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Barney S. Heath
Director

MEMORANDUM

DATE: August 13, 2021

TO: Councilor Deborah Crossley, Chair, Zoning & Planning Committee
Members of the Zoning and Planning Committee

FROM: Barney S. Heath, Director of Planning and Development
Jennifer Caira, Deputy Director, Department of Planning & Development
Devra Bailin, Director of Economic Development

RE: #77-21 Request for review of Lab, Research and Development Permitting Process
COUNCILORS MARKIEWICZ, KRINTZMAN, CROSSLEY, LAREDO AND LIPOF requesting a discussion with Planning and Health and Human Services Departments in order to understand the process and controls under Chapter 30 and Chapter 12 of the City of Newton Ordinances, for obtaining Lab, Research and Development facility permits. (Ordinance 30 and Ordinance 12)

MEETING DATE: August 16, 2021

CC: City Council
Planning & Development Board
Economic Development Commission
John Lojek, Commissioner of Inspectional Services
Neil Cronin, Chief of Current Planning
Alissa O. Giuliani, City Solicitor
Jonathan Yeo, Chief Operating Officer

Massachusetts is known for its powerhouse laboratory and research and development (R&D) industry. Biotech R&D jobs reached 46,000 in 2019, an increase of 18% from 2018, according to MassBio's 2020 Industry Snapshot Report. There is also currently an exodus away from high-

cost urban areas, accelerated by COVID-19, creating an opportunity for new R&D activities in Newton. The Economic Development Commission (EDC) has been working with the Planning Department to identify zoning obstacles that may be preventing R&D companies from locating in Newton and in the past six months the City Council clarified and modernized the definitions for Laboratory, Research and Development and Manufacturing and adopted a change to how building height is regulated to allow flexibility for the taller floor to floor heights necessary for lab buildings (without increasing the overall height permitted). Newton is ranked at the gold level for MassBio's [BioReady Communities](#). The City's 2019 Economic Development Strategy (Camoin) also lists the following goals related to increasing commercial tax revenue and attracting R&D:

- Objective A: Increase lab space to capitalize highly skilled workforce with science background and regional economic trends.
- Objective B: Increase office space in Newton...to attract and retain companies and increase the commercial tax base.
- Objective H: Target growth sectors based on Newton's strengths – bio/life sciences; healthtech; professional and technical services.

In addition to zoning updates and EDC's efforts to attract new R&D companies to Newton, the City Council has recently undertaken review of proposed new R&D uses at Riverside Station and 275 Grove Street as part of the special permit process. While many surrounding communities have extensive experience permitting lab and R&D facilities, the recent focus on R&D is somewhat new for Newton. Lab and R&D uses are highly regulated, and this memo will describe the regulatory environment, permitting process, as well as recommendations for the review process.

Regulatory Environment

Lab uses are regulated at the federal, state, and local level. Standard practices come from *Biosafety in Microbiological and Biomedical Laboratories*, a guidance document from the US Department of Health and Human Services, the Centers for Disease Control, and the National Institutes of Health. This document serves as the cornerstone of biosafety practices and policy in the US. Individual lab tenants typically implement an environmental health and safety program through the designation of an onsite safety representative or by engaging a consultant. The safety representative or consultant monitors the overall program and compliance to ensure safety of workers and to protect the public and the environment. Below is an overview of the regulations that are typically applied to lab and R&D facilities.

Federal

The Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) are the primary agencies that regulate lab uses at the federal level. OSHA is notified and investigates if there is an incident or a complaint in the facility and most leases contain language about compliance with OSHA. Federal funding also requires full compliance with OSHA and it is often necessary to provide reporting on OSHA compliance to investors.

Companies must register with the EPA in order to generate hazardous waste and have it picked up.

OSHA

- Lab Standard: Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) – applies to non-production labs to protect workers from laboratory hazards, such as chemical or physical hazards. Requires a Chemical Hygiene Plan and appointment of a Chemical Hygiene Officer.
- Hazard Communication (29 CFR 1910.1200) – stipulates the methods for communicating information concerning hazards and appropriate protective measures to employees.
- Bloodborne Pathogens (29 CFR 1910.1030) – applies to all occupational exposure to blood or other potentially infectious materials, requires an Exposure Control Plan.
- PPE (Personal Protective Equipment)
 - General requirements (29 CFR 1910.132)
 - Eye and face protection (29 CFR 1910.133)
 - Respiratory protection (29 CFR 1910.134)
- Other OSHA standards may also apply depending on the nature of the work

EPA

- Resource Conservation and Recovery Act (RCRA) – (40 CFR parts 239-282): regulates hazardous waste generation and disposal. Waste is collected in approved containers for off-site treatment and disposal by an approved waste hauler.

State

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

Massachusetts Sanitary Code

- Minimum Requirements for the Management of Medical or Biological Waste (105 CMR 480) – requires facility to keep logs of bio waste and the state does pop inspections. Biomedical solid and liquid waste must be collected in special containers for treatment and disposal.

Massachusetts Plumbing Code

- Sections related to laboratories (248 CMR 10) – linked to MWRA. Regulates how lab waste is to be piped.

MWRA

- Sewer use (360 CMR 10) – requires a permit from MWRA. MWRA does an initial inspection and then pop inspections. MWRA also may conduct periodic water sampling.

MassDEP

- Massachusetts Hazardous Waste Regulations (310 CMR 30) – MassDEP works with the EPA (federal) and the facility must register with both MassDEP and EPA. Both agencies perform pop inspections.
- Air Pollution Control (310 CMR 7) – a permit is required if emissions exceed a certain level. MassDEP does inspections.

Local

At the local level, Newton primarily regulates lab uses through the Department of Health and Human Services, the BioSafety Committee, Inspectional Services Department (ISD), and the Fire Department (NFD). The Department of Health and Human Services staffs the BioSafety Committee, which oversees facilities undertaking recombinant DNA research (rDNA). ISD issues building permits which require approval from NFD and NFD issues permits and oversees safety protocols when there are flammable substances on site. Additionally, ISD and Planning ensure compliance with the Newton Zoning Ordinance.

Zoning Ordinance

- The Newton Zoning Ordinance allows Laboratory, Research and Development in all business, mixed use, and manufacturing zoning districts, either by-right or by special permit. Section 6.5.9 defines the use and Section 6.5.11 defines the manufacturing uses that may be permitted as accessory to Laboratory, Research and Development.

BioSafety Committee

- rDNA is regulated by [Sections 12-21 through 12-30](#) of Revised Ordinances of the City of Newton. The National Institutes of Health (NIH) define rDNA as “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”. Research involving rDNA is also subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- The rDNA ordinance created the BioSafety Committee, which is comprised of nine members. Approval from the BioSafety Committee and a permit from Health and Human Services is required prior to initiating rDNA research. The permit must be renewed annually.
- The ordinance requires an institutional biosafety committee (IBC) be established for each institution conducting rDNA research or technology. The IBC shall include the Commissioner of Health and Human Services, two community representatives with expertise in rDNA research and technology and/or safety issues, as well as three members of the institution conducting rDNA research, including their safety officer. The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once a year to enforce the rDNA regulations. Each institution must also appoint a safety officer, who is responsible for enforcing the policies of the IBC.

- rDNA use requiring physical containment greater than biosafety level 3 (BSL3) is not permitted in Newton. There are four biosafety levels and you can find a description of them here: <https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/Biosafety-Levels.aspx>.

Fire Department

- Buildings that will use or store hazardous materials are regulated by 780 CMR (Section 414) and 527 CMR. 780 CMR is the Building Code and section 414 applies to hazardous materials. 527 CMR is the fire safety code. NFD may request a third-party reviewer, to be paid by the applicant.
- Every tenant that works with or stores chemicals must get a flammable permit from NFD. The permit must also be reviewed annually. Permits are tenant specific and cannot be passed on to a future tenant or sublessor.
- An Emergency Action or Contingency Plan must be developed to address potential emergencies per OSHA 29 CFR 1910.38 & 157, Massachusetts Comprehensive Fire Safety Code 527 CMR 1.0, and MassDEP 310 CMR 30.
- NFD reviews fire protection system and special hazard protection required by 527 CMR. The fire protection system is dependent upon the chemicals contained in the building.
- NFD requests detailed information on the use and the material safety data sheets (MSDS) for all chemicals. MSDS sheets must also be readily accessible outside of the lab. NFD follows the state emergency response guidebook.
- In the case of a hazmat spill, the MetroWest hazmat team would be activated.

Permitting Process

New lab or R&D uses in Newton may require a Special Permit from the City Council, depending upon the zoning district, current use of the site, and whether a new building is being constructed. All lab facilities will require a building permit from the Inspectional Services Department and the Fire Department. Chemical storage will require a flammable permit from the Fire Department, which must be renewed annually. rDNA research and technology require approval from the BioSafety Committee and a permit from Health and Human Services (and must be renewed annually). A permit is required from MWRA for sewer use, a permit is required from MassDEP if emissions exceed a certain level, and registration is required with MassDEP/EPA for hazardous waste disposal. Initial and ongoing inspections are also performed by ISD, the Fire Department, the IBC (only for rDNA), MWRA and MassDEP. See attached diagram for more information on the permitting process (**Attachment A**).

Recommendations

Lab and R&D facilities are highly regulated at the federal, state, and local level to ensure employee and public safety and environmental protection. New regulations or ordinance amendments are not necessary given the existing regulatory environment. However, staff recommends standard conditions be included in the Council Order for special permits involving

lab or R&D uses. As long as new tenants comply with all conditions of approval, they should not be required to seek an amendment to the original special permit. Council Orders could include conditions such as:

- Laboratory, 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.
- All tenants and sublessors must obtain all necessary permits, including building permits and flammable permits. Permits are not transferrable.
- 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.

The Newton Fire Department will also implement changes to the review and inspection process for lab and R&D uses based upon best practices from Cambridge. The Fire Department is not mandated by code or law to inspect labs. However, the Newton Fire Department will train one or two officers and start conducting annual inspections of all labs, in addition to initial inspections. The Fire Department will focus on identifying hazards, containment, confinement, mitigation and disposal of materials.

Attachment A: City of Newton Laboratory and Research and Development Permitting Process

City of Newton Laboratory and R&D Permitting Process

Discretionary Approvals for Use

Special Permit

Granted by the City Council, Laboratory, Research and Development uses require a Special Permit in the BU1, BU2, BU3, BU4, BU5, MU3, and MU4 zoning districts. New buildings or additions of more than 20,000 sf also require a Special Permit.

Special Permit reviews may focus on the site plan, parking, traffic, and transportation aspects of the project, building siting and massing, screening for mechanical equipment, loading plan, landscaping, sustainability and energy efficiency, etc.

Biosafety Permit

rDNA research and technology needs approval from the Biosafety Committee and a permit from Health and Human Services. rDNA is subject to Article III of the Newton General Ordinances, Sections 12-21 through 12-30. Permits must be renewed annually. An institutional biosafety committee (IB/C) is formed with representatives from the city, qualified community members, and representatives from the institution conducting rDNA research.

Applicants must submit plans, information regarding organisms and containment levels, training program descriptions, waste monitoring plans, health monitoring, surveillance and safety manuals, rodent and insect control programs, and emergency plans and procedures.

Permitting

Building and Fire Permits

Granted by the Inspectional Services Department in conjunction with the Fire Department. Applicant must demonstrate compliance with 780 CMR and 527 CMR. 780 CMR Section 414.1.3 requires documentation describing the materials to be used and stored in the building, the quantities and classification of hazardous materials, methods of protection, fire protection systems and compliance with all other codes. Must be prepared by a qualified person or firm.

Storage of chemicals also requires a flammable permit from the Fire Department. Applicant must provide material safety data sheets and detailed information about the use and quantities and types of chemicals to be stored onsite. Requires ventilation system and alarm. Flammable permit must be renewed annually.

MassDEP/EPA and MWRA Permits

A permit is required from MWRA for sewer use (360 CMR 10)

A permit is required from MassDEP if emissions exceed a certain level (310 CMR 7)

Registration is required with MassDEP/EPA for hazardous waste disposal

Occupancy

Inspections and Occupancy

Inspections are performed by ISD prior to issuance of a Certificate of Occupancy.

The Fire Department performs an initial inspection and then annual inspections will be performed for all flammable permits.

For rDNA research the IBC performs an initial inspection and then annual inspections.

All Special Permit conditions must be met prior to issuance of a Certificate of Occupancy.

MWRA performs an initial inspection for sewer permits and then may conduct pop inspections and water samplings.

MassDEP may perform regular inspections for air emissions.