

Laboratory Research Regulatory Term Sheet Outline

Zoning and Public Health and Safety

Zoning/Land Use: Defines the permitted uses and where in Town it will be allowed.

1. Proposed Zoning Use Definition:

“Research and Development Laboratory. A facility for scientific or medical research, testing, and prototype development in one or more scientific fields, including, but not limited to, life sciences, biotechnology, biomedical research, robotics, photonics, electronics, or computer science. *Research and Development Laboratory* may include a research laboratory for scientific or medical research with a Biosafety Level of Level 1 or Level 2, as defined by and subject to all applicable requirements of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health (but shall not include Biosafety Level 3 or higher laboratories).”

2. Permitted Locations:

Industrial, General Business, Office Districts, plus applicable existing or new Special Overlay Districts.

3. Other Zoning Provisions

Subject to other applicable Brookline Zoning Bylaw requirements (special permit and/or site plan review for relief from existing dimensional and parking standards; design review for major impact projects; special standards as applicable in Special Overlay Districts).

Public Health and Safety: regulates how laboratory uses operate within laboratory research facilities

New Biosafety General Bylaw

1. Purpose:

- a. To oversee and regulate those Laboratory and Research Development facilities that work with biologic agents and/or recombinant DNA (rDNA) technology.
- b. Condition operation of life science laboratories and any associated vivarium on continuing compliance with [NIH Guidelines](#) for research, the CDC’s [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#); with all applicable state of Massachusetts regulations; and specialized design codes and operational requirements promulgated by ASHRAE, the National Research Council, and the U.S. Department of Agriculture for animal research.

2. Scope:

- a. All life science laboratories.

3. Exclusions:

- a. The use of finished products which contain rDNA molecules, and which have been approved by other government regulatory agencies for medical or other purposes, and
- b. Medical facilities using rDNA materials for diagnostic testing.

4. Oversight

c. Establishment of a Brookline Biosafety Board (BBSB)

i. Size: 5 or 7 members

- 1.** Advisory Council on Public Health Chair or designee,
- 2.** Director of Public Health and Human Services (the “Director”) or designee,
- 3.** Hazardous materials advisor appointed jointly by the Director and the Fire Chief, and
- 4.** Two (or four) Brookline residents with relevant training and experience in the areas of biotechnology, occupational health, infectious disease, and/or environmental health. To be nominated by the Director and confirmed by the Brookline Select Board.

ii. Authority & Responsibilities

1. Licensing:

- a. Conducts inquiry and public hearings as required under BSL-2 licensing procedures.
- b. Upon review of a BSL-2 license application along with the relevant Town staff and Town consultant reports, Director of Public Health license recommendations, and the completion of the required public hearing, vote to issue or deny the requested BSL-2 license.

2. Regulations:

- a. The BBSB would be authorized to promulgate Biosafety Regulations setting forth detailed procedures and standards for registration and licensing
- b. The BBSB would periodically reviews the appropriateness and effectiveness of any Biosafety Regulations established under this Bylaw, would recommend and promulgate modifications to the Regulations, and would advise the Director, Building Inspector, and Fire Chief with respect to ongoing oversight and enforcement issues concerning life science laboratory operations.

- c. The Director would have authority to establish policies and procedures consistent with the Regulations to further effective program operation.

4. Registration & Licensing

- a. Registration
 - i. Required for BSL 1 laboratories and those exempt from NIH Guidelines.
 - ii. Annual requirement
 - iii. Fee schedule to be established by Director of Public health
 - iv. Registration submission requirements to be established by BBSB and Director in conjunction with other appropriate Town Departments.
 - v. Consent to inspections by appropriate Town authorities.
- b. Licensing
 - i. Required for BSL 2.
 - ii. Schedule:
 - 1. One-year term renewable annually for four additional successive one-year terms.
 - 2. Full license re-issuance required after five years, requiring submission of a new application.
 - iii. Applications:
 - 1. Form to be established by Director in conjunction with BBSB.
 - 2. Application materials to include, but not be limited to: plot and floor plans, lists of organisms with associated containment levels and decontamination procedures, plans to test purity of host organisms and resistance to commonly used antibiotics, waste management and pest control plans, and safety manuals.
 - iv. Licensing conditions to include but not be limited to:
 - 1. Consent to inspection of facilities and records by Town employees or consultants.
 - 2. Inclusion of one or more community representatives on applicant's federally required Institutional Biosafety Committee.
 - 3. Payment of application and renewal fees as may be established from time to time by the Town, and reimbursement to the Town of the cost of any consultants whose expertise is required in the review of applicant's license application.
 - 4. Such other conditions as may be established by the Director in conjunction with BBSB and other area of relevant Town authority.
 - 5. Public Hearing to obtain community input, to be conducted by BBSB prior to initial license approval and every 5 years upon relicensing.