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Barney Heath
Director

MEMORANDUM

DATE: May 5, 2017

TO: Councilor Ted Hess-Mahan, Chairman
Members of the Zoning and Planning Committee

FROM: Barney Heath, Director, Department of Planning and Development
James Freas, Deputy Director

RE: #81-17 – THE BIOSAFETY COMMITTEE, COUNCILORS AUCHINCLOSS, HESS-MAHAN, LIPOF, AND SCHWARTZ requesting amendments to Sections 12-21 through 12-30 in order to update guidelines and procedures for the regulation of recombinant DNA technology; and requesting amendments to Section 12-24 and Chapter 30 to remove the requirement that laboratories or research facilities obtain a special permit from the City Council in order to utilize recombinant DNA research or technology.

MEETING DATE: May 8, 2017

CC: City Council
Planning and Development Board
Donnalyn Kahn, City Solicitor
Deborah Youngblood, Commissioner of Health & Human Services

The biotech/life sciences sector is one of the strongest in the greater Boston economy. The potential for this sector to grow in Newton is considerable as indicated in the N² study report, which identified the industry as one of our priority focus areas. Newton's Recombinant DNA Research ordinance, Sections 12-21 through 12-30 of the City's Ordinances, and the special permit requirement for rDNA laboratory uses in the City's Zoning Ordinance, have been a deterrent to biotech/life sciences sector growth in Newton. The proposed amendments will modernize Newton's approach to this issue, streamline the ability of biotech companies to locate in Newton without affecting the stringent safety standards set and regulated by the Biosafety Committee through their existing permit process. This change would make Newton eligible for a higher ranking in the state BioReady Program, thereby raising the City's profile for companies looking for laboratory space in greater Boston.

The Newton Biosafety Committee

Any institution or company planning to conduct research or otherwise make use of rDNA technology in the City of Newton must first get a permit from the Commissioner of Health and Human Services. Before that permit may be issued, the Newton Biosafety Committee must first approve the application. The Biosafety Committee was re-established in September 2013 after a hiatus of several years. The nine-member committee includes the Commissioner of Health and Human Services and eight other members. The committee is predominantly made up of members with expertise and experience in scientific research, public health, infectious diseases and related areas (see attached bios of current members).

Before approving a proposed rDNA laboratory, the Committee does an extensive review of their proposed operations, focused particularly on safety protocols. The overall intent of this review is to ensure public health and safety so attention is paid to such topics as the handling of laboratory program waste, monitoring of employee health, and employee training and manuals. The Committee discusses the application in an open public meeting with opportunity for public comment and notice provided to all abutting properties.

N² Innovation District Study Report

The N² Innovation District is a joint project of Newton, Needham and the Newton Needham Chamber designed to grow the innovation economy in a district encompassing significant economic development opportunity areas on both sides of the municipal border. In June 2016 a report was released presenting an analysis of the district's existing strengths and challenges and laying out an action program for accomplishing this goal. Amongst those strengths is an opportunity to expand biotech/life sciences industry in the area. With the prominence of this industry in the greater Boston region and the need for new laboratory and office space coupled with Newton's highly educated population and strong access to the regional transportation network, the N² District is well positioned for growth. One of the challenges, as identified in the report, is Newton's permitting process, which puts it at a competitive disadvantage with many of its neighboring communities.

BioReady Program

The BioReady Communities list is a program created by the Massachusetts Biotechnology Council intended to highlight cities and towns that have taken steps to ease the pathway for new or expanding biotech and life sciences companies locating in their communities. The list ranks communities from Bronze to Platinum. Newton has for many years been ranked as a Bronze community. Needham and Watertown are both Gold-level communities while Boston, Cambridge, Waltham, and Lexington are Platinum. A community's ranking serves to draw attention for companies seeking to relocate and is therefore a powerful marketing tool.

The principal obstacle to Newton achieving a higher ranking is the special permit requirement for rDNA laboratory uses. With this requirement removed, Newton could readily advance its ranking to the Gold level and potentially even to Platinum.

Proposed Amendments

The proposed amendments would accomplish the following:

Zoning Amendment – Chapter 30:

1. Removes the special permit requirement for laboratories utilizing rDNA

Amendment to Chapter 12, Article III Recombinant DNA Research (non-zoning amendment):

2. Updates the City's rDNA ordinance to refer to the most current version of the National Institute of Health Guidelines for Research Involving Recombinant DNA Molecules;
3. Restructures the make-up of the 8 member biosafety committee to include 4 mayoral appointees and 4 city council appointees (Removes the requirement that 2 members of the Biosafety Committee must come from the Newton health advisory council);
4. Requires separate notice be provided to the Newton Biosafety Committee before rDNA use requiring physical containment at the BL3 level (above BL3 is prohibited);
5. Clarifies the penalties associated with violation of this ordinance;
6. Updates requested information for initial applications;
7. Streamlines inspections by eliminating the need for an inspection by a third party. Inspection to be done by Newton NBC or IBC members with a report to the health commissioner before rDNA work can commence.

Next Steps

A public hearing on the zoning amendment portions of the proposed amendments will be conducted on June 12th.

Attachments

Attachment A: Biosafety Committee Member Bios

Attachment B: Recombinant DNA Research ordinance, Sections 12-21 through 12-30, redline

Attachment C: Recombinant DNA Research ordinance, Sections 12-21 through 12-30, clean version

Attachment D: Proposed Zoning Amendments, redline

Biosafety Bio's

Carl Cohen

Carl M. Cohen, Ph.D. is President of Science Management Associates and provides, consultation, training and coaching in interpersonal, group and organizational skills to scientists and science executives in both the public and private sectors. Carl has more than 30 years of biomedical research and management expertise, including having been Chief Operating Officer of Biovest International focused on cancer immunotherapy and Vice President for Research and Development at Creative BioMolecules. Carl served as Chief of the Division of Cellular and Molecular Biology and Acting Chair of the Department of Biomedical Research at St. Elizabeth's Medical Center of Boston. During that same period he also held the positions of Professor of Medicine and Professor of Anatomy and Cellular Biology at Tufts University School of Medicine. Carl is co-author, with his wife Suzanne of **"Lab Dynamics: Management and Leadership Skills for Scientists"** (Cold Spring Harbor Laboratory Press, 2012). Carl has done training and on-site management consulting for top ten pharmaceutical companies, biotechnology companies and government agencies both in the US and internationally. He has been the Director of the annual Cold Spring Harbor Laboratory workshop on **Leadership in Bioscience** since 2011.

Thekla Diehl

Thekla Diehl is a Senior Research Grant Administrator / Financial Specialist at Partners Health Care, where 60% of her portfolio are National Institute of Health grants.

Her undergraduate focus was Biochemistry and Genetics. After graduating from the University of Cape Town in South Africa with a Masters in Medical Biochemistry, she left for Europe in protest of the apartheid system.

Upon arrival in America in the early eighties she worked in the laboratory at the Harvard teaching hospitals for over twenty year, first as a scientist and later as a laboratory manager.

After obtaining a MBA at the Simons School of Management, her focus shifted from the laboratory to the business side of science.

She has been a resident of Newton for the past thirty years, where she lives with her husband and her two boys, who graduated through the Newton Public School.

William Dietrich

Dr. William Dietrich's is a biologist/pharmacologist whose work has focused on creative interdisciplinary collaborations aimed at large scientific problems such as the Genome Project, genetic determinants of host susceptibility to infectious disease, and drug discovery. His current position is as Director of Discovery and Translational Pharmacology in the Developmental and Molecular Pathways department at Novartis Institutes of BioMedical Research in Cambridge. He is a co-author/inventor on more than 60 scientific publications and patents, and has led or performed IND-enabling pharmacology research for 4 different drug discovery programs.

Gary du Moulin

Gary C. du Moulin, Ph.D., M.P.H. is Associate Professor of Drug Regulatory Affairs at the Massachusetts College of Pharmacy and Health Sciences University following a 25 year career at Genzyme where he participated in the development and execution of quality systems for Genzyme's products including biologics and cell based therapies. Prior to his industrial experience, Dr. du Moulin was Assistant Professor of Anesthesia (microbiology) at the Harvard Medical School in the Department of Anesthesia at Beth Israel Hospital and has more than 150 publications in the areas of microbiology, epidemiology, biosafety and the regulation and quality control of living cells as a therapeutic modality. Dr. du Moulin currently serves on U.S. Pharmacopoeia's General Chapters Biological Analysis Expert Committee as well as the Scientific and Medical Research Funding Working Group for the California Institute of Regenerative Medicine. He is retired from the U.S. Army Reserve at the rank of Colonel after 38 years of service.

Ted Marple

Ted has worked in the health care industry for over 20 years. Most recently as CEO of a Contract Research Organization based in Worcester, MA. Prior to that, he led the business operations at a biomanufacturing technology company that was acquired by GE. He was worked at biotech and large pharma companies leading business development efforts, and has broad experience in strategy, development and operations for life science companies.

Brenda Mulligan

Brenda Mulligan is the Communications Director for Dana-Farber/Harvard Cancer Center. She is also a board member of South Boston Community Health Center and a member of the Newton Health and Human Services Advisory Council. Her interests include health and research communications and public health initiatives, especially those related to supporting the needs of our most vulnerable populations. She currently resides in West Newton with her husband and two children.

Aric Parnes

Aric Parnes, MD, is a staff hematologist at Dana-Farber Cancer Institute and Brigham and Women's Hospital focusing on bleeding disorders and premalignant hematology. He has lived in Newton since 2010 with his wife and four-year old twins. He serves on the Newton Health Advisory Council and Biosafety Committee.

John "Jay" Schwartz

Dr. Schwartz received his Ph.D. in Biochemistry and Molecular Biology at New York Medical College and was a Post-doctoral fellow at the M.I.T. Department of Biology / Harvard Medical School. He served as a lab head as Research Scientist Faculty at the M.I.T. Center for Biomedical Engineering. The CEO, Dr. John 'Jay' Schwartz, was co-founder of engeneOS, Inc. a venture-backed bio-nanotechnology company with a highly successful exit through acquisition. Prior to joining AcuityBio, he was a consultant in his capacity as Director of Life Sciences at Stage1 Strategies, LLC, a strategy and management-consulting firm focused on assisting emerging technology and early stage companies to develop, grow and achieve exits for investors through strategic aqusuision with large pharmaceutical companies.

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ARTICLE III. RECOMBINANT DNA RESEARCH

Sec. 12-21. Regulation of recombinant DNA technology.

(a) All recombinant deoxyribonucleic acid (DNA) research or technology in the City of Newton shall be undertaken only in strict conformity with the "Guidelines", so called, of the National Institutes of Health (NIH), by other Federal Agencies, or by Act of Congress, and in conformity also with such other health regulations as the commissioner of health and human services may from time to time promulgate or as the Newton biosafety committee (NBC) may adopt.

(b) In the context of this article the following definitions are adopted:

(1) *Recombinant DNA molecules (rDNA)*, and organisms and viruses containing rDNA, are those defined in the NIH Guidelines promulgated in the Federal Register on May 7, 1986 ~~July 1, 1981~~.

(2) An *institution* is any person, group of persons, business entity, association or any other organization, whether public or private, for profit or non-profit.

(3) *Guidelines* are defined as:

a) National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, as published in the Federal Register on August 27, 1982 ~~May 7, 1986 and any subsequent federal amendment thereto recommended by the commissioner of health and human services and approved by the NBC.~~

b) Any amendments, revisions or substitutions subsequent to the above-referenced guidelines, including, but not limited to:

Notices of actions under NIH Guidelines for Research involving recombinant DNA Molecules on August 24, 1978, July 29, 1988, October 26, 1988, March 13, 1989, March 1, 1990, September 12, 1990, July 18, 1991, November 21, 1991, January 28, 1992 and April 22, 1992. National Institutes of Health Physical Containment Recommendations for Large Scale Use of Organisms Containing Recombinant DNA Molecules, as published in the Federal Register of April 11, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and adopted by the NBC.

c) Such amendments to the documents in subsections a) and b) above which are adopted by the National Institutes of Health and approved by the Commissioner. Amendments not acted upon by the Commissioner within sixty days shall be considered approved. In the event that the NIH shall discontinue or abolish its guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in Newton. Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules, as issued by the Office of Recombinant DNA Activities, November, 1980, and any subsequent federal amendment thereto recommended by the commissioner of health and human services and adopted by the NBC.

~~(4) *Large-scale* means the use, for the purpose of containing recombinant DNA culture media, of any stainless steel vessel which has a volume greater than sixteen liters, or such use of any non-stainless steel vessel which has a volume greater than ten liters.~~

(Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 5-26-2005)

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Sec. 12-22. Newton biosafety committee.

(a) There shall be a Newton biosafety committee (NBC) which shall be comprised of nine (9) members which include the following:

The commissioner of health and human services or his/her designee;

~~Two (2) members of the Newton health advisory council, appointed by the commissioner of health;~~

Four (4) ~~Three (3)~~ members appointed by the mayor, at least one of whom is a scientist knowledgeable in the field of rDNA research and technology. The other ~~two~~ three shall represent the fields of public health, occupational health, infectious disease or environmental health, and shall preferably include one member of the Newton health advisory council.

Four (4) ~~Three (3)~~ members appointed by the board of aldermen, at least one of whom represents the fields of public health, occupational health, infectious disease or environmental health.

Members appointed by the mayor and the board of aldermen shall serve three (3) year terms; provided however, that of the first three members appointed to the committee by the mayor and the board of aldermen ~~one two~~ shall serve for a term of one (1) year, one shall serve for a term of two (2) years, and one shall serve for a term of three (3) years.

(Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Sec. 12-23. Institutional ~~biotechnology~~ biosafety committee.

(a) An institutional ~~biotechnology~~ biosafety committee (IBC) must be established for each institution conducting rDNA research or technology. The IBC shall include the commissioner of health and human services or his/her designee and two community representatives with expertise in rDNA research and technology and/or safety issues. One of these representatives shall be appointed by the mayor and one shall be appointed by the board of aldermen for a term of three years. The IBC shall meet at least once a year. Each institution shall name at least three (3) members of its staff to the IBC, including the safety officer.

(b) The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once annually to enforce these regulations. Each institution shall name a safety officer who shall be responsible for enforcing the policies of the IBC. In addition, the IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of any incident, accident or significant deviation and/or non-compliance by the institution with any section of this ordinance or the NIH guidelines.

(Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

Sec. 12-24. Permit requirement.

(a) All institutions planning to conduct rDNA research or to use rDNA technology must obtain a permit from the commissioner of health and human services with the prior approval of the NBC, before commencing said research or technology. Institutions receiving such permits shall conduct research or technology only as specifically set out in its permit application and supporting documents filed with such application.

(b) All institutions requesting ~~a permit from the commissioner of health and human services to commence rDNA research or technology in the Limited Manufacturing Zoning District (Sec. 30-12), the Manufacturing Zoning District (Sec. 30-12), and the Mixed Use 1 and 2 Zoning Districts (Sec. 30-13), must~~

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~~also receive a special permit from the board of aldermen pursuant to section 30-24 prior to the original issuance, but not the renewal, of said permit. Institutions seeking~~ such permit from the commissioner of health and human services must first submit the following to the NBC:

- (1) A completed application form obtained from the Newton health and human services department.
 - (2) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.
 - (3) A listing of all proposed organisms, including containment levels, to be employed in rDNA research or technology, and including the screening process to be performed by institutions conducting rDNA research or technology in order to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process.
 - (4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.
 - (5) A description of Establish a the training program of safeguards and procedures for personnel using rDNA, and a copy of the training manual;
 - (6) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC and in accordance with NIH guidelines for all persons engaged in the use of rDNA. ~~Such programs shall include, but shall not necessarily be limited to:~~
 - ~~a) A pre-employment medical examination for employees. Facilities using rDNA research or technology requiring BL2 or BL3 as defined in the National Institutes of Health (NIH) guidelines published in the Federal Register, as amended, physical containment, or large scale use, shall take employee serum samples at the time of employment and maintain said samples to permit future testing for at least ten years.~~
 - ~~b) Prompt reporting of significant or potentially related employee illnesses to the IBC.~~
 - ~~c) Retention of medical and health records for at least ten years. Medical or employee health records shall be made available for inspection and may be used for public health studies.~~
 - ~~(7)d). A description of Effective the~~ rodent and insect control programs must be in place to be used in the facility.
 - ~~(78)~~ The name of the safety officer who shall be responsible for enforcing the policies of the IBC.
 - ~~(89)~~ A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.
- (c) The ~~N~~BC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the commissioner of health and human services.
- (d) Not later than sixty (60) days after an institution has commenced rDNA research or technology as determined by the commissioner of health and human services, the institution shall file with the commissioner:
- (1) The names and qualifications of members of IBC.

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(2) Copies of Newton building department and Newton fire department certification.

(3) Evidence of certification, as necessary, from the Massachusetts Department of Environmental Quality Engineering and the Massachusetts Department of Public Health.

(e) Permits granted by the commissioner of health and human services shall be renewed annually.

(f) The fee for a permit granted by the commissioner of health and human services, or annual renewal thereof, shall be \$250.

(Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

Sec. 12-25. Inspection and review.

(a) The institution shall allow inspections and review of the facility and of procedures and practices of rDNA use for compliance with this ordinance.

~~(b) The Newton Health and Human Services Department shall retain a competent professional person, agency, or institution to perform inspections and review. All institutions must undergo an initial inspection before the permit is granted.~~ The results shall be reported to the commissioner of health and human services, the NBC and the institution involved.

~~(c) Inspections will be conducted at least annually.~~

~~—(d) The institution shall reimburse the city for the direct expense of inspections and review.~~

(Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

Sec. 12-26. Procedure for requesting and holding a hearing.

Institutions denied a permit, or the renewal thereof, or any person aggrieved by the granting of a permit, may request a hearing by filing a written petition with the commissioner of health and human services within ten (10) days from the denial or grant of a permit. Upon receipt of such petition the commissioner of health and human services shall set a time and place for such hearing and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing the petitioner shall be given an opportunity to be heard and to show why the permit should be granted or denied. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

Sec. 12-27. Appeal.

Any institution or person aggrieved by the final decision of the commissioner of health and human services with respect to the denial or grant of a permit may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of this commonwealth. (Ord. No. R-237, 3-15-82)

Sec. 12-28. Restrictions.

Recombinant DNA use requiring physical containment greater than the BL3 level shall not be permitted in the City of Newton. An institution shall provide the NBC with thirty days' notice prior to recombinant DNA use requiring physical containment at the BL3 level.

(Ord. No. R-237, 3-15-82).

Sec. 12-29. Violations.

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(a) An institution which violates any provision of this article shall be subject to a fine of three hundred dollars (\$300.00) per offense, each day of violation constituting a separate and distinct offense. The commissioner of health and human services shall be empowered to enforce this ordinance.

~~(b) in any court of competent jurisdiction~~ The commissioner may revoke, suspend, modify or not renew a permit upon determination, after notice and hearing, if one is requested by the permit holder in accordance with the procedures in Sec. 12-26, that the permit holder has failed to comply with this ordinance, the permit conditions or the guidelines.

~~(c) Notwithstanding the above, the commissioner may, upon a determination that any violation constitutes an immediate threat to the public health or environment, order the immediate closure of an institution without prior notice or hearing. In addition to a fine, an institution which violates any provision of this ordinance or whose continued conduct of recombinant DNA technology poses an immediate threat to the public health or environment may be closed by the commissioner of health and human services. Any institution aggrieved by such action of the commissioner of health and human services shall appeal the same under the provisions of Sections 12-256 and 12-27.~~ and 12-26
(Ord. No. R-237, 3-15-82; Ord. no. X-175, 05-26-05)

Sec. 12-30. Severability.

If any provision(s) or portion(s) of this article or the application of any provision(s) or portion(s) thereof to any person or circumstance is/are held to be invalid, such invalidity shall not affect the validity of the remainder of said provision or other provisions of this article.

(Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Secs. 12-31—12-39. Reserved.

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(b) In the context of this article the following definitions are adopted:

- (1) *Recombinant DNA molecules (rDNA)*, and organisms and viruses containing rDNA, are those defined in the NIH Guidelines promulgated in the Federal Register on May 7, 1986.
- (2) An *institution* is any person, group of persons, business entity, association or any other organization, whether public or private, for profit or non-profit.
- (3) *Guidelines* are defined as:
 - a) National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules, as published in the Federal Register on May 7, 1986
 - b) Any amendments, revisions or substitutions subsequent to the above-referenced guidelines, including, but not limited to:

Notices of actions under NIH Guidelines for Research involving recombinant DNA Molecules on August 24, 1978, July 29, 1988, October 26, 1988, March 13, 1989, March 1, 1990, September 12, 1990, July 18, 1991, November 21, 1991, January 28, 1992 and April 22, 1992.

- c) Such amendments to the documents in subsections a) and b) above which are adopted by the National Institutes of Health and approved by the Commissioner. Amendments not acted upon by the Commissioner within sixty days shall be considered approved. In the event that the NIH shall discontinue or abolish its guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in Newton.

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(a) There shall be a Newton biosafety committee (NBC) which shall be comprised of nine (9) members which include the following:

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Four (4) members appointed by the mayor, at least one of whom is a scientist knowledgeable in the field of rDNA research and technology. The other three shall represent the fields of public health, occupational health, infectious disease or environmental health, and shall preferably include one member of the Newton health advisory council.

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Four (4) members appointed by the board of aldermen, at least one of whom represents the fields of public health, occupational health, infectious disease or environmental health.

Members appointed by the mayor and the board of aldermen shall serve three (3) year terms; provided however, that of the first three members appointed to the committee by the mayor and the board of aldermen two shall serve for a term of one (1) year, one shall serve for a term of two (2) years, and one shall serve for a term of three (3) years. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

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(b) The IBC shall inspect each facility conducting rDNA research or technology annually and meet at least once annually to enforce these regulations. Each institution shall name a safety officer who shall be responsible for enforcing the policies of the IBC. In addition, the IBC shall immediately notify the commissioner of health and human services and the NBC upon discovery of any incident, accident or significant deviation and/or non-compliance by the institution with any section of this ordinance or the NIH guidelines. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

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- (4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.
- (5) A description of the training program of safeguards and procedures for personnel using rDNA, and

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a copy of the training manual;

(6) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC and in accordance with NIH guidelines for all persons engaged in the use of rDNA.

(7). A description of the rodent and insect control programs to be used in the facility..

(8) The name of the safety officer who shall be responsible for enforcing the policies of the IBC.

(9) A plan for orienting representatives of the Newton health and human services, fire and police departments to the physical plant and to procedures to be utilized in the event of an emergency.

(c) The NBC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the commissioner of health and human services.

(d) Not later than sixty (60) days after an institution has commenced rDNA research or technology as determined by the commissioner of health and human services, the institution shall file with the commissioner:

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(2) Copies of Newton building department and Newton fire department certification.

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(e) Permits granted by the commissioner of health and human services shall be renewed annually.

(f) The fee for a permit granted by the commissioner of health and human services, or annual renewal thereof, shall be \$250. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-05)

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(b) All institutions must undergo an initial inspection before the permit is granted. The results shall be reported to the commissioner of health and human services, the NBC and the institution involved.

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Institutions denied a permit, or the renewal thereof, or any person aggrieved by the granting of a permit, may request a hearing by filing a written petition with the commissioner of health and human services within ten (10) days from the denial or grant of a permit. Upon receipt of such petition the commissioner of health and human services shall set a time and place for such hearing and shall so inform the petitioner, and the institution if other than the petitioner, in writing. At the hearing the petitioner shall be given an opportunity to be heard and to show why the permit should be granted or denied. (Ord. No. R-237, 3-15-82; Ord. No. X-175, 05-26-05)

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Any institution or person aggrieved by the final decision of the commissioner of health and human services with respect to the denial or grant of a permit may seek relief therefrom in any court of competent jurisdiction, as provided by the laws of this commonwealth. (Ord. No. R-237, 3-15-82)

Sec. 12-28. Restrictions.

Recombinant DNA use requiring physical containment greater than the BL3 level shall not be permitted in the City of Newton. An institution shall provide the NBC with thirty days' notice prior to recombinant DNA use requiring physical containment at the BL3 level. (Ord. No. R-237, 3-15-82).

Sec. 12-29. Violations.

(a) An institution which violates any provision of this article shall be subject to a fine of three hundred dollars (\$300.00) per offense, each day of violation constituting a separate and distinct offense. The commissioner of health and human services shall be empowered to enforce this ordinance.

(b) The commissioner may revoke, suspend, modify or not renew a permit upon determination, after notice and hearing, if one is requested by the permit holder in accordance with the procedures in Sec. 12-26, that the permit holder has failed to comply with this ordinance, the permit conditions or the guidelines.

(c) Notwithstanding the above, the commissioner may, upon a determination that any violation constitutes an immediate threat to the public health or environment, order the immediate closure of an institution without prior notice or hearing. Any institution aggrieved by such action shall appeal the same under the provisions of Sections 12-26 and 12-27. (Ord. No. R-237, 3-15-82; Ord. no. X-175, 05-26-05)

Sec. 12-30. Severability.

If any provision(s) or portion(s) of this article or the application of any provision(s) or portion(s) thereof to any person or circumstance is/are held to be invalid, such invalidity shall not affect the validity of the remainder of said provision or other provisions of this article. (Ord. No. R-237, 3-15-82; Ord. No. T-319, 12-20-93; Ord. No. X-175, 05-26-06)

Secs. 12-31—12-39. Reserved.

Business, Mixed Use & Manufacturing Districts													Definition/ Listed Standard
	BU1	BU2	BU3	BU4	BU5	MU1	MU2	MU3	MU4	M	LM		
Radio or television broadcasting studio	SP	SP	SP	SP	SP	--	SP	--	--	L	--		Sec. 6.4.27
Radio, or television transmission station	--	--	--	--	SP	SP	--	--	--	SP	--		Sec. 6.4.27
Research and development	--	--	--	--	--	--	--	P	--	--	--		Sec. 6.4.28
Restaurant	L/ SP	L/ SP	L/ SP	L/ SP	--	SP	P/ SP	P/ SP	P/ SP	--	L/ SP		Sec. 6.4.29
Retail sales, under 5,000 square feet	P	P	P	P	--	--	P	P	P	--	P		Sec. 6.4.30
Retail sales, over 5,000 square feet	P	P	P	P	--	SP	P	SP	SP	--	P		Sec. 6.4.30
Service establishment, up to 5,000 sq. feet	P	P	P	P	--	SP	P	--	P	--	--		Sec. 6.4.31
Service establishment, over 5,000 sq. feet	P	P	P	P	--	SP	P	--	SP	--	--		Sec. 6.4.31
Stable, public	--	--	--	--	--	--	--	--	--	--	SP		Sec. 6.4.32
Taxidermist	--	--	--	--	--	--	--	--	--	--	P		Sec. 6.4.33
Vehicle repair shop, minor	--	SP	--	--	--	SP	SP	--	--	SP	SP		Sec. 6.4.34
Vehicle repair shop, major	--	SP	--	--	--	SP	SP	--	--	SP	SP		Sec. 6.4.34
Vehicles sales and service facility, indoor	--	SP	--	--	--	SP	SP	--	--	SP	--		Sec. 6.4.35
Vehicles sales and service facility, outdoor	--	SP	--	--	--	SP	--	--	--	SP	--		Sec. 6.4.35
Veterinary hospital	--	SP	--	--	--	SP	SP	--	SP	P	P		Sec. 6.4.36
Industrial Uses													
Assembly or fabrication of materials manufactured off premise	--	--	--	--	--	P	SP	--	--	P	--		Sec. 6.5.1
Bakery, wholesale	--	--	--	--	--	--	--	--	--	SP	P		Sec. 6.5.2
Boat building, storage and repair	--	--	--	--	--	--	--	--	--	L	P		Sec. 6.5.3
Bottling works (except for alcoholic beverages)	--	--	--	--	--	--	--	--	--	P	P		Sec. 6.5.4
Building materials sales yard and storage building	--	--	--	--	--	--	--	--	--	SP	P		Sec. 6.5.5
Contractor's yard	--	--	--	--	--	--	--	--	--	P	--		Sec. 6.5.6
Feed and seed store	--	--	--	--	--	--	--	--	--	SP	P		Sec. 6.5.7
Food processing, wholesale	--	--	--	--	--	--	--	--	--	P	P		Sec. 6.5.8
Laboratory and research facility, no-recombinant DNA	SP	SP	SP	SP	SP	P	P	SP	P	P	P		Sec. 6.5.9
Laboratory and research facility, recombinant DNA	--	--	--	--	--	SP	SP	--	--	SP	SP		Sec. 6.5.9
Laundry, cleaning & dyeing establishment	--	--	--	--	--	--	--	--	--	P	P		Sec. 6.5.10
Manufacturing	--	--	--	--	--	L	--	--	--	P	P		Sec. 6.5.11
Manufacturing, molding, shaping or assembly from prepared materials (including repairs)	--	--	--	--	--	--	--	--	--	P	P		Sec. 6.5.11
Paint store	--	--	--	--	--	--	--	--	--	SP	P		Sec. 6.5.12
P = Allowed by Right L = Allowed Subject to Listed Standards SP = Special Permit by Board of Aldermen Required -- Not Allowed													

6.5.9. Laboratory and Research Facility

A. ~~With No Recombinant DNA~~

- B. Defined.** Research and development facility, laboratory or research facility with or without ~~no~~ recombinant DNA research or technology, as defined in Revised Ordinances Chapter 12, Sections 12-20 et. seq.

C. Standards.

- a. ~~No recombinant DNA research or technology is involved.~~
- b. In the Business 5 district, the facility is exclusively for research purposes with no manufacturing on the premises.

- D. ~~With Recombinant DNA. Research and development facility, laboratory or research facility that includes recombinant DNA research or technology, as defined in Revised Ordinances Chapter 12, Sections 12-20 et. seq.~~**

(Ord. No. S-260, 08/03/87; Ord. No. T-319, 12/20/93)

6.5.10. Laundry, Cleaning and Dyeing Establishment

- A. Defined.** [reserved]

6.5.11. Manufacturing

- A. Defined.** Manufacturing includes:

1. Canvas products, fabrication and sales;
2. Glass fabrication or installation;
3. Ice manufacturing or storage;
4. Light metal fabrication such as sheet metal, ducts, gutters and leaders;
5. Lightweight and nonferrous metal casting (no noxious fumes);
6. Machine shop (excluding presses over 10 tons), plumbing shop, blacksmith shop;
7. Molding, shaping or assembly from prepared materials (including repairs) of boxes, staging, toys, stationery, novelties, paper boxes, toilet preparations, drugs, perfumes, flavoring extracts, medical and hygienic appliances, clothing, textiles, hats, leather and sporting

goods, mattresses, store, house, office, theater, playground equipment, signs, musical instruments, art goods, industrial models, tools, appliances or electrical goods;

8. Optical, scientific instrument and jewelry manufacturing;
9. Wearing apparel fabrication and processing; and
10. Other similar manufacturing uses.

- B. Standards.** Such use shall not be injurious, noxious or offensive to the neighborhood by reason of noise, smoke, odor, gas, dust or similar objectionable features, or dangerous to the neighborhood on account of fire, or any other cause.

(Ord. No. S-260, 08/03/87; Ord. No. T-65, 12/18/89; Ord. No. T-185, 11/18/91)

6.5.12. Paint Store

- A. Defined.** [reserved]

6.5.13. Printing, Publishing and Reproduction Establishments

- A. Defined.** [reserved]

6.5.14. Sign Painting Shop

- A. Defined.** [reserved]

6.5.15. Telecommunications and Data Storage Facility

- A. Defined.** A facility for the operation, monitoring and maintenance of telecommunications switching equipment, data storage computers, internet connectivity routers, and ancillary equipment.

(Ord. No. W-34, 03/05/01)

6.5.16. Trash or Yard Waste, Collection, Storage, Transfer-Haul or Composting

- A. Defined.** On-site collection or storage for wholesale sale of trash or yard waste of any sort, including, but not limited to recyclable materials, brush, leaves, grass clippings and any other similar materials.

(Ord. No. W-33, 03/05/01)

feet, the model shall show the proposed development and all properties within 1,000 feet of the lot line of the proposed development or all abutting properties and abutters to such abutting properties, whichever is greater. The model shall be provided to the City in a file format acceptable to the Director of Planning and Development, in consultation with the Clerk of the Board of Aldermen, the City Solicitor, and the Chief Information Officer.

- C. As part of an application for special permit, an applicant must comply with the Rules and Orders of the Board of Aldermen pertaining to special permit and site plan approval.

(Ord. No. S-260, 08/03/87; Ord. No. A-6, 10/01/12; Or. No. A-73, 04/04/16)

7.3.2. Review

- A. The Board of Aldermen or a committee of the Board of Aldermen shall hold a public hearing within 65 days of the filing of an application for special permit.
- B. Notice of such public hearing shall be provided as required by M.G.L. Chapter 40A, Section 11.
- C. The Board of Aldermen shall act upon any application for special permit not later than 90 days following the the public hearing.
- D. The application for special permit shall be deemed approved if the Board of Aldermen fails to act upon the application not later than 90 days following the public hearing.
- E. Any approval of an application for special permit shall lapse not later than 3 years from the grant of such approval unless a substantial use of such special permit or construction required by such special permit has begun. The Board of Aldermen may extend the period of time granted under this Paragraph for good cause, whether or not such period of time shall have expired, without the necessity of a further public hearing thereon, unless the Board of Aldermen or its Committee on Land Use shall vote to require a public hearing. Notwithstanding the above, no extensions shall be granted which shall extend the time for substantial exercise of the special permit for more than 2 years from the date of the grant of the special permit.
- F. The Newton Biosafety Committee shall serve as an advisory body to the Board of Aldermen with

regard to any application for a special permit for a research and development facility. ~~The Newton Biosafety Committee shall be consulted by the Board of Aldermen for its recommendations on the siting of any institution intending to conduct recombinant DNA research or technology, which recommendations shall be in writing and shall be submitted within such time as the Board of Aldermen shall specify to assure said board's ability to act within the time periods set forth in this Sec. 7.3.~~

(Ord. No. S-260, 08/03/87; Ord. No. V-9, 02/21/95; Ord. No. A-6, 10/01/12; Ord. No. A-99, 01/17/17)

7.3.3. Grant of Permit

- A. A special permit from the Board of Aldermen for any purpose for which a permit is required under this Chapter shall be granted only by 2/3 vote of all the Board of Aldermen.
- B. The Board of Aldermen may grant a special permit when, in its judgment, the public convenience and welfare will be served, and subject to such conditions, safeguards and limitations as it may impose.
- C. The Board of Aldermen shall not approve any application for a special permit unless it finds, in its judgment, that the use of the site will be in harmony with the conditions, safeguards and limitations of this Sec. 7.3, and that the application meets all the following criteria:
 1. The specific site is an appropriate location for such use, structure;
 2. The use as developed and operated will not adversely affect the neighborhood;
 3. There will be no nuisance or serious hazard to vehicles or pedestrians;
 4. Access to the site over streets is appropriate for the types and numbers of vehicles involved; and
 5. In cases involving construction of building or structures or additions to existing buildings or structures, if those proposed buildings or structures or additions contain individually or in the aggregate 20,000 or more square feet in gross floor area, the site planning, building design, construction, maintenance or long-term operation of the premises will contribute significantly to the efficient use and conservation of natural resources and energy.

7.3.5. Special Requirements for Recombinant DNA Research or Technology

- A. In the case of a special permit involving recombinant DNA research or technology, as defined in Revised Ordinances Chapter 12, Article III, Recombinant DNA Research, as amended, the applicant shall be required to meet the requirements of ~~Sec. 7.3.3~~ and shall also be required to demonstrate that the proposed use meets applicable health and safety criteria, including, without limitation, the following:
 - 1. The National Institute of Health guidelines published in the Federal Register of May 7, 1986, as amended and as adopted by the biosafety committee, and any other health guidelines and regulations the federal government may from time to time promulgate;
 - 2. The Massachusetts Department of Public Health guidelines known as, "State Sanitary Code, Chapter VIII: Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste", 105 CMR 480.000, as amended;
 - 3. Revised Ordinances Chapter 12, Article III, Recombinant DNA Research, as amended; and
 - 4. Code of Federal Regulations, Title 10, Parts 0 to 199, as amended, pertaining to low-level radioactive waste management.
- B. The Newton Biosafety Committee shall serve as an advisory body to the Board of Aldermen with regard to the additional health and safety findings required by ~~this Sec. 7.3.5~~
- C. The Newton Biosafety Committee's findings on the above criteria shall be deemed presumptively valid unless the Board of Aldermen makes contrary written findings. The Newton Biosafety Committee may make recommendations relating to the above criteria, and shall render its report within a time to be specified by the Board of Aldermen.

(Ord. No. T-319, 12/20/93)

Hospital: See [Sec. 6.3.7](#)

Hotel: See [Sec. 6.4.17](#)

I

Indoor Recreation Facility: See [Sec. 6.6.2](#)

Institution, Single-Use: A religious or nonprofit educational use having no more than one principal building and less than 50,000 square feet of lot area.

Institution, Multi-Use: A religious or nonprofit educational use having one or more buildings and at least 50,000 square feet of lot area.

Interior Lot: See Lot, interior.

J

[reserved]

K

Keno: See [Sec. 6.10.2](#)

L

Laboratory and Research Facility, No Recombinant DNA: See [Sec. 6.5.9](#)

Landing: A level area at the top of a staircase or between one flight of stairs and another.

Laundry, Cleaning and Dyeing Establishment: See [Sec. 6.5.10](#)

Library: See [Sec. 6.3.8](#)

Listed Standards: Rules and regulations for land uses otherwise allowed by right.

Live/Work Space: See [Sec. 6.2.11](#)

Lodger: A person who occupies space for living and sleeping purposes without separate cooking facilities, paying rent, which may include an allowance for meals; and who is not a member of the housekeeping unit

Lot, Corner: See Corner Lot.

Lodging Establishment: See [Sec. 6.4.17](#)

Lot Coverage: See [Sec. 1.5.2](#)

Lot, Interior: Any lot or part of a lot other than a corner lot.

Lot Line: See [Sec. 1.5.2](#)

M

Maneuvering Aisle: A maneuvering space which serves a row or rows of parking stalls.

Manufacturing: See [Sec. 6.5.11](#)

Mass Below First Story: See [Sec. 1.5.5](#)

Mixed-Use Residential Building: A building occupied by both residential and nonresidential uses.

Molding, Shaping or Assembly from Prepared Materials (Including Repairs): See [Sec. 6.5.12](#)

Multi-Family Dwelling: See [Sec. 6.2.4](#)

Museum: See [Sec. 6.3.8](#)

N

Nonconforming Building: See Building, nonconforming.

Nonconforming Use: See Use, nonconforming.

Nonprofit Institution: See [Sec. 6.3.8](#)

Nursing Home: See [Sec. 6.2.5](#)

O

Occupy/Occupancy: When used in connection with accessory apartments, this term shall mean physical presence and residency on the subject premises except for short periods of temporary absence.