safety practices were based, and the name(s) of the principal investigator(s) who shall be responsible for each protocol.

h. Submit (with permit application and renewal) a protocol for strain verification of all known human pathogens that are considered to be attenuated or noninfectious approved by the IBC within the previous year for use within the permitted facility, if any, or sufficient documentation to demonstrate that such a screening process has been completed by another laboratory, in order to ensure the proper characterization of the virulence, replication competence, and extent of resistance to therapeutic antibiotics.

E. All facilities will be required to submit a summary of protocols approved by the IBC that identifies the specific regulated biological agents and describes the nature of the associated research, manufacturing and/or use to be conducted. This summary may conform to the NIH project registration format or may follow any other format that provides sufficient detail to understand the nature and extent of the biological risk associated with that project. A copy of each approved protocol must be submitted with the permit application.

F. Institutions permitted pursuant to these regulations shall file an annual report with the Board of Health upon permit renewal. Such report, at a minimum, shall include complete copies of all IBC minutes for the previous year, certification that the entity is in compliance with this regulation and the NIH Guidelines and CDC's BMBL, a report on any quality assurance and quality improvement efforts made during the previous year, and a complete roster of current IBC members. To the extent IBC minutes contain information regarding the agent, its location, or security measures, where the release of the information may jeopardize the health and safety of the public or proprietary information, such information may be deemed confidential under the Massachusetts Public Records Law, however, the Board of Health cannot guarantee same.

All information sent to the Board of Health 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.

The Board of Health may develop procedures for assuring confidentiality to the extent allowable under the Massachusetts Public Records Law.

G. Institutions permitted pursuant to these regulations shall provide the following in the case of an incident or adverse event:

- a. Verbal notification to the Board of Health within 24 hours of occurrence of event.
- b. A complete Incident Report form submitted to the Medford Board of Health within 30 days following the verbal notification.

SECTION 7: PERMIT APPLICATION REQUIREMENTS

All Institutions which are subject to these Regulations shall obtain a permit from the Board of Health. Each regulated facility must submit a completed application form obtained from the Board of Health, accompanied by a nonrefundable permit application fee as indicated on the current Board of Health schedule of fees. The application must include the following information:

- A. Institution name and address.
- B. Name(s) of corporate officer(s) authorized to sign the application and emergency contact information for those individuals signing on behalf of the institution.
- C. Name and emergency contact information of the institution's designated official responsible for compliance with this regulation. This is most often the designated biosafety officer, as defined in the NIH Guidelines.
- D. Designation of the appropriate biosafety levels (as defined in this regulation) for all laboratory areas, which are consistent with the NIH Guidelines or BMBL for all IBC-approved protocols. This designation should be reflected in the IBC minutes before work commences in the permitted facility or, at latest, no more than 60 days after that work commences.
- E. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building.
- F. A plan for systematic security of the premises.
- G. The applicant shall provide proof of Liability Insurance in an amount deemed sufficient by the Board of Health, but not less than \$50,000, and naming the City of Medford as an additional insured, and shall agree to release, indemnify, defend and hold the City of Medford and its agents harmless as to any claims, assessments, damages or causes of action arising out of or related to the Work
- H. A plan for systematic monitoring of waste to assure that surviving organisms will not be released into the environment. a. 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
- I. A plan for orienting representatives of the Medford Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.

J. Written agreement to allow inspection of facilities and pertinent records by the Medford Board of Health, Agents, Health Department employees, or their designated consultants.

K. Copy of the biosafety manual. Copies of updated biosafety manual(s) are to be submitted upon annual permit renewal.

L. Floor plans showing laboratory areas and hazardous materials storage areas. All biosafety containment, biosafety levels, and designated waste storage areas should be indicated. Updated floor plans to reflect any changes in assigned biosafety level or expansion of laboratory areas shall be submitted upon annual permit renewal.

M. Documentation of a medical surveillance agreement with a qualified provider.

N. Upon submission of a permit application, the applicants will present an overview of the use of rDNA or regulated biological agents during a regularly scheduled meeting of the Board of Health. The presentation shall include a general introduction of the institution, its mission, its research or production plans, a timeline of the use of rDNA or regulated biological agents, an overview of the applicant's biosecurity risk assessment and program, and a discussion of the facilities. A presentation is not required for permit renewals unless otherwise determined by an Agent of the Board of Health.

O. Permit renewal applications must be submitted by March 31st each year. Permits are valid for one year from May 1st to April 30th. New permits issued after May 1st shall be valid from the date of issue through April 30th.

P. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be \$500.00 with exemptions for nonprofits and institutions of higher education.

SECTION 8: PROHIBITIONS AND EXEMPTIONS

A. Educational institutions utilizing only commercially available molecular biology teaching kits that have been designated by the manufacturer for use at Biosafety Level 1 shall not be required to obtain a permit or comply with any permit requirements stated herein.

B. The use of biological agents requiring Biosafety Level 3 or 4 (BSL-3 and BSL-4) containment (as defined herein), as well as the use of Select Agents as identified by the CDC and the USDA shall not be permitted in City of Medford.

C. **REGISTRATION OF LOW RISK FACILITIES:** Low Risk Facilities, as defined in Section 2 of these Regulations, may conduct rDNA Work without a permit, provided that they register with the Board of Health. Written registration is required prior to commencement of Work and includes:

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 DNA 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.
 - f. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.
 - g. Description of annual safety training and refresher training provided to laboratory staff.
1. A registration fee of \$100.00, due upon initial application and upon annual renewals.
 2. Upon receiving and reviewing the submitted information, the Board of Health may require additional information to be submitted, and it may recommend other procedures or safeguards as it deems appropriate up to and including full permit application under the existing Board of Health Regulation.
 3. Release of agents that require reporting to Federal, State or Local agencies shall be reported to the Board of Health
 4. A registration shall be valid for a period of one year, unless sooner revoked in accordance with these Regulations.
 5. Applications for renewal shall be submitted to the Board of Health by March 31st each year. Applications submitted late may be rejected or subject to a late fee

SECTION 9: CONFIDENTIALITY OF INFORMATION

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 Board of Health 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).

- A. Information submitted to the Medford Board of Health is subject to public records laws. Upon receipt of any request for public records under these laws, the Medford Request for Public Records Officer may consult with the Board of Health and will make a determination as to whether the requested information is exempt from disclosure for safety and security or other enumerated purposes under G. L. c. 4, § 7(26) and withhold any documents, or portions thereof, that are covered by an exemption.
- B. Notwithstanding this designation by the institution, any documents that are referred to during a public meeting may be subject to public review. The exchange of information pertaining to compliance with the permit may take place

in an executive session, if the information shared in a public meeting would pose a security threat or compromise proprietary information.

SECTION 10: ENFORCEMENT

This regulation shall be enforced by the Medford Board of Health or its agent.

SECTION 11: PENALTIES

Whoever violates any provision of this regulation may be subject to penalties as follows:

A. If a designated agent of the Board determines that a party has violated this regulation, such agent may issue a written order (“Order”) to the Institution (permit holder) and its designated agent to correct the offending deficiencies within a reasonable specified time; and/or,

B. The Board of Health shall be empowered to enforce this regulation in any court of competent jurisdiction pursuant to the authority granted in G.L. c. 111 §31. Each day or portion thereof shall constitute a separate offense; and/or whoever violates any provision of this by-law may be penalized by indictment or on complaint brought in the district court. Except as may be otherwise provided by law and as the district court may see fit to impose, the maximum penalty for each violation or offense shall be one thousand dollars (\$1,000). Each day or portion thereof shall constitute a separate offense. If more than one, each condition violated shall constitute a separate offense. The Board of Health may enforce these Regulations or enjoin violations thereof through any lawful process, and the election of one remedy by the Board of Health shall not preclude enforcement through any other lawful means

C. In addition to a fine, an institution which violates any provisions of this regulation, or for which continued conduct or recombinant DNA technology or other activity covered under this regulation poses an immediate threat to the public health or environment may be closed by the Board of Health; and/or,

D. The Board of Health may suspend or revoke a permit if it determines that the institution has failed to comply with this regulation, or other applicable permit conditions. Suspension or revocation shall follow written notice and a hearing in accordance with the timeframe set forth in Section 12.

E. In the event the Board of Health or its agent determines there is an imminent threat to public health and safety it may suspend a permit immediately without prior notice. Any Institution thereafter may invoke the hearing process in Section 12 to appeal said suspension in which case a hearing shall be scheduled as soon as reasonably practicable.

F. In the event that a permitted establishment does not comply with these regulations, the Board of Health reserves the right to report violations to applicable State and Federal regulatory agencies.

SECTION 12: HEARING

Any person that has received an Order issued pursuant to Section 11 of this regulation may request a hearing before the Board of Health. Such request shall be in writing and shall be submitted to the office of the Board of Health in writing so as to be received by the Board of Health within ten (10) days after receipt of the Order. After said hearing, the Board may affirm, modify, or rescind said Order or take any other action it deems warranted and appropriate.

SECTION 13: VARIANCES

Upon written application of specific variance sought and reasons thereof, the Board of Health may in its sole discretion vary the application of any provision of this regulation with respect to any particular case when it determines that the enforcement thereof would do manifest injustice; provided that the decision of the Board of Health shall not conflict with the spirit of this regulation or any minimum standards required by Federal or State law; and provided that the applicant demonstrates to the reasonable satisfaction of the Board that a sufficiently equivalent level of protection can be achieved. Any variance granted by the Board of Health shall be in writing and shall be subject to such conditions as the Board deems appropriate. Any variance granted must be in writing with a copy available to the public, during normal business hours, in the office of the Board of Health. Any variance granted must be posted on the premises in a prominent location for the duration that the variance is in effect.

SECTION 14. INTERACTION WITH OTHER LAWS

This Regulation is intended to further the objectives of and to act in concert with any existing federal, state or local laws concerning the use of rDNA, and nothing herein shall be deemed to limit or restrict City officials or any other public officials whatsoever from acting in accordance with such laws.

SECTION 15: SEVERABILITY

Each provision of this regulation shall be construed as separate to the end that if any part of it shall be held invalid for any reason, the remainder shall continue in full force and effect.

Adopted by the Board of Health at its meeting held on: September 20, 2022