

- **ARTICLE IV. - BIOTECHNOLOGY RESEARCH**^[CH006_4]
- **Sec. 6-56. - Biotechnology ordinance.**

This article shall be known and may be cited as the "Somerville Biotechnology Ordinance."

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-57. - Biotechnology ordinance purpose.**

It is the purpose of this article and the policy of the city to protect the public health, safety and general welfare of the residents of the city, and to promote the development of clean and pollution-free industry, through the regulation of all recombinant deoxyribonucleic acid ("rDNA") research and all other use of biological agents. The research and other use of rDNA and biological agents in the city shall be undertaken only in strict conformity with this ordinance and the SBC policies and procedures authorized herein.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-58. - Biotechnology ordinance applicable to rDNA and/or Biological Agent research**

This article shall apply to all institutions in the city which use rDNA technology and/or Biological Agents. This article shall require that all rDNA and/or Biological Agent research and use be done only in strict conformity with the guidelines, hereinafter defined, this article and the SBC policies and procedures authorized herein. However, should a conflict arise between this article and the guidelines, this article shall take precedence.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-59. - Definitions.**

The following words, terms and phrases, when used in this article shall have the meanings ascribed to them in this section, except where the context clearly indicates otherwise:

Biological Agents: 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 the National Institutes of Health ("NIH") Guidelines (as defined below); or
2. Requires BSL-3 through BSL-4 containment as determined by an Institutional Biosafety Committee (as defined below); or
3. Is identified by the United States Department of Health and Human Services ("DHHS") or the United States Department of Agriculture ("USDA") as "Select Agent" (as defined below)

Brown-out: is an intentional or unintentional drop in voltage in an electrical power supply system. Intentional brownouts are used for load reduction in an emergency. A voltage reduction may be an

effect of disruption of an electrical grid, or may occasionally be imposed in an effort to reduce load and prevent a power outage, known as a blackout.

Chair: the Chair of the Somerville Biosafety Committee, unless the context clearly indicates otherwise.

Guidelines are defined as:

(1) *NIH Guidelines*: National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules as published in the Federal Register of May 7, 1986.

(2) *BMBL*: Biosafety in Microbiological and Biomedical Laboratories 6th edition.

(3) Any amendments, revisions, new editions or substitutions to the NIH Guidelines or the BMBL which are adopted by the DHHS, Centers for Disease Control and Prevention (“CDC”) and NIH and accepted by the SBC. Amendments not acted upon by the SBC within sixty days shall be considered accepted. In the event that NIH Guidelines or BMBL are discontinued or abolished, those Guidelines in effect at the time of such discontinuance shall remain in effect in Somerville.

(4) In the event that there is a conflict between the NIH Guidelines and the BMBL, the BMBL shall control.

Institution: A single individual, group of individuals, association, organization, corporation, educational institution, or medical facility conducting rDNA and/or Biological Agent research, development, production, therapies or diagnostics.

Institutional Biosafety Committee: a committee established in accordance with the guidelines, section 6-62 and the SBC Policies and Procedures.

SBC Policies and Procedures: the policies, procedures and criteria established by the SBC to aid in the implementation of this ordinance pursuant to Section 6-60(e)(1).

Recombinant deoxyribonucleic acid (rDNA) and molecules and organisms and viruses containing RDNA: As defined in the NIH Guidelines promulgated in the Federal Register on May 7, 1986, and such amendments thereto unless otherwise not accepted by the Somerville Biosafety Committee. Biological materials therapies or diagnostics include, but are not limited to, living cell therapy.

Select Agents: any microbial and toxic agents listed at 42 CFR § 73.3, 42 CFR § 73.4, 42 CFR § 73.5, 42 CFR § 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 shall not include any de minimus amount of agents or toxins which are excluded from 42 CFR 73.00 et seq.

(Ord. No. 1994-4, 2-24-94)

Cross reference— Definitions and rules of construction, [§ 1-4](#).

- **Sec. 6-60. - Biosafety committee.**

(a) *Establishment*: There is hereby established a Somerville Biosafety Committee (SBC) which shall oversee the permitting of research involving the use of, and developments in, rDNA, and Biological Agents. The Committee shall address safety concerns associated with areas of biotechnology research.

(b) *Composition; terms of members; vacancies*: The SBC shall be composed of the director of sustainability and environment or their designee, the director of the board of health or their designee, the emergency management director or their designee, a representative from the fire department, the director of the office of strategic planning and community development or their designee; and three members to be appointed by the mayor and approved by the city council, which shall include an expert in the biotechnology field from the academic community and two members representative of the community members of Somerville. The membership should be broad-based and as representative as possible. The members appointed by the mayor shall serve for a three-year term. Any person appointed to fill a vacancy shall serve for the unexpired term of that vacancy.

(c) *Appointment of the Chair*: The Chair shall be designated by a majority vote of the SBC.

(d) *Professional assistance authorized; costs*: The SBC may retain competent professional assistance in carrying out their duties under this article, in accordance with the regular City procedures for obtaining such assistance.

(e) *Responsibilities*: Specific responsibilities of the SBC shall include:

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

(2) Determining the manner in which permit holders, pursuant to this Ordinance, make reports or applications to the SBC and the type of information required in such reports or applications.

(3) Reviewing reports, applications, and recommendations by the institutional biosafety committees (IBC), and all other relevant documents.

(4) Conducting site visits to proposed and permitted facilities.

(5) Reviewing manuals and worker training programs, approving health-safety programs, waste removal processes and emergency response contingency plans, and monitoring the procedures required by this article.

(6) Establishing procedures for individuals reporting violations of this article, the guidelines or any health regulations to the SBC.

(7) Providing assistance to institutions during the permitting process.

(8) Accepting all amendments to the guidelines before implementation.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-61. - Biosafety permits.**

All institutions proposing to employ rDNA and/or Biological Agent technology must obtain a permit from the SBC and shall comply with the Zoning Ordinance of the City of Somerville. The institution shall submit an application for a permit to the SBC containing the following information:

- (a) A statement by the institution that it shall comply with the provisions of this article, the NIH guidelines and all federal and state laws.
- (b) A written agreement that reasonable inspections of facilities and pertinent records by the SBC shall be allowed.
- (c) A health and safety manual which shall contain all procedures relevant to use of rDNA and/or Biological Agents at all levels of containment in use at the particular facility.
- (d) A plan for waste disposal in compliance with all applicable federal, state and local laws.
- (e) A training program of safeguards and procedures for personnel using rDNA and/or Biological agents.
- (f) An emergency response contingency plan which addresses , but is not limited to addressing containment during fire or other emergencies and the education/safeguarding of first responders such as fire fighters, responses to inclement weather and power loss or Brown-outs, and protection of employees and visitors in the building, responders, and the surrounding community.
- (g) An appropriate medical and environmental surveillance program in accordance with the guidelines.
- (h) A risk assessment of the activities to take place in the lab and possible impacts to employees, other building occupants, and the public.
- (l) Proof of Insurance in the form and amount satisfactory to the SBC as defined in SBC policies and procedures established pursuant to this ordinance.
- (j) Effective rodent and insect control programs shall be in place on premises where permitted research and use takes place in accordance with Article 2 section 11-38.

A permit to employ rDNA and/or Biological Agent technology shall be issued to the applicant if all of the above information is completed and complies with current technical standards. Permits shall be issued and renewed on an annual basis. The SBC may establish fees for the issuance and renewal of permits as defined by SBC policies and procedures.

Confidentiality of Documents. Proprietary documents as designated by the institution proposing to use Biological Agents shall be separated from the documents available to the public. Subject to applicable public records law, the SBC shall develop policies and procedures to protect the confidentiality of any information including but not limited to that which, if released, could jeopardize the health and safety of the public, such as but not limited to lab locations and security measures.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-62. - Institutional biosafety committee.**

An institution applying for a permit pursuant to this ordinance shall establish an IBC in accordance with the guidelines. The IBC shall be the final arbiter within an institution with regard to the implementation of this article and the guidelines.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-63. – IBC Reports**

Each permit holder shall file regular reports with the SBC and IBC, in a manner to be determined by the SBC. The IBC shall forward all meeting minutes to the director of the board of health or their designee and the SBC, and shall submit to the SBC in a timely manner copies of all reports submitted to outside regulatory agencies.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-64. Emergency Procedure: Accident, illness and violation reports.**

ny accidental release or exposure, or research or use related accident or illness, which represents a potential hazard to employees or the public shall be reported by the permit holder immediately to the fire department via 911, the directors of the board of health and emergency management and to the SBC in no case more than 24 hours after such release or exposure.

The permit holder shall report to the SBC any violations of the guidelines or ordinance within seven days after such violation is known or should be known; unless the violation creates an emergency situation that represents a potential hazard to employees or the public in which case the permit holder shall immediately report the violation to the fire department via 911, the Directors of the board of health and emergency management and to the SBC in no case more than 24 hours after the permit holder knew or should have known about any such release..

The mayor may, in their discretion, if satisfied that a dangerous condition exists relating to any rDNA and/or Biological Agent research or use, declare an emergency and take action as necessary to remedy the emergency.

The permit-holder shall demonstrate how emergency measures complied with the emergency response contingency plan. The permit-holder shall also provide the SBC, within 14 days of any problems, violations, accidents or illnesses as contemplated by this section, a written report describing how emergency measures complied with the emergency response contingency plan, and what actions shall be taken to correct the problem or violation and prevent the problem or violation from recurring.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-65. - BL4 containment.**

Research and use requiring containment defined by the guidelines as "BL4" shall not be permitted in Somerville.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-66. - Enforcement.**

(a) Any institution which violates any provision of this article shall be subject to a fine in accordance with the provisions of [section 1-11](#). Each day a violation continues shall constitute a separate and distinct offense.

(b) Once a permit has been issued, it may be revoked, suspended, or modified by the SBC upon determination by the SBC, after due notice and hearing, that the permit-holder has materially failed to comply with this article, the terms of the permit, or the guidelines.

(c) Notwithstanding the above, the SBC, upon a determination that any violation constitutes an immediate and severe threat to the public health and safety, may order the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice and hearing, but with subsequent timely notice and hearing.

(Ord. No. 1994-4, 2-24-94; [Ord. No. 2006-09](#), § D, 4-11-2006)

- **Sec. 6-67. - Permit procedure.**

(a) Applications for a permit under this article shall be made to the SBC on a form provided for that purpose, accompanied by the required fee, if any. When an application has been received in a completed form, as designated herein, the SBC shall forward a copy to the city clerk. The stamp of the city clerk shall designate the date of filing. Copies of the completed application shall be distributed to those boards and departments as determined by the SBC, which shall include, but not be limited to, the board of health, the office of sustainability and environment, the office of strategic planning and community development, the inspectional services division, the fire department and the planning board.

(b) The SBC shall meet to discuss the application within 45 days after the filing of such application with the city clerk and shall take final action on a completed application within 60 days after such completed application has been submitted. If no action is taken within the time permitted, the permit is deemed denied.

(Ord. No. 1994-4, 2-24-94)

- **Sec. 6-68. – Severability**

If any section, subsection, sentence, clause, or portion of this article is for any reason held invalid by any court of competent jurisdiction, such portion shall be deemed a separate, distinct, and independent provision, and such holding shall not affect the validity of the remaining portions thereof.

(Ord. No. 1994-4, 2-24-94)