

TEWKSBURY BOARD OF HEALTH REGULATIONS

CHAPTER 8: FOR THE USE OF RECOMBINANT DNA TECHNOLOGY

8.1 AUTHORITY

The Tewksbury Board of Health (“Board”) acting under the authority of MGL c. 111 § 31, and other applicable provisions of the Massachusetts General Laws and amendments there to enabling, has duly made and adopted the following Regulations in the interest of and for the protection of public health.

8.2 PURPOSE

These regulations are promulgated for the oversight and protection of the worker, community, environment, public health, welfare, and safety within the Town of Tewksbury (the “Town”).

8.3 DEFINITIONS

Board: The Town of Tewksbury Board of Health.

Director: The Director of Public Health

Guidelines: The most recent version including any additional and future amendments or approvals of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register and the Centers for Disease Control and Prevention Guidelines, "Biosafety in Microbiological and Biomedical Laboratories." In the event that such Guidelines are discontinued or abolished, those Guidelines in effect and approved by the Board of Health at the time of such discontinuance shall remain in effect.

Institution: Any single individual, group of individuals, corporation, firm, partnership, or organization, whether public or private.

Institutional Biosafety Committee (IBC): is a committee established by the institution in accordance with the Guidelines and terms set forth in these regulations.

Person(s): Any individual, partnership, company, corporation, trustee, trust, organization, or other legal entity.

Recombinant DNA (rDNA) or RNA (rRNA) Molecules:

- (1) Molecules constructed outside living cells by joining natural or synthetic DNA or RNA segments to DNA or RNA molecules that can replicate in a living cell or
- (2) Molecules that result from the replication of those described in (1) above. This includes synthetic DNA or RNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent); these are considered as equivalent to their natural DNA or RNA counterparts.
- (3) Genomic DNA/RNA organisms that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are subject to the NIH and CDC Guidelines and this Regulation only in the case where the transpose itself contains rDNA or rRNA.

Significant Deviation: Any deviation from NIH and CDC guidelines that might have an adverse effect on personal or public health.

8.4 PERMIT:

8.4.1 No person shall operate a DNA/RNA facility within the limits of the Town, in any building facility, or dwelling, or premises without a permit from the Board.

8.4.2 New permit(s) shall require a public hearing before the Board. Said hearing shall be held in accordance with the Board Regulations Chapter Two Request for an Administrative Determination of Applicability.

8.4.3 All permits will expire annually on May 31st.

8.4.4 A permit(s) may be revoked at any time with cause. The Board or its agent may revoke said permit without a public hearing if, in its or his or her opinion, conditions exist which may endanger the health, safety, or welfare of the workers, general public, or the environment.

8.4.5 The permit holder shall have the right to appeal the revocation at a public hearing of the Board if no hearing had been held prior to the revocation.

8.4.6 The permit is not transferable.

8.5 APPLICATION

The application must include the following documentation:

8.5.1 A completed application form supplied by the Health Department.

8.5.2 A plot plan showing the proposed location of the facility.

8.5.3 A floor plan showing the internal layout of the facility.

8.5.4 A list of all organisms, recombinant and infectious, the taxonomic groups from which they are obtained, containment levels, and decontamination procedures to be employed.

8.5.5 A plan for treatment and disposal of biological waste in accordance with 105 CMR 480.000, Chapter 8, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.

8.5.6 A plan for pest control management in laboratories, contiguous facilities, and food service establishments in the same building.

8.5.7 A plan for systematic security of the premises.

8.5.8 A report summarizing the work subject to the Guidelines performed over the past year.

8.5.9 The names of the members of the IBC.

8.5.10 The facility's safety manuals and employees training program, with a plan for an appropriate medical oversight program, including a copy of the medical oversight contract, as determined by the IBC, for all persons engaged in the use of rDNA, rRNA and infectious agents.

8.5.11 A plan of orientation for the Town's Health, Police, and Fire Departments to the facility and the appropriate emergency procedures. This may include bordering communities when necessary.

8.6 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

8.6.1 The IBC required by the NIH Guidelines should be broad-based in its composition. It should include members from a variety of disciplines within the institution. It must include at least two (2)

community representatives appointed by the Board, one who shall be the Chairman of the Board of Health or his or her designee.

8.6.1.1 The two (2) community representatives shall be bound to the same provisions on non-disclosure and non-use of proprietary information and trade secrets as other members of the IBC Committee, except to the extent that disclosure is necessary to alleviate any public health hazard.

8.6.1.2 The IBC and or facility must inform the Board of significant changes to the Guidelines and other applicable regulations.

8.6.1.3 The IBC must meet a minimum of three (3) times per year

8.6.2 The minutes of all meetings of the IBC shall be delivered to the Board within ten (10) days of the meeting. Information sent to the Board shall not contain any proprietary information and trade secrets. The full text shall remain on file in the records of the Institution for inspection at all times by any member of the Committee and the Board.

8.6.3 Minutes supplied to the Board shall be considered public records.

8.6.4 IBC must review, approve, and monitor the Institution's manuals, worker training programs, health and safety programs and procedures.

8.6.5 IBC must inform the Board of any changes in membership within 10 days.

8.7 SAFETY MANUALS

The institution shall prepare a Biosafety Manual which describes how the NIH Guidelines will be implemented at the institution. The manual should include provisions defining the following:

8.7.1 Work project and containment level approval process.

8.7.2 Personnel training requirements.

8.7.3 Medical surveillance program,

8.7.4 Standard laboratory rules and practices.

8.7.5 Emergency procedures.

8.7.6 Manual shall be approved by the IBS Committee.

8.8 USE OF RECOMBINANT DNA TECHNOLOGY

8.8.1 The experimentation with, or use of, recombinant DNA technology shall be undertaken only in strict conformity with the current "Guidelines" of the National Institute of Health (NIH), or in conformity with such superseding laws and regulations as may be established by other Federal Agencies or by Act of Congress; and in conformity with this regulation and other health regulations as the Board may from time to time promulgate.

8.8.2 The institution shall observe the following requirements:

(a) Personnel training requirements shall be appropriate to the task assigned. Training shall

include orientation to the NIH Guidelines and/or any superseding laws and regulations, the Biosafety Manual and general laboratory safeguards.

(b) Emergency procedures shall describe actions to be taken if an accident contaminates personnel, the laboratory or the environment, and procedures for notification of appropriate governmental agencies.

(1) Facility must offer and provide training to the Tewksbury Police, Fire, and Public Health Officials in the appropriate emergency response procedures.

(2) When and as needed this training must include Police, Fire and Health Officials of neighboring communities.

(c) The institution shall, subject to the limitations of available technology, utilize personnel and laboratory monitoring techniques appropriate to each organism's degree of hazard.

(d) The Institution shall, to the extent possible, ensure the purity of host organism strains and test resulting recombinant containing organisms for resistance to commonly used therapeutic antibiotics.

(e) Any significant breach of containment and the associate remedial action shall be reported to the IBC. Any environmental release shall be reported immediately.

(f) Any significant or potentially rDNA related employee illness shall be reported to the IBC.

(g) It shall be the duty of the IBC to investigate any case of potentially work-related illness associated with the use of rDNA. The results of such investigation shall be forwarded to the Director of Public Health. All personnel medical records shall be kept confidential and shall not be public records.

(h) The Institution shall allow inspection and review of practices and procedures under this regulation. The Board may retain competent professional assistance in the conduct of such inspection. The institution shall reimburse the Town of Tewksbury for the direct expense of up to one (1) inspection or review per year. Any inspector shall be subject to the same requirements regarding the confidentiality of trade secret and proprietary information as a community resident member of the IBC. Any inspection reports shall be delivered to the Board of Health only after all confidential and proprietary information has been removed. Such reports shall then become public record. The full text of the inspection report or review shall remain on file in the records of the institution for inspection at all reasonable times by any member of the Committee.

8.9 RESTRICTIONS ON THE USE OF RECOMBINANT DNA TECHNOLOGY:

8.9.1 Experimentation with, or use of, recombinant DNA, rRNA, or infectious agents requiring a P3 or P4 level of containment shall not be permitted.

8.9.2 Use of recombinant DNA technology shall not be permitted in areas for residential purposes.

8.9.3 Propagation or handling of more than 1,000 liters per vessel of rDNA, rRNA culture or infectious agents shall not be permitted.

8.9.4 There shall be no deliberate release into the environment, that is, to the sewers, storms drains, land or air, of any organisms containing viable rDNA, rRNA, or infectious agents.

8.9.5 The Institution shall report within 24 hours to the Director of Public Health, followed by a written report within 15 days to the IBC and Director of Public Health, of any significant deviations, accidents, illnesses or releases related to the use of rDNA, rRNA or infectious agents. An inspection of the facilities, records and procedures may be deemed necessary by the IBC and/or Board based upon its judgment of the nature of the incidents.

8.10 MEDICAL OVERSIGHT

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If the IBC determines that a medical oversight program is necessary, that program shall include, but not be limited to, the following:

8.10.1 Prompt reporting to the IBC of illnesses that are potentially related to the use of rDNA, rRNA, and infectious agents.

8.10.2 Employee medical and health records shall be retained for at least ten years.

8.10.3 A training program including illness and injury reporting procedures for all personnel.

8.11 INSPECTION AND REVIEW

8.11.1 All Institutions subject to this Regulation shall allow inspection of its facilities, procedures, practices, and records by the IBC and the Board designee, in order to confirm compliance with this Regulation.

8.11.2 The Board, its employees, all members of the IBC, and any organization employed to perform inspections shall maintain the confidentiality of all proprietary information and trade secrets released to them by reason of the Regulation.

8.12 ASSESSMENT

The salaries and expenses incurred by the Town for testing, inspections, reviews, staff and consultants for work directly related to carrying out the requirements of this Regulation shall be assessed to the Institutions holding permits under this Regulation.

8.13 INDEMNIFICATION

Each Institution engaging in, or intending to engage in, any activities regulated hereunder agrees to indemnify, defend, protect, and hold harmless the Town, its officers, agents and employees from and against any and all claims, demands, losses, damages, liabilities, fines, charges, penalties, administrative and judicial proceedings and orders, judgments, remedial actions of any kind, all costs and cleanup actions of any kind, and all costs and expenses incurred in connection therewith, including reasonable attorney's fees and costs of defense (collectively, the "Losses"), directly or proximately resulting from the Institution's negligence with regard to any acts, omissions or conduct in any way related to any activity regulated hereunder, pursuant to its permit, its application therefore, or resulting from the Institution's failure to comply with the terms of the permit, the Regulation or the Guidelines.

8.14 FEES

Fees shall be set by the Board annually and published as part of its fee schedule.

8.15 VARIANCE

8.15.1 Any applicant for, to holder of a permit hereunder, may request a variance from any of the provisions herein. The Board may grant the request for a variance upon a showing that enforcement of such provision would, in the Board's determination after review of evidence presented by the applicant, result in a hardship which would result from strict enforcement or regulations for the applicant or holder. Said hardship shall not be solely based upon economic circumstances and the granting of the variance may not be detrimental to public health.

8.15.2 Every request for a variance must be in writing on forms supplied by the Health Department and in accordance with “Tewksbury Board of Health Regulations Chapter Two Request for an Administrative Determination of Applicability Section 2.5 Variance Request Procedure/Abutter Notification.”

(a) When a variance is requested a hearing shall be scheduled and held in accordance with the requirements of “Tewksbury Board of Health Regulations Chapter Two Request for an Administrative Determination of Applicability Section 2.6 Conduct of Hearing.”

8.15.3 Any variance granted by the Board must be posted on the premise in a prominent location for the duration that variance is in effect.

8.15.4 Any and all variance(s) are not transferrable.

8.16 ENFORCEMENT

8.16.1 These regulations and the permits hereunder shall be enforced by the Board, its designee, or Health Agent. Any violations hereunder may be enforced by a violation notice, administrative order and civil or criminal court action as applicable.

8.16.2 Critical Violations: Any violation hereof which is deemed an immediate threat to the public health and welfare by either the Board or the Agent or any permit holder who has been the subject of repetitive “Non-critical” violations, which shall mean three (3) or more violations within a six (6) month period, shall be deemed a Critical Violation and shall have its permit immediately revoked hereunder. Following revocation of a permit, the Board shall hold a hearing on the matter within thirty (30) days.

8.16.3 Non-critical Violations: Any violation hereof which is not deemed an immediate threat to the public health or welfare. A Person who has received a Non-critical Violation shall be subject to a fine in accordance with G.L.c. 40 §21D and as more fully set forth in the Town By-laws.

8.16.4 Each day of non-compliance herewith shall be deemed a separate offense hereunder.

8.16.5 Past violations of any type and the Applicant’s resolution thereof, or not, of said violations may be considered by the Board during the Annual Renewal process.

8.17 APPEAL

Any Applicant or Permit Holder aggrieved by a final decision of the Board may appeal said decision to a court of competent jurisdiction.

8.18 PENALTIES

8.18.1 Any person(s) violating or failing to comply with any provision of any Regulations of the Board, shall be warned in writing that said person(s) shall be subject to the appropriate enforcement action and/or to the non-criminal disposition process adopted by Special Town Meeting at its meeting of May 8, 1991 (warrant article number 47) as follows:

1st offense – written warning.

2nd offense – one hundred (\$100) dollar fine.

3rd offense – two hundred (\$200) dollar fine.

4th and subsequent offenses – three hundred (\$300) dollar fine and/or enforcement action.

8.18.2 The Board may modify, suspend, or revoke, for just cause, any permit issued by the Board. In addition, the Board Health Agent or his or her designee may enforce the Board Regulations using any other established means of enforcement in addition to or in lieu of non-criminal disposition process.

8.19 SEVERABILITY

If any paragraph, sentence, phrase or word of this TBOH Regulation shall be finally declared invalid by a court of competent jurisdiction, such decision shall not affect the validity of any other provision of this Regulation, which Regulation shall remain in full force and effect; and to this end the provisions of the this Regulation are declared severable.

8.20 EFFECTIVE DATE

Regulations adopted on July 18, 2011 and shall take effect on September 28, 2011.