

Lab and R&D Process

#77- 21
Zoning and Planning Committee
August 16, 2021
Department of Planning and Development



Laboratory and R&D

Biotech and R&D jobs are increasing in Massachusetts

New opportunities in places like Newton as companies leave higher cost urban areas

Consistent with economic goals to increase the commercial tax base and capitalize on highly skilled Newton workforce

Recent zoning updates, in partnership with EDC, have clarified and modernized R&D use definition and have allowed flexibility in building floor to floor heights

The use is highly regulated at the federal, state, and local level



Federal Regulations

OSHA and the EPA are the primary federal regulatory agencies for labs. EPA requires registration and OSHA is notified if there is an incident or complaint. OSHA compliance is also typically a requirement in lease agreements and for federal funding.

EPA:

- Resource Conservation and Recovery Act (RCRA) (40 CFR parts 239-282) - must register with EPA when generating hazardous waste and must collect in approved containers and dispose by an approved waste hauler



Federal Regulations

OSHA:

- Lab Standard: Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)
- Hazard Communication (29 CFR 1910.1200)
- Bloodborne Pathogens (29 CFR 1910.1030)
- PPE - General Requirements (29 CFR 1910.132); Eye and face protection (29 CFR 1910.133); Respiratory protection (29 CFR 1910.134)
- Other standards depending upon the nature of the work



State Regulations

State oversight happens through the MA sanitary and plumbing codes, the Massachusetts Water Resources Authority (MWRA), and the Massachusetts Department of Environmental Protection (MassDEP)

MA Sanitary Code

- Minimum Requirement for the Management of Medical or Biological Waste (105 CMR 480) - regulations for the disposal and tracking of biomedical waste. State may do pop inspections.

MA Plumbing Code

- Sections related to laboratories (248 CMR 10) - linked to MWRA, regulates the piping for lab waste.



State Regulations

MWRA

- Sewer use (360 CMR 10) - requires a permit from MWRA. Initial inspection plus pop inspections and MWRA may conduct periodic water sampling.

MassDEP

- MA Hazardous Waste Regulations (310 CMR 30) - must register with EPA and MassDEP to dispose hazardous waste. Both agencies perform pop inspections.
- Air Pollution Control (310 CMR 7) - regulates emissions. Permits required at certain thresholds. MassDEP performs inspections.



Newton Regulations

Local regulations include zoning, rDNA ordinance, building code and fire code

Zoning Ordinance

- Laboratory, Research and Development (Section 6.5.9) allowed in all business, mixed use, and manufacturing zones either by-right or special permit. Ancillary manufacturing allowed per definition in Section 6.5.11
- Special permit required for additions or new buildings greater than 20,000 sf



Newton Regulations

rDNA Ordinance

- rDNA research and technology is regulated under Sections 12-21 - 12-30 of the Revised Ordinances of the City of Newton and NIH Guidelines
- rDNA is molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those described above
- rDNA must be reviewed and approved by the BioSafety Committee, which is comprised of nine members and must approve an rDNA research or technology. HHS issues a permit, which must be renewed annually



Newton Regulations

BioSafety Committee cont.

- Institutional Biosafety Committee (IBC) is established for each institution conducting rDNA research or technology. IBC includes Commissioner of HHS, two community reps with expertise in rDNA and/or safety issues, and three members of institution, including the safety officer
- IBC performs an initial inspection plus annual inspections and must meet at least once a year to enforce rDNA regulations
- rDNA requiring physical containment greater than biosafety level 3 is not permitted in Newton

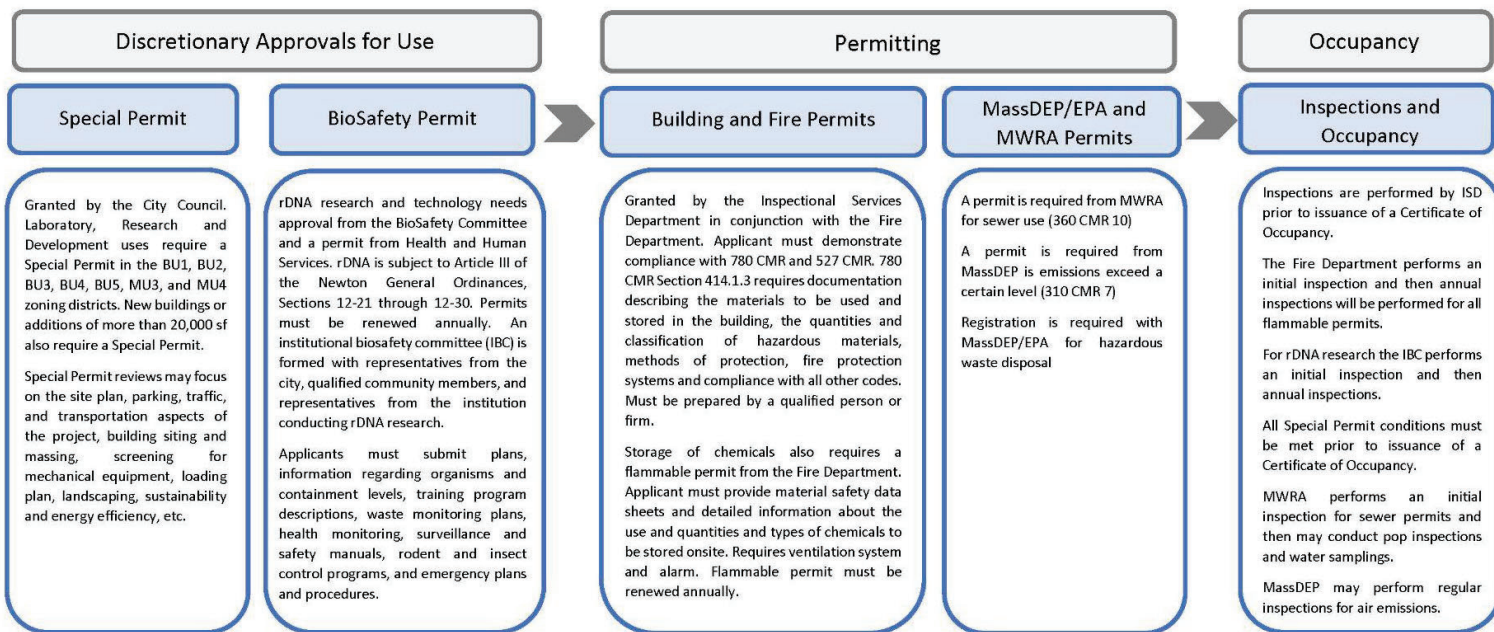


Newton Regulations

Building and Fire Codes

- Buildings with hazardous materials regulated by 780 CMR Section 414 (hazardous materials) and 527 CMR (fire safety code)
- Each tenant working with or storing chemicals must get a flammable permit from the fire department. Permits must be renewed annually. Fire Department does an initial inspection and will be training officers and doing annual inspections of all labs.
- Emergency Action or Contingency Plan required per OSHA 29 CFR 1910.38 & 157, MA Fire Safety Code 527 CMR 1.0, and MassDEP 310 CMR 30.
- Fire Department reviews fire protection system and special hazard protection. Detailed information on the use and material safety data sheets for all chemicals must be provided.
- In the case of a hazmat spill the MetroWest hazmat team may be activated

Permitting Process



Recommendations

No ordinance amendments necessary. Planning recommends new standard Special Permit conditions to allow flexibility for changes in tenants while reinforcing the requirement for all tenants to obtain the proper permits.

- Lab, Research and Development uses shall comply with all local, state, and federal regulations and guidelines, including *Biosafety in Microbiological and Biomedical Laboratories* and *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. All tenants shall adhere to any current or future licensing, rules, or regulations required by the City.
- rDNA research and technology shall not be permitted without approval from the BioSafety Committee and a permit from the Department of Health and Human Services.



Recommendations

Special Permit conditions continued...

- All tenants and sublessors must obtain all necessary permits, including building permits and flammable permits. Permits are not transferable.
- Each laboratory, research and development tenant must provide and implement an environmental health and safety program through the designation of an onsite safety representative or consultant. Each tenant shall provide detailed information about the proposed use and the contact information for the safety representative to the Planning and Development Department, Inspectional Services Department, and Newton Fire Department.