Town of Lexington

Land Use, Health and Development Department
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ARTICLE V Use of Recombinant and Synthetic Nucleic Acid Molecules and Biological Agents [Adopted 11-19-1997; amended 3-3-99; amended 6-13-07; amended 3-14-2023; amended 5-16-2023]

§ 155-33. APPLICABILITY.

All activities associated with constructing and/or propagating: a) recombinant and/or synthetic nucleic acid molecules, b) organisms and viruses containing recombinant and/or synthetic nucleic acid molecules 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 (the "Guidelines") as defined in Section § 155-34. These regulations shall govern where they differ from the Guidelines. These regulations do not apply to finished products that contain recombinant and/or synthetic nucleic acid molecules and that have been approved by other government regulatory agencies for medical or other purposes.

§ 155-34. DEFINITIONS.

For the purpose of these regulations, the following definitions are adopted:

a) Large-scale: More than ten (10) liters, but less than five thousand (5000) liters of recombinant and/or synthetic nucleic acid culture.

b) Significant deviation: Any deviation that might have an adverse effect on personal or public health

c) Guidelines: The most recent version, including any additional approvals, of the National Institutes of Health Guidelines for Research Involving Recombinant and/or Synthetic Nucleic Acid Molecules published in the Federal Register. 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. Amendments not acted upon by the Director within sixty days shall be considered approved.

d) "Recombinant DNA molecules" and "organisms and viruses containing RDNA" are those defined in the Guidelines, and such amendments as may be approved by the Director of Health. Amendments not acted upon by the Director of Health within sixty days shall be considered approved.

e) 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 of 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.

f) 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.

§ 155-35. ROLE OF LEXINGTON BOARD OF HEALTH

a) The Lexington Board of Health shall oversee all uses of recombinant and/or synthetic nucleic acid in Lexington.

b) Specifically, the BOH is responsible for:

(1) Establishing policies, procedures and criteria to aid in the implementation of this ordinance.

(2) Reviewing all amendments to the Guidelines.

(3) Reviewing all applications for permits for the use of recombinant and/or synthetic nucleic acid and biological materials in Lexington 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 information required to be included in, and the manner in which institutions and institutional biosafety committees make and evaluate, reports or applications developed pursuant to this bylaw.

(6) Reviewing such reports, applications, and recommendations, and approving where appropriate.

(7) Carrying out or designating a consultant to conduct site visits to institutional facilities.

(8) Approving the community members of the Institutional Biosafety Committees (IBCs) appointed by the IBC chairperson at each institution.

(9) Developing a procedure for members of institutions to report to the BOH violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.

§ 155-36. REGISTRATION.

a) Recombinant and/or synthetic nucleic acid users in any of the following categories are required to register proposed work with the BOH 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 recombinant and/or synthetic nucleic acid organisms but merely propagating them; and

(3) Users storing these materials in the laboratory but not actively conducting research.

b) Written registration is required prior to commencement of such work and must include:

(1) Name and CV of a person in the organization familiar with the proposed recombinant and/or synthetic nucleic acid work and the Guidelines.

(2) A brief summary, signed by the above-named person, describing the proposed work and providing the following:

a. Name and type of organisms (host/donor [foreign DNA]/vector) being used.

b. Reference(s) to the relevant section(s) of the Guidelines.

c. If recombinant molecules containing eukaryotic viruses are propagated in cells, 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 Guidelines, at the appropriate BSL level, and that exempt work will be done at BSL-1.

f. Name of biological waste handler (if any) and 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.

(3) An annual report summarizing the work performed over the previous year and addressing any ongoing work according to the format given in § 155-36(b)(2) above.

(4) Any fees required by the Lexington Board of Health for the issuance and renewal of registration permits, due upon initial application and upon annual renewals in accordance with the Lexington Board of Health fee schedule.

c) Upon receiving and reviewing the submitted information, the BOH may require an applicant to submit additional information, and may require the applicant to comply with other procedures or safeguards as it deems appropriate, up to and including a full permit application under the existing Town Bylaw.

d) Immediate reporting to the BOH of any employee exposure or illness, facility spill, release or explosion that could be potentially related to the use of recombinant and/or synthetic nucleic acid or biologicals used on site. The administrative officials at the registered facility must provide a verbal report to the Town of Lexington, Director of Health, within 30 days 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 Lexington, The Director of Health within two weeks of the verbal report. Submitting written reports before the deadline is encouraged. A determination as to whether there was a release of recombinant and/or synthetic nucleic acid material as described in Section (7)D should also be addressed to the Town of Lexington.

e) If the institution closes or cease operation of Recombinant and Synthetic Nucleic Acid Molecules and Biological Agents, they must notify the Lexington Board of Health as soon as possible to close out their registration. The institution must submit a letter on company letterhead requesting the registration to be closed.

f) All registrations are non-transferable.

§ 155-37. **PERMITS.**

a) All institutions planning to use recombinant and/or synthetic nucleic acid in any way other than those described in § 155-36, or non- recombinant and/or synthetic nucleic acid biological research and manufacturing that requires BSL-3 or higher containment or attenuated strains requiring lower Biosafety Level, must obtain a permit from the Board of Health before commencing such use. All permits are issued for one year and may be revoked for cause. All permits are non-transferable.

b) Institutions seeking such a permit from the Board of Health must first submit the following:

(1) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.

(2) A list of all organisms, containment levels, and decontamination procedures to be employed at the facility.

(3) A plan for a screening process to ensure 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 recombinant and/or synthetic nucleic acid organisms will not be released into the environment.

(5) A plan for systematic management of pest control management in laboratories, contiguous facilities and food service establishments in the same building.

(6) 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.

(7) A plan for systematic security of the premises.

(8) List of names and CVs of members of the IBC

(9) 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 Lexington, who shall report back to the Director of Health or his/her designee. The community representative shall be appointed by the facility holding the recombinant and/or synthetic nucleic acid permit, and notification of the community appointment should be sent to the Director of Health, who shall report to the BOH (see section § 155-37(9)(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.

c) The IBC community representative shall have no financial interest in the institution or any other institution in competition therewith, and 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 the 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 recombinant and/or synthetic nucleic acid use for compliance with the Guidelines and approves those projects that conform with the Guidelines. The instituted shall file with the BOH a description of each project approved by the IBC, including all organisms and the containment to be used, and a statement signed by the IBC stating that the experiment conforms with the Guidelines,.

e) All information sent to the BOH shall have any proprietary information and 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 BSL-3 or BSL-4 (the latter of which is prohibited in Lexington). 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.

(10) 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 recombinant and/or synthetic nucleic acid shall include, but shall not necessarily be limited to:

a) 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 recombinant and/or synthetic nucleic acid or biologicals sed on site from an approved IBC protocol. The IBC Chairman should consult with administrative officials at the permitted facility and provide a verbal report to the Town of Lexington, Director of Health, within 2 days 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 Lexington. The Director of Health requires a written report within two weeks following the verbal report. Submitting written reports before the deadline is encouraged. A determination as to whether there was a release of recombinant and/or synthetic nucleic acid material as described in § 155-37(B)(9)(d) should also be addressed to the Town of Lexington.

b) Retention of employee medical and health records for at least ten years. Such records shall be made available for inspection and may be used for public health studies.

c) An annual training program of safeguards and safety procedures for personnel.

(11) The name(s) of the Principal Investigator(s) responsible for enforcing the Policies of the IBC.

(12) A plan for orienting representatives of the Lexington Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.

(13) Written agreement to allow inspection of facilities and pertinent records by the BOH.

(14) For BSL-3 laboratories, evidence that the facility has been designed according to the latest standards for BSL-3, including the most recent edition of the CDC/NIH publications: Biosafety in Microbiological and Biomedical Laboratories." In addition, documentation of a maintenance schedule and annual commissioning by a 3rd party agent is required to be produced during the annual inspection by Town of Lexington.

c) The BOH shall review the institution's application for a permit and supporting documents and make its recommendation. Copies of the application, supporting documents, and the BOH recommendation shall be filed with the Board of Health and the Planning Board within 45 days after the application is filed with the BOH. The Board of Health shall take final action on the permit application within 75 days after the application is filed with the BOH. 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.

d) Permits shall be issued and renewed on an annual basis. The Board of Health may establish fees for the issuance and renewal of permits.

e) An annual report summarizing the work performed over the previous year and addressing any ongoing work according to the format given in § 155-36(b) and shall also include 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 recombinant and/or synthetic nucleic acid permit renewal date.

(g) If the institution closes or ceases operation of Recombinant and Synthetic Nucleic Acid Molecules and Biological Agents, the institution must notify the Lexington Board of Health as soon as possible to close out their permit. The institution must submit a letter on company letterhead requesting the permit to be closed.

§ 155-38. INSPECTION AND REVIEW.

a) All institutions involved in the use of recombinant and/or synthetic nucleic acid and biological materials as described in Section 155-36 Registration and 155-37 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 and the institution involved.

c) The Board of Health, its employees, 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) The Board of Health may request additional information as needed.

§ 155-39. RESTRICTIONS

a) Recombinant and/or synthetic nucleic acid use classified by the Guidelines as requiring any BSL-4 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) A special permit from the Board of Health is needed if recombinant and/or synthetic nucleic acid use classified by the guidelines as requiring any BSL3 physical containment measures as prescribed in Appendix F of the Guidelines under Standard Microbiological Practices, Special Practice Containment Practices, Containment Equipment or Laboratory Facilities

c) Biological agents that are classified as requiring BSL-4 containment shall not be permitted in the Town of Lexington.

d) Experiments for which containment levels are not prescribed in the Guidelines shall be approved by the BOH before the experiment is initiated.

e) Use of more than 5,000 liters of recombinant and/or synthetic nucleic acid culture shall not be permitted, unless a variance is obtained by the Board of Health.

f) There shall be no deliberate release into the environment, including to sewers, drains, or the air, of any organisms containing recombinant and/or synthetic nucleic acid.

§ 155-40. VIOLATIONS AND PENALTIES.

a) Each violation of the conditions of these regulations shall subject the violator to a fine of five-hundred dollars ($500.00) per day. In addition, the facility in which the violation occurs may be closed by the Board of Health. Each day the violation remains unresolved shall constitute a separate and distinct offense. **Violation of the provisions of these regulations shall also subject the violator to fines according to Chapter 155 of the Lexington Health Regulations and Article I of the Lexington Town By-laws.**

b) Once a permit has been issued or a registration filed, it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements, or the Guidelines, or if, in the opinion of the Board of Health, the recombinant and/or synthetic nucleic acid use causes a nuisance, or adversely affects the public health, safety and welfare in Lexington.

§ 155-41. **ASSESSMENT OF EXPENSES.**

The salaries and expenses paid by the Town for inspections, reviews, staff and consultants for work directly related to carrying out the requirements of these regulations shall be assessed to the institutions holding permits under these regulations. An accounting of these costs will be furnished annually to each institution.

§ 155-42. **SEVERABILITY.**

The invalidity of any section or provision of this bylaw does not invalidate any other section or provision of it.

§ 155-43. **VARIANCES.**

The Board of Health may vary the application of any provision of these regulations with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board of Health is not in conflict with the spirit of these standards. Any variance granted by the Board of Health must be in writing with a copy available to the public at all reasonable hours in the Office of the Town Clerk and in the Office of the Board of Health.

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