

ARTICLE 27

BIOMEDICAL RESEARCH AND PRODUCTION

SECTION 1. Purpose.

To recognize the existence and potential growth of the biotechnology industry in Grafton and provide standardized requirements for those industries to protect the public health, safety and welfare

SECTION 2. Definitions.

“Biological Agent”: 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 through 4 Agent by NIH Guidelines;
2. requires BSL-3 through BSL-4 containment based on the Risk Assessment.; or
3. is classified by the DHHS or the USDA as a “Select Agent”.

“Biosafety in Microbiological and Biomedical Laboratories” or “BMBL”: The most current edition of Biosafety in Microbiological and Biomedical Laboratories, including any amendments, revisions, or substitutions that are adopted by DHHS, CDC and NIH.

“BoH”Board of Health

“BoS”Board of Selectmen

“BSL”biosafety level

“CDC”Centers for Disease Control and Prevention

“DNA”deoxyribonucleic acid

“DHHS”U.S. Department of Health and Human Services

“EPA”United States Environmental Protection Agency

“Institution”: Any single individual, group of individuals, corporation, partnership, hospital, academic institution, society, association, firm, sole proprietorship, or any other legal entity, whether public or private. For the purposes of this By-Law, a corporation or non-profit entity and its laboratories, subsidiaries and affiliates shall be deemed a single institution.

“Institutional Biosafety Committee (IBC)”: An Institutional committee, established and functioning in accordance with the NIH Guidelines, whose mandate includes reviewing and overseeing certain basic and clinical research involving rDNA or Biological Agents conducted at that Institution, evaluating safety of such research and identifying potential risk to public health or the environment.

“Large scale”: Any research or production activity involving more than 10 liters of culture of DNA Material or a Biological Agent.

“LEPC”Local Emergency Planning Committee

“MADEP”Massachusetts Department of Environmental Protection

“MADPH”Massachusetts Department of Public Health

“NIH”The National Institutes of Health

"NIH Guidelines"

- a) Guidelines for Research Involving Recombinant DNA Molecules;
- b) Recombinant DNA Research; Physical Containment Recommendations for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules" (NIH Large Scale Recommendations); and
- c) Any further amendments to (a) or (b) above, wherever published, which are adopted by NIH.

“OSHA”Occupational Safety and Health Administration

“Principal Investigator” The individual designated by the Institution to direct the biological research project or program conducted at BSL 3 through BSL 4. The Principal Investigator is responsible for conducting such research in accordance with applicable regulations, including NIH Guidelines and the provisions of this By-Law, as well as any conditions specified by the IBC. Principal Investigator should adhere to any serious adverse reporting requirements in accordance with federal regulations, state laws and local institutional policies.

“Project” A biological research experiment or biological research experiments or biological production activities, under a Principal Investigator, in which the risk assessment has been designated at Biosafety Level 3 through 4.

“Public Records Law” Massachusetts General Laws c. 66, and related provisions.

“Recombinant DNA” or **“rDNA”** Shall have the meanings specified in the current “NIH Guidelines” (as defined above).

“rDNA Materials” Any biological compound or materials falling within the definition of ‘rDNA Molecules’ specified in the current NIH Guidelines, which:

- a) is classified as a Risk Group 3 through 4 Agent by NIH Guidelines;
- b) requires BSL-3 through BSL-4 containment based on the Risk Assessment.; or
- c) is classified by DHHS or the USDA as a “Select Agent”.

“Registration” A written application for research protocol approval for use of rDNA Materials or Biological Agents containing the information necessary to perform a risk assessment.

“Risk Assessment” An evaluation of the appropriate biosafety level for research with rDNA Material or Biological Agents, conducted by the Institution’s Biosafety Officer. Risk assessments resulting in a BSL-3 classification require full review and approval by the Institutional Biosafety Committee.

“**Select Agent**” Any microbial and toxic agents listed at 42 CFR 72.3 and 73.4, 42 CFR 73.5, 7 CFR 331 and 9 CFR Part 121.4, and the rulings made by the United States Centers for Disease Control and USDA relative thereto, as such regulations and rulings may be amended from time to time.

“**USDA**”United States Department of Agriculture.

SECTION 3. Scope.

This By-Law shall apply to all Institutions in the Town of Grafton engaged in research or production activities involving rDNA Materials or Biological Agents.

SECTION 4. Restrictions.

All rDNA Materials and Biological Agents classified as Risk Group 4 agents, or any work with rDNA Materials or a Biological Agent that requires BSL-4 containment based on the Risk Assessment, shall be prohibited in the Town of Grafton.

SECTION 5. Regulations.

All research or production activities involving rDNA Materials or Biological Agents by Institutions in the Town of Grafton shall be undertaken only in conformity with current and NIH Guidelines and the BMBL, as promulgated in the Federal Register and as may be amended from time to time by the NIH or DHHS or by any successor agency. Any Institution engaged in research or production involving rDNA Materials or Biological Agents shall also comply at all times with any other applicable federal and state regulations covering such work; e.g., regulations promulgated by the CDC, OSHA , EPA, MADEP and MADPH.

After public notice and public hearing, and specific written notice to any individual Institution holding or applying for a permit, the Board of Health shall have the authority to promulgate reasonable and appropriate rules and regulations, consistent with the provisions of this bylaw, to implement this bylaw, provided however, that any such rules and regulations promulgated by the Board of Health shall go no further than this Bylaw in terms of their scope, jurisdiction, or their operational, financial, compliance or other impacts on affected Institutions, and shall not grant or purport to grant the Board of Health any further power or authority, including any further power to levy or collect fees, assessments or other costs or charges on or from any Institution, or to the require the submission of any further information from Institutions, beyond what is explicitly specified in this Bylaw.

SECTION 6. Administrative Requirements.

Each Institution in the Town of Grafton which conducts research or production activities involving rDNA Materials or Biological Agents shall comply with the administrative practices set forth in the NIH Guidelines. In addition, the Institution shall comply with the following additional rules, which may exceed the requirements of the NIH; provided, however, that nothing in these Bylaws shall create an obligation which would directly conflict with applicable NIH guidelines.

- a. The establishment of an Institutional Biosafety Committee (IBC) which shall contain at least five members, at least two of whom (but no less than 10%) shall not be affiliated

with the Institution. Additionally, an alternate non-affiliated member, who would attend meetings and vote if one of the regular non-affiliated members was unable to attend will also be appointed. When a non-affiliated representative vacates for any reason, the alternate non-affiliated representative will automatically fill the vacated position and a new alternate will be chosen in accordance with the procedure outlined in 2. below. The IBC shall be considered an instrumentality of the Institution and shall not be deemed to be an "agency", "board" or "office" of the Town for the purposes of the Public Records Law.

1. The IBC shall contain at least one representative from the Institution's biosafety staff. If any work is being done at the BSL-3 level and/or if the Institution is engaged in Large Scale research or production activities, the Institution shall appoint a Biological Safety Officer who shall be a member of the IBC.
 2. Any prospective community representatives shall submit their qualifications to the BoH and to the BoS. The non-affiliated representatives on the IBC shall be nominated by the BoS with input by BoH within 60 days after an Institution requests a permit to operate or a vacancy occurs. The non-affiliated representatives on the IBC shall be persons active in the community and shall represent the interest of the community with respect to the environment and public health.
 3. The non-affiliated representatives on the IBC shall be bound by the same rules prohibiting use and disclosure of proprietary information and trade secrets as other members of the IBC. The Institution may require that any non-affiliated representatives sign confidentiality agreements.
 4. The IBC shall establish set of rules and administrative procedures governing its operations in accordance with NIH guidelines.
 5. The Board of Health Agent or a designee of the Board of Health Agent who is a member of the Board of Health will be an ex-officio non-voting member of all IBC's.
- b. The provisions of Biosafety Registrations, Standard Operating Procedures and any specific manuals, such as a Biosafety Manual and an Emergency Response Plan, shall be subject to the review and approval of the IBC.
 - c. The IBC shall ensure that proper training and appropriate safeguards and procedures for minimizing potential environmental and personal exposure are followed.
 - d. If the Institution is engaged in Large Scale activities involving rDNA Materials or Biological Agents, the IBC shall confirm that the Institution is compliant with all additional administrative requirements contained in the NIH Large Scale Recommendations.
 - e. Institutions should prepare IBC meeting minutes that not only serve the Institution's need for a record of the IBC's proceedings, but that also document for the NIH and the public that the IBC is fulfilling the performance expectations of the NIH Guidelines. Minutes of all IBC meetings shall be forwarded to the BoH and, upon request, the Institution shall make the IBC meeting minutes available to the public subject to the provisions of Section 11 of this bylaw.

- f. In the event that two or more members of the IBC believe in good faith that approval by the IBC of a new registration of particular research or production involving rDNA Materials or Biological Agents was given in violation of NIH Guidelines, BMBL, this By-Law, or any other applicable laws or regulations, and such members have expressed their concerns at the meeting of the IBC approving such registration, such members may dispute such approval in writing to the chief research officer of the Institution and the Town, through its Board of Selectmen (with a copy to the Board of Health), no later than seven (7) days after such IBC approval was granted, setting forth specific reasons why such members believe that applicable laws, regulations or procedures have not been followed. In such event, no research or production involving the disputed procedures or alleged violation shall take place until the dispute has been resolved, in accordance with the procedures set forth in this paragraph.

This dispute resolution procedure shall not apply to re-approval of an existing Project, unless the terms on which the work or procedure is conducted have been materially changed.

During the seven (7) day period following receipt of such notice, the Board of Selectmen and the Institution will each designate a representative who shall meet and seek to resolve any such dispute.

If the Town and the Institution are not able to resolve such dispute within such seven (7) day period, the dispute shall be referred to a panel of three members experienced in scientific, medical, occupational, health and/or environmental areas. One panel member shall be selected by the Town, one by the Institution, and the third panel member selected by mutual agreement of the first two panel members. The Institution may require that panel members sign confidentiality agreements similar to those being signed by other persons who are not employees of the Institution and are being granted access to confidential information. Establishment of the panel shall be completed within an additional period of not more than fourteen (14) days. The panel's recommended decision shall be rendered within fourteen (14) days after the date such dispute is referred to it. Any costs associated with the dispute resolution shall be borne by the Institution. The panel's recommended decision shall be forwarded to the IBC, which after giving full consideration and substantial deference to the panel's recommended decision, shall take any further action it deems appropriate. Final disposition of the disputed approval shall be communicated to the Town through the Board of Selectmen.

SECTION 7. Permits, Annual Reports, Inspections and Fees.

No research or production involving rDNA Materials or Biological Agents in the Town of Grafton may be undertaken without a permit from the Board of Health. Institutions are responsible for obtaining all required federal, state and local permits and regulatory approvals for site location, construction, occupancy and use of proposed facilities before commencing operations under any permit granted pursuant to this bylaw.

Institutions shall submit a permit application to the Board of Health, signed by the Institution's Chief Research Officer and Biosafety Officer, which includes, (subject the provisions of Section 11 of this Bylaw), the following information:

- Name, address and phone number of the Institution
- Address of building at which permitted work will be performed

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- Type and Biosafety Containment Level (e.g. rDNA Material at BSL-3, Biological Agents at BSL-3, Select Agents at BSL-2, or Select Agents at BSL-3) of the proposed work.
 - Whether any of the proposed work will be “Large Scale”(e.g. rDNA Materials, Biological Agents, Select Agents)
 - Name, address and contact information for Biosafety Officer, Chief Research Officer and Alternative Emergency Contact (if any)
 - Executive Summary describing the Institution’s general operations, regulated protocols, title and brief project descriptions, and the names of the Principal Investigators.
 - A description of the Institution’s procedures and policies relating to lab safety, including; training, inspections, transportation, waste disposal, decontamination, pest control, termination of work, evacuation and emergency response.
 - Documentation of an Occupational Health program including a description of any medical surveillance required for employees.
 - Institutional Biosafety Committee membership (names, affiliations and curricula vitae).
 - a. Prior to commencing operation and every two years thereafter, the Institution shall complete and submit a permit application or renewal. The BOH shall issue such permit upon certification by the IBC to the Board of Health and an independent finding by the Board of Health that the Institution is in compliance with the provisions of this Bylaw and NIH Guidelines and BMBL. The submission of the IBC certification and independent finding by the BOH shall occur within sixty (60) days of submission of a completed permit application, including all information therein required. The permit shall cover all laboratories at the Institution.
 - b. Each Institution’s IBC shall submit an annual report on any research or production involving rDNA Materials, Biological Agents, and Select Agents to the Board of Health, which report shall include (i) a list of IBC members’ names and their affiliations, a curriculum vitae and (ii) a report on quality assurance and safety efforts made during the reporting period with respect to laboratories engaged in research or production involving rDNA or Biological Agents. Any change in IBC membership, research or production should be reported within ten business days to the BoH.
 - c. The Board of Health or its representative may annually inspect laboratories which have been permitted to conduct work with rDNA Materials and/or Biological Agents, to ensure compliance with the provisions of this By-Law. Such inspection shall be scheduled in advance with the Institution’s Chief Research Officer or Biosafety Officer and shall be carried out in a manner that maintains the health and safety systems of such laboratories.
 - d. A fee shall be charged for issuance or renewal of each permit, which fee is intended to cover the expenses of the annual inspection and costs incurred by the BoH for issuance of permits.

SECTION 8. Environmental Surveillance Programs.

All institutions engaged in research or production involving rDNA Materials or Biological Agents within the Town of Grafton shall provide appropriate medical and environmental surveillance programs in accordance with NIH guidelines.

- a. The environmental surveillance program shall include a plan for the disposal of waste to ensure that rDNA Materials or Biological Agents will not be released into the environment.
- b. In accordance with the Grafton Biological Emergency Response Plan administered by the Grafton LEPC, the Institution's emergency response plan shall include provisions to train representatives or consultants of the Grafton LEPC, BoH, Grafton Fire Department and the Grafton Police Department in the procedures to be used in the event of an emergency. A copy of the Institution's list of Biological Agents registered with the IBC, included as part of the Grafton Biological Emergency Response Plan, shall also be made available annually to the BoH.
- c. Any release into the environment of rDNA Materials or Biological Agents posing a threat to public health and safety must be immediately reported in accordance with the terms of the Grafton Biological Emergency Response Plan.
- d. The Institution shall cooperate with the state and local public health departments by reporting any research-related illness or accident arising from such Institution's research with rDNA Materials or Biological Agents that may be hazardous to the public in accordance with the Grafton Biological Emergency Response Plan and NIH guidelines as well as MADPH regulation 105 CMR 300.000 Reportable Diseases, Surveillance and Isolation and Quarantine Requirements in accordance with MGL Chapter 111. If the affected individual(s) does not reside in Grafton, the required surveillance information will be reported to the Health Department where they reside. The results of investigations conducted into any research-related illness or accident should also be reported back to the BoH within seven days of completion.

SECTION 9. Penalties.

Any Institution, person, or organization that violates any provision of this By-Law shall be punished by a fine of up to \$300 for each separate violation. Each day shall constitute a separate and distinct offense.

SECTION 10. Enforcement.

Enforcement of this By-Law shall be the duty and responsibility of the BoH. In appropriate circumstances, the Board of Health may also deem any violation of this By-Law to be a nuisance pursuant to Massachusetts General Laws c. 111 and may take such action as it deems proper. In addition to any other penalties set forth herein, the BoH, after notice to the Institution and an opportunity for the Institution to be heard, may order a suspension of any work permitted to be conducted under this By-Law until such violations are corrected and may revoke any permit if it finds that the Institution has repeatedly, through gross negligence, or deliberately violated any of the provisions of this By-Law or regulation promulgated hereunder, or any other law, state or federal or any standards applicable thereto. The BoH reserves the right to hire a mutually agreed upon (by the BoH and the Institution) biomedical expert at a reasonable cost to the Institution in order to administer and enforce this By-Law.

SECTION 11. Confidentiality.

Proprietary documents as designated by an Institution will be separated from documents available to the public in accordance with the Public Records Law. The BoH shall develop procedures to protect the confidentiality of any such proprietary information and any information which, if released, could jeopardize the health and safety of the public (including, without limitation, lab locations and security measures).

SECTION 12. Exclusions.

The provisions of this By-Law are not intended to apply to clinical, non-research operations of doctors, dentists and veterinarians within the Town when governed by other local, state and federal agencies and regulations.

SECTION 13. Appeals.

Any Institution aggrieved by the final decision of the BoH with respect to the denial of a permit, failure to renew a permit, or any other order issued under the provisions of this By-Law may seek relief in the Superior Court of the Commonwealth of Massachusetts .

SECTION 14. Severability.

If any provision of this By-Law or the application thereof is held to be invalid by a court of competent jurisdiction, the invalidity of this By-Law shall be limited to said provision(s) and the remainder of this By-Law shall remain valid and effective. Any part of this By-Law subsequently invalidated by a new state law or modification of an existing state law shall be brought into conformity with the new or amended law.

(Replaced Existing Article 27, T.M. 10/20/08)