

Summary of Proposed Changes to the Biotechnology Ordinance

The purpose of this document is to aid in review of the proposed, updated Biotechnology Ordinance

The City of Somerville's [Ordinance governing Biotechnology Research](#) was established in 1994. The City submitted proposed changes to modernize the Biotechnology Ordinance based on the input of the Somerville Biosafety Committee, industry experts and other municipalities, constituent feedback, and staff review. The Ordinance, generally, is meant to provide oversight and regulation of institutions conducting research or use of rDNA or biological agents; including requiring registration or permitting depending on the level of containment required, and annual renewal of such, and requiring emergency procedures and notification of any incidents or violations. Below are the primary substantive changes proposed:

- Amended to cover Biological Agents in addition to rDNA.
 - See, for example, Cambridge's [rDNA Ordinance](#) and [Biosafety Regulations](#), which also cover Biological Agents.
- Requiring registration for low risk facilities (those conducting certain rDNA research or use and/or requiring BSL-1 containment) and permitting for facilities conducting research or use of rDNA or biological agents that require BSL-2, BSL-2 Enhanced, or BSL-3 containment. Facilities requiring BSL-4 containment are prohibited.
 - Based on feedback and a review [Watertown's Ordinance](#), this ordinance establishes a two-tier system requiring low risk facilities to register, so that there is still oversight, but they aren't required to go through the more vigorous permitting process that's required of facilities conducting research or use that requires more advanced containment levels.
 - Registrations and permits require annual renewal.
 - The SBC may revoke, suspend or modify a registration or permit in the event of a violation or threat to the public health and safety, and may hold hearings on revocation, suspension or modification of permits.
- Adding exemptions for medical/clinical facilities that collect patient samples for testing at offsite laboratories, and laboratories in educational institutions used exclusively for instruction and not research experiments.
 - Based on feedback and similar to Watertown and Boston.
- Adding additional required documents for permit application, including but not limited to:
 - a list of facilities in the City
 - a risk assessment
 - proof of liability insurance
 - rodent and insect control and waste disposal
 - emergency response contingency plan
 - plot plan
- Adding and refining definitions
 - Including definition of "Biological Agents", "Low-Risk Facilities", "Biosafety Level"
 - Clarifying definition of "Guidelines"

- Clarifying the role and responsibilities of the Somerville Biosafety Committee.
 - Clarifying Biosafety Committee membership consistent with existing positions (for example, “environmental protection officer” = OSE Director or designee, OHCD is OSPCD); allowing for the appointment of a Chair.
 - Listing duties of the SBC.
- Clarifying requirements for procedures in the event of an emergency or violation and the process for notifying the City.
- Requiring institutions to include two community representatives on their Institutional Biosafety Committee (IBC).
- Codifying Federal guidelines from the NIH and CDC in the City Codes, to ensure the highest standards of safety, training and reporting are being met by institutions operating within the City.
- Providing for a process through which institutions make reports or applications to the Biosafety Committee, electronically through CitizenServe, streamlining the process and allowing the city to: 1) keep accurate records of laboratory employees, and emergency contacts, 2) process payments, and 3) request annual resubmittal.
- SBC Policies and Procedures will be established in accordance with the amended ordinance.