



Town of Randolph, Massachusetts

Board of Health

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Regulation for the Use of Recombinant DNA Molecule Technology and Infectious Agents

Section 1: Authority

The Board of Health, Town of Randolph, Massachusetts, acting under the authority of Chapter 111, Section 31 of the General Laws and amendments and additions thereto, and by any other power thereto enabling, has duly made and adopted the following Regulation in the interest of and for the protection of the public health. While many permits are common to all businesses, biotechnology research and development requires a specific Town permit. The Town of Randolph permit process must be completed prior to the initiation of research that uses rDNA technologies and requires that companies form an Institutional Biosafety Committee (IBC) as the internal mechanism of research oversight and the point of contact for the Town of Randolph Biosafety Committee (RBSC).

Section 2: Applicability

This Regulation shall apply to all activities associated with (a) constructing, propagating, handling, synthesizing, or storing recombinant DNA (rDNA) or RNA (rRNA) molecules [if these segments are not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, the synthetic DNA or RNA segments are exempt from this Regulation] b) any plants, animals, bacteria or viruses containing rDNA or rRNA molecules and c) other non-recombinant infectious agents shall be performed in strict accordance with this Regulation and with the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) Guidelines as defined below. This Regulation shall apply where it differs from the NIH and CDC Guidelines. This Regulation does not replace nor modify applicable Federal, State and local requirements.

Section 3: Definitions

For the purpose of this Regulation, the following definitions are adopted:

a) Guidelines

Guidelines shall mean the most recent version and any additional and future amendments or approvals of the National Institutes of Health 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.

b) Institution

Institution shall mean any person, natural or otherwise, sole proprietor, corporation, limited liability company, partnership, trust, association, public or private organization, federal, state or local government agency, or any other individual or entity acting in its own or any representative capacity.

c) 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. 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 transposon itself contains rDNA or rRNA.

d) Significant Deviation

Significant deviation means any deviation from the NIH and CDC Guidelines that might have an adverse effect on personal or public health.

Section 4: Randolph Biosafety Committee

- a) A Randolph Biosafety Committee (RBSC) shall be established for the purpose of overseeing all activities to which this Regulation applies.
- b) The RBSC shall:
 - 1) Establish policies, procedures and criteria to aid in the implementation of this Regulation.
 - 2) Inform the Board of Health of significant changes to the Guidelines and other applicable regulations.
 - 3) Review all applications for permits under this Regulation and recommend action to the Board of Health.
 - 4) Determine the manner in which Institutions and Institutional Biosafety Committees (IBCs) make reports, applications or recommendations to the RBSC and the type of information required.
 - 5) Review Institutions' manuals, worker training programs, health and safety programs, monitoring procedures and reports.
 - 6) Implement site visits to Institutions' facilities and review inspection reports.
 - 7) Advise the Board of Health on the appointment of community members for the IBCs.
 - 8) Develop a procedure for individuals to report alleged violations of this Regulation to the RBSC.
- c) The RBSC shall be composed of no fewer than 5 members, to include the Chairman of the Board of Health or designee, the Director of Health, and a minimum of three community members. These community members shall be appointed by the Board of Health..

Section 5: Permits

a) Each Institution intending to engage in any activities as defined in Section 2 of this Regulation, shall obtain a permit from the Board of Health prior to commencing such activities.

The permit application shall include the following documentation:

- 1) A completed Board of Health application form.
 - 2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.
 - 3) A list of all organisms, recombinant and infectious, the taxonomic groups from which they are obtained, containment levels, and decontamination procedures to be employed.
 - 4) 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.
 - 5) A plan for pest control management in laboratories, contiguous facilities and food service establishments in the same building.
 - 6) A plan for systematic security of the premises.
 - 7) A report summarizing the work subject to the Guidelines performed over the past year.
 - 8) The names of members of the Institutional Biosafety Committee (IBC).
 - 9) The Institution's safety manuals and an employee training program, together 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.
 - 10) A plan for orientation of the Health, Police and Fire Departments of the Town to the facility and to appropriate emergency procedures.
 - 11) Written agreement to allow inspection of facilities and pertinent records by the BBSC.
- b) The RBSC will review the Institution's application for a permit and supporting documents and make its recommendation to the Board of Health within 45 business days of receipt of the application in the Health Department office. The Board of Health shall take final action on the permit application within thirty business days of receipt of the recommendations from the RBSC. The period within which final action shall be taken may be extended by mutual consent of the Board of Health and the applicant.
- c) The fees for permits issued by the Board of Health under this Regulation shall be:
- 1. Initial Application Fee \$500
 - 2. Renewal Application Fee \$500
- d) Application for permit renewal must be made annually.

Section 6: Institutional Biosafety Committee

- a) The Institutional Biosafety Committee (IBC) shall have as members, in addition to the Institution's representatives and the Director of Health or designee, one community representative appointed by the Board of Health..
- b) The IBC shall meet at least annually. All minutes of the IBC meetings shall be forwarded to the Board of Health.
- c) The community member of the IBC and the Director of Health, or designee, shall have no controlling or substantial financial interest in the Institution or any other Institution in competition therewith. All financial interests shall be disclosed prior to appointment. Such representatives 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 or Federal statutes.
- d) The IBC reviews all projects for compliance with the Guidelines. Project protocols must be approved by the IBC and a statement certifying that each project protocol conforms with the Guidelines shall be filed with the Board of Health.
- e) Information sent by the IBC to the Board of Health shall not contain proprietary information and trade secrets. Full documentation of IBC reviews and determinations shall remain on file in the records of the Institution for inspection by authorized individuals.

Section 7: Medical Oversight

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

- a) Prompt reporting to the IBC of illnesses that are potentially related to the use of rDNA, rRNA and infectious agents.
- b) Employee medical and health records shall be retained for at least ten years.
- c) A training program including illness and injury reporting procedures for all personnel.

Section 8: Inspection and Review

a) All Institutions subject to this Regulation shall allow inspection of its facilities, procedures, practices, and records by the RBSC or Board of Health designee, in order to confirm compliance with this Regulation.

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

Section 9: Restrictions

a) Use of rDNA, rRNA and infectious agents classified by the Guidelines as requiring **BL3 or BL4** containment measures may not be permitted..

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

c) The Institution shall report within 48 hours to the Director of Health, followed by a written report within 15 days to the RBSC, 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 RBSC based upon its judgment of the nature of the incidents.

Section 10: Penalties

a) Violations of this Regulation shall subject the Institution to a fine of first offense \$25 dollars, second \$50 and third \$100 per day thereafter. Each day of violation shall constitute a separate and distinct offense.

b) If deemed necessary to protect public health, the Board of Health may close the facility in which the violation occurred.

c) Permits 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 this Regulation, permit conditions, or the Guidelines, or if in the opinion of the Board of Health, activities at the Institution cause a nuisance, or adversely affect the public health, safety and welfare in the Town of Randolph.

Section 11: Assessments

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.

Section 12: Indemnification

Each Institution engaging in, or intending to engage in, any activities regulated hereunder agrees to indemnify, defend, protect, and hold harmless the Town of Randolph, its selectmen, 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.

Section 13: Severability

Each part of this Regulation is construed as separate to the end, and that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of this Regulation shall continue in full force and effect.

Section 14: Variance

The Board of Health may vary the application of any provision of this Regulation. Any variance granted by the Board of Health must be based on written finding of fact and be preceded by a public hearing. A copy of the variance will be made available to the public during business hours in the Offices of the Town Clerk and Board of Health.

This Regulation becomes effective .

BY ITS BOARD OF HEALTH

Chairman Board of Health APPROVED AS TO FORM:

Vice Chair Member