Town of Watertown

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To: The Honorable Town Council
Michael J. Driscoll, Town Manager

From: Steve Magoon, DCDP Director, Assistant Town Manager
Larry Ramdin, MPH, MA, REHS, CP-FS, CHO HHS, Director Department of Health

Date: September 7, 2018

Subject: Regulation of Laboratories

We are writing in response to the requests of the Town Council President and Town Manager regarding the regulation of laboratories (labs) as a use in Watertown.

Labs as a use are heavily regulated beyond what exists on a local basis, and there are a number of local checks and balances as well. Please see attached memorandum. Many of the surrounding jurisdictions have a greater level of local oversight of these uses than we have here in Watertown. These have typically taken the form of a Committee that has expertise and can provide review based on industry knowledge. Attached is an example of such a regulation from Lexington. These Committees are often supported by the Health Department. We will be discussing the establishment of such a committee with the Board of Health at their meeting on September 24 and will then report to the Honorable Town Council with the results.

From a zoning and land use perspective, labs are listed in the Table of permissible uses, Section 5.01.5.e. which are allowed generally in the industrial zones, RMUD, and the PSCD by special permit with site plan review.

Moving forward, the Department of Community Development and Planning will recommend conditions for any approvals of this type of use that will require compliance with the subsequent framework that the Board of Health develops.

Thank you for your continued concern regarding this important issue.

Cc Board of Health
Planning Board
Zoning Board of Appeals
Mark R. Reich, KP Law
Gideon Schreiber, Senior Planner
Michael Mena, Zoning Enforcement Officer
Andrea Adams, Senior Planner

Town of Lexington

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ARTICLE V, Use of Recombinant DNA Molecule Technology [Adopted 11-19-1997; amended 6-13-07]

§ 155-33. APPLICABILITY.

All activities associated with constructing and/or propagating: a) recombinant DNA (rDNA) molecules b) organisms and viruses containing rDNA molecules within the Town of Lexington and (c) biological organisms having a containment of Biosafety Level Three (BSL-3) or attenuated organisms derived from a BSL-3 shall be performed in strict accordance with these regulations and with the NIH Guidelines as defined in Section 2-c below. The regulations shall govern where they differ from the Guidelines. These regulations do not apply to finished products which contain rDNA molecules and which have been approved by other government regulatory agencies for medical or other purposes.

§ 155-34. DEFINITIONS.

For the purpose of these regulations, the following definitions are adopted:

a. Large-scale: The use of more than ten liters but less than 5000 liters of rDNA culture.
b. Significant deviation: Any deviation that might have an adverse effect on personal or public health
c. Guidelines:
   1. The most recent version and any additional approvals of the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register.
   2. In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect and approved by the Board of Health at the time of such discontinuance shall remain in effect.
d. Biosafety Level Three organisms

Classification of the level of biological containment required for certain organisms categorized as "BSL-3." These organisms typically contain a risk by aerosol transmission and the diseases produced by these agents are serious but treatable. Additional facility requirements as well as administrative and engineering controls are required for their safe use. The most recent version of the CDC/NIH Publication: "Biosafety in Microbiological and Biomedical Laboratories (BMBL)" will be followed for detailed guidance on BSL-3 organisms.

e. Attenuated organism: A bacteria, virus, or other biological organism that has a wild-type counterpart. The attenuated strain is a weakened strain that can be safely worked on at a lower level of biosafety.

§ 155-35. LEXINGTON BIOSAFETY COMMITTEE (LBSC).

A. Lexington Biosafety Committee (LBSC) shall be established for the purpose of overseeing all uses of rDNA in Lexington and advising the Board of Health.

B. Specific responsibilities of the LBSC are as follows:

1. Establishing policies, procedures and criteria to aid in the implementation of this ordinance.
2. Reviewing all amendments to the Guidelines before submitting their recommendations to the Board of Health for approval.
3. Reviewing all applications for permits for the use of rDNA and biological materials in Lexington for compliance with the Guidelines and conformity with such other regulations as the Board of Health may from time to time promulgate.
4. Reviewing institutions' manuals, annual worker training programs, health-safety programs and monitoring procedures.
5. Determining the manner in which institutions and institutional biosafety committees make reports, applications or recommendations to the LBSC and the type of information required. Reviewing such reports, applications and recommendations and approving where appropriate. Carrying out site visits to institutional facilities. Approving the community members of the Institutional Biosafety Committees (IBCs) who are appointed by the IBC chairperson at each respective institution.
6. Developing a procedure for members of institutions to report to the LBSC violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.

C. The LBSC shall be composed of the Chairman of the Board of Health or his/her designee, the Director of Health and a minimum of one other member to be appointed by the Town shall serve three-year terms.

§ 155-36. REGISTRATION.

A. rDNA users in the following categories: Both (1) and (2) are required to register proposed work with the LBSC through the Director of Public Health.

1. Users whose experiments are all exempt from the NIH Guidelines under Section III-E;
2. Users not constructing rDNA organisms but merely propagating them;

B. Written registration is required prior to commencement of work and includes:

1. Name and c.v. of a person in the organization familiar with the proposed rDNA work and the NIH Guidelines.
2. A brief summary from the above-named person describing the proposed work and giving:
   a. Name and type of organisms (host/donor [foreign DNA]/vector) being used.
   b. Reference to the section of the NIH Guidelines where the work falls.
   c. If recombinant molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
   d. The scale (in liters) on which the organisms will be grown.
   e. An assurance that all work will be carried out following the NIH Guidelines, where applicable, at the appropriate BL level and that exempt work will be done at BL1.
   f. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state, and local codes.

g. Description of annual safety training and refresher training provided to laboratory staff.

3. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in 2 above.
4. A registration fee of $100.00, due upon initial application and upon annual renewals.

C. Upon receiving and reviewing the submitted information, the LBSC may require additional information to be submitted, and it may recommend to the Board of Health other procedures or safeguards as it deems appropriate up to and including full permit application under the existing Town Ordinance.

D. Immediate reporting to the IBC Chairman of any employee exposure or illness, facility spill, release or explosion that could be potentially related to the use of rDNA or biologicals or chemicals used on site from an approved IBC protocol. The IBC Chairman should consult with the administrative officials at the permitted facility and provide a verbal report to the Town of Lexington, Director of Health, within 2 days of the potential exposure or release. A formal accident report containing details of the accident, laboratory decontamination and follow-up of the potentially exposed personnel should be submitted to the Town of Lexington Director of Health the next business day following the verbal report. A determination as to whether there was a release of rDNA material as described in Section 7) D. should also be addressed to the Town of Lexington.

§ 155-37. PERMITS.

A. All institutions planning to use rDNA [in any way other than those described in the Registration (Section 4)] or non-rDNA biological research and manufacturing that requires Biosafety Level Three or higher containment or attenuated strains requiring lower Biosafety Level must obtain a permit from the Board of Health. All institutions planning to use rDNA in any way other than those described in the Registration (Section 4) must obtain a permit from the Board of Health with the prior approval of the LBSC before commencing said technology. All permits are issued for one year and may be revoked for cause.

B. Institutions seeking such a permit from the Board of Health must first submit the following to the LBSC:

1. A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.
2. A listing of all organisms, containment levels, and decontamination procedures to be employed.
3. A plan for a screening process 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 plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building. All waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.
6. A plan for systematic security of the premises.
7. Institutional Biosafety Committee (IBC)
   a. The Institutional Biosafety Committee (IBC), established by the Guidelines, shall have as members, in addition to the corporate representatives, one community

representative of the Town of Lexington, who shall report back to the Director of Health, or his/her designee. The community representative shall be appointed by the facility holding the rDNA permit and notification of the community appointment should be sent to the Director of Health, who shall report to the LBSC (see section c. Below).

b. The IBC shall meet a minimum of at least once per year. All minutes of the IBC meetings must be forwarded to the Board of Health and the LBSC.

c. The community member of the IBC shall have no financial interest in the institution or any other institution in competition therewith, and such representatives shall be bound to the same provisions as to non- disclosure and non-use of proprietary information and trade secrets as all other members of IBC, except to the extent necessary to alleviate any public health hazard. As used in this regulation, proprietary information and trade secrets shall be defined as set forth under the laws of the Commonwealth of Massachusetts.

d. In accordance with the Guidelines the IBC, acting on behalf of the institution, reviews all rDNA use for compliance with the Guidelines and approves those projects that conform with the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying the experiment conforms with the Guidelines, shall be filed with the LBSC and the Board of Health.

e. All information sent to the Board of Health and the LBSC shall have any proprietary information trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC.

f. The IBC must develop a policy for the verification of attenuated pathogens. These pathogens are biological agents that in the wild-type strain, are virulent pathogens, typically requiring lab containment biosafety level of three or four. The policy should contain steps to ensure the IBC approves the method and verifies the data prior to the laboratory reducing the biocontainment and/or handling requirements of an attenuated agent. Typical methods for distinguishing wild type from attenuated strains include restriction analysis or related methods.

8. 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 for all persons engaged in the use of rDNA. Such programs shall include, but shall not necessarily be limited to:

   a. Immediate reporting to the IBC Chairman of any employee exposure or illness, facility spill, release or explosion that could be potentially related to the use of rDNA or biologicals or chemicals used on site from an approved IBC protocol. The IBC Chairman should consult with the administrative officials at the permitted facility and provide a verbal report to the Town of Lexington, Director of Health, within 2 days of the potential exposure or release. A formal accident report containing details of the accident, laboratory decontamination and follow-up of the potentially exposed personnel should be submitted to the Town of Lexington Director of Health the next business day following the verbal report. A determination as to whether there was a release of rDNA material as described in Section 7) D. should also be addressed to the Town of Lexington.

   b. 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.

c. An annual training program of safeguards and safety procedures for personnel.

9. The name(s) of the Principal Investigator(s) responsible for enforcing the Policies of the IBC.
10. A plan for orienting representatives of the Lexington Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
11. Written agreement to allow inspection of facilities and pertinent records by the LBSC.
12. For Biosafety Level Three (BSL3) laboratories, evidence that the facility has been designed according to the latest standards for BSL-3, including the CDC/NIH Guidelines: Biosafety in Microbiological and Biomedical Laboratories." In addition, documentation of a maintenance schedule and annual commissioning by a 3rd party agent is required to be produced during the annual inspection by Town of Lexington.

C. The LBSC shall review the institution's application for a permit and supporting documents and make its recommendation of the same to the Board of Health. Copies of the application, supporting documents and the LBSC recommendation shall be filed with the Board of Health and the Planning Board within 45 days after the application is filed with the LBSC. The Board of Health shall take final action on the permit application within 75 days after the application is filed with the LBSC. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and the applicant.

D. The fee for a permit granted by the Board of Health, or annual renewal thereof, shall be $500.00.

E. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in Section 4 (Registration) # 2. and in addition the following:
   1. Current list of IBC members
   2. Copies of the previous year's IBC minutes
   3. Summary of the research and any changes in the past year

F. Annual report deadline will vary by company. Deadline is based on the rDNA permit renewal date.

§ 155-38. INSPECTION AND REVIEW.

A. All institutions involved in the use of rDNA and biological materials as described in Section 5) a. permits, shall allow annual inspection of their facilities, procedures and practices in order to confirm compliance with this ordinance.

B. The Board of Health shall retain a professionally competent person, agency or institution to perform inspections and reviews. The results shall be reported to the Board of Health, the LBSC and the institution involved.

C. The Board of Health, its employees, all members of the LBSC, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of this ordinance.

§ 155-39. RESTRICTIONS.

A. rDNA use classified by the guidelines as requiring any BL3 or BL4 physical containment measures as prescribed in Appendix G of the guidelines under Standard Microbiological Practices, Special Practice Containment Practices, Containment Equipment or Laboratory Facilities shall not be permitted.

B. Biological agents that are classified as requiring Biosafety Level four containment shall not be permitted in the Town of Lexington.

C. Experiments for which containment levels are not prescribed in the Guidelines shall be approved by the LBSC before the experiment is initiated.
D. Use of more than 5,000 liters of rDNA culture shall not be permitted, unless a variance is obtained by the Board of Health
E. There shall be no deliberate release into the environment that is to sewers, drains, or the air, of any organisms containing rDNA.

§ 155-40. VIOLATIONS AND PENALTIES.

A. ***Violation of the conditions of these regulations shall subject the violator to a fine of five hundred dollars ($500.00)*** *per day* and in addition the facility in which the violation occurs may be closed by the Board of Health. Each day of violation shall constitute a separate and distinct offense.

Violation of the provisions of these regulations shall subject the violator to fines according to Chapter xxx of the Lexington Health Regulations and Article I of the Lexington Town By-laws.

B. Once a permit has been issued or a registration filed, it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements or the guidelines or if in the opinion of the Board of Health the rDNA use causes a nuisance, or adversely affects the public health, safety and welfare in Lexington.

§ 155-41. ASSESSMENT OF EXPENSES.

The salaries and expenses paid by the Town for inspections, reviews, staff and consultants for work directly related to carrying out the requirements of these regulations shall be assessed to the institutions holding permits under these regulations. An accounting of these costs will be furnished annually to each institution.

§ 155-42. SEVERABILITY.

Each part of these regulations is construed as separate to the end, and that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

§ 155-43. VARIANCES.

The Board of Health may vary the application of any provision of these regulations with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board of Health is not in conflict with the spirit of these standards. Any variance granted by the Board of Health must be in writing with a copy available to the public at all reasonable hours in the Office of the Town Clerk and in the Office of the Board of Health.

Town of Lexington

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Office of Community Development - Health Division
Fee Schedule Effective September 1, 2009

Fee Title		Fee
Food Program		
Food Risk Category 1, (Low Risk - Annual Inspection)		$85.00
Food Risk Category 2, (Bi- Annual Inspection -Simple 1.5 Hours per Inspection)		$170.00
Food Risk Category 3, (Bi - Annual Inspection-Complex, 3 Hours per Inspection)		$290.00
Food Risk Category 4, (High Risk - Annual Inspection, includes Sushi and multiple food prep locations)		$390.00
Food Plan Review - New Establishment / New Owner / Complex		$190.00
Food Plan Review - New Equipment / No Change in Owner / Simple		$75.00
Catered Temporary Food Permit - (PHF - temperature control)	Per Event	$50.00
Non-catered Temporary Food Permit - (Fundraisers, etc.)	Per Event	$15.00
Catering		$170.00
Farmer's Market Location Permit		$150.00
Farmer's Market Vendors with PHF Permit		$50.00
Camps		
Recreation Day Camp - 0- 50 campers annually		$200.00
Recreation Day Camp - 51- 200 campers annually		$300.00
Recreation Day Camp - Over 201 campers annually		$400.00
Pools		
Swimming - Annual (Indoor and Seasonal)		$170.00
Special Purpose		$125.00
Wading		$50.00
Plan Review - Complex		$170.00
Plan Review - Simple		$100.00
Septic		
Installer's Permit		$85.00
New System Construction		$0.00
Repair or Replace Existing System		$150.00
Percolation Test - New and Repair (per test)		$50.00
Deep Hole - New and Repair (per hole)		$50.00
New Permit Plan Review - 0 - 1999 gallons per day		$130.00
New Permit Plan Review - 2000 - 5999 gallons per day		$230.00
New Permit Plan Review - 6000 - 9000 gallons per day		$330.00
Septic Hauler		$75.00

Hazardous Materials	
Haz Mat Risk Category 1, (Low Risk: Retail Store / Medical / Dry Cleaner / Gas Station / Contractor / Landscaper / School Lab)	$35.00
Haz Mat Risk Category 2, (Medium Risk: Industrial Facilty / Vehicle Repair / Service Industry / Manufacturing)	$115.00
Haz Mat Risk Category 3, (High Risk: Laboratory Setting / Research)	$195.00
New Permit Haz Mat Plan Review - Category 1	$30.00
New Permit Haz Mat Plan Review - Category 2	$45.00
New Permit Haz Mat Plan Review - Category 3	$70.00
Remediation Discharge Annual Permit	$115.00
Asbestos Removal Permit	$30.00
Lead Paint Removal / Abrassive Sanding Permit	$30.00
Environmental Engineering Database Review - Information Request (RTN Release Tracking, monitoring wells, 21 E ect.)	$60.00
Rubbish / Refuse Hauler Permit	
Rubbish / Garbage/Refuse Hauler Permit (per business-blanket permit for all vehicles)	$100.00
Animal Permit	
Large Farm Animal (horses, cattle, goats, sheep, lama's), per animal	$10.00
Small Hobby Animal (chickens, rabbits, ect)- per species, not to exceed five (5) animals	$10.00
Lodging Permit	
Motel / Hotel / Bed Breakfast Permit- includes an annual State Sanitary Code Inspection	$75.00
Tanning Permit	
Tanning Establishment Permit- includes an annual State Sanitary Code Inspection	$100.00
Massage	
Massage Establishment Permit- includes an annual State Sanitary Code Inspection	$0.00
Massage Therapist Permit- includes CORI check and verification of credentials.	$0.00
Body Art	
Body Art Establishment Permit- includes an annual State Sanitary Code Inspection	$150.00
Body Art Therapist Permit- includes CORI check and verification of credentials.	$100.00
Tobacco Sales Permit	
Tobacco Sales Permit- includes Tobacco Compliance Inspections	$200.00
Well Permit	
Potable Water Permit :Domestic -Annual Permit - includes review of water quality/data analysis	$100.00
Non - Potable Water Permit : Irrigation, Monitoring, Geothermal	$50.00
Funeral	
Funeral Director, Annual Permit	$100.00
Burial Permit	$15.00
Biological Safety and Technology	
Biotechnology (rDNA experiments which reconstruct cells or require biosafety level three or higher containment) Permit	$500.00
Biotechnology (rDNA experiments which are NIH exempt or growing cells only) Registration	$200.00
Miscellaneous	
Late Permit Fee	$100.00

TOWN OF WATERTOWN
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Zoning/Land Use

Watertown's Zoning Ordinance classifies laboratories as a Principal Use, and allows Laboratory in the I-1, I-2, I-3, RMUD, and PSCD within existing industrial buildings by right and requires a Special Permit with Site Plan Review for new construction, conversions from commercial uses, or additions greater than 4,000 s.f. This framework treats laboratory space similarly to surrounding communities and is consistent with how other similar light industrial uses are treated within the Zoning Ordinance.

Permitting

There are multiple local and state permits and inspections required of laboratory users.

1. Building and Plumbing – Any building and plumbing permit submitted for a laboratory triggers a series of requirements from state regulations. The Building Inspector reviews all aspects of the proposed use and determines the requirements for construction to ensure adequate protocols and safety features are incorporated. The Plumbing Inspector also reviews all plumbing connections to ensure proper code compliance. Unless the nature of the laboratory space is altered, these are a one-time permit and inspection process during initial fit out.
2. DPW Cross-Connections – Any water supply connections within laboratories are required to have certified backflow devices. The backflow testing is required to be completed twice per year.
3. Fire Inspections – As with other uses that have hazardous materials, laboratory uses undergo a review by the Fire Prevention Officer which is coordinated with any other permitting of a project. There is also a requirement for hazardous materials to be reviewed by the Health Department.
4. MWRA Sewer Connections – Initial permitting is completed in coordination with the municipal Plumbing Inspector and subsequent monitoring and permitting is completed by the Massachusetts Water Resources Authority (MWRA).
5. MassDEP – The state requires registration for any hazardous waste generators with biennial reports as a possible requirement, use of a waste manifest for shipments off site, with submission to the state, and specific management protocols. There is also air permitting if necessary.

Surrounding Municipal Zoning Examples

Examples of Zoning regulations in regard to laboratories in surrounding communities:

Boston - Laboratories are generally defined as an Allowed Use. The permitting is very complex, enough so that the Boston Planning and Development Authority has a "Zoning Check" tool on the website. A distinction has been made between Research Laboratories (linked in many cases to Universities) and Clinical Laboratories (Hospitals, Dana Farber).

Cambridge - Laboratories are a Principal Use allowed By Right in several Business and Industrial Districts.

Lexington - Laboratories are a Principal Use are allowed By Right in the Commercial/Manufacturing and Regional Office Districts. When By Right, they are subject to Development Performance Criteria.

Waltham - Laboratories as a Principal Use are allowed By Right in the Hope Avenue Redevelopment District 1. Laboratories are also by Special Permit for new or "Intensity of Use" in the Hope Avenue Redevelopment District 2, Limited Commercial, Commercial and Industrial Districts via the City Council (Hope Avenue Redevelopment District 2) or Zoning Board of Appeals.

LOCAL OVERSIGHT IN SURROUNDING COMMUNITIES

The surrounding communities mentioned have also established a permitting and review process under the purview of the Health Department/Commission. Most have also implemented an advisory Biosafety Committee to assist the local Public Health entity in the review and permitting of labs. The Biosafety Committees primarily focus on those labs working with recombinant DNA technologies. Recombinant DNA involves splicing the genes of the same species or different species together. These Communities also further regulate at biosafety Level 3 and/or Level 4 and Cambridge prohibits labs at Level 4 regardless if it is using recombinant DNA technology. The Biosafety levels are further explained below.

LEVELS OF BIOSAFETY

The local regulatory framework implements a series of federal and state regulations in regard to biosafety. *Biosafety in Microbiological and Biomedical Laboratories*, by the U.S. Department of Health and Human Services, the Center for Disease Control and Prevention, and the National Institutes of Health, provides the guidance on biosafety. The intent of biosafety controls is to prevent exposure to the agent being worked with, both within the lab, and to the outside environment and people.

At the Federal level, four levels of laboratory biosafety were created. The levels denote the types of actions, administrative (procedures, training) or physical controls (protective gear, filtration) that should be used to contain the agent(s) being worked with. Containment means protection of the lab workers, those in the building, and the greater environment.

Level 1 is the lowest level of biosafety. Many high school biology classes do laboratory projects at Level 1. This level is suitable for work involving agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.

Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment, such as work with bacteria and viruses that cause only mild disease to humans, or are difficult to contract such as Lyme disease, Salmonella, mumps, and measles. Most hospital clinical testing labs are Level 2. Some more advanced high school laboratories could also be the equivalent of a Level 2 Lab.

Level 3 is for clinical, diagnostic, teaching, research or production facilities working with bacteria, parasites, and viruses that can cause severe or fatal disease through the inhalation route of exposure in humans but for which treatment exists such as tuberculosis, West Nile Virus, anthrax, and yellow fever. The main difference with this Level is that the disease can be aerosolized or inhaled.

Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted/inhaled laboratory infections, agents which cause severe to fatal disease in humans for which vaccines or other treatments are not available, such as Ebola virus, Lassa fever, smallpox, and various hemorrhagic fevers. As of the date of this Memo, there are 10 Level 4 labs in the United States, of which only one will be located in Massachusetts, located in Boston, at Boston University. That facility is in the planning/permitting process.

BioReady Community – Massachusetts Biotechnology Council

Many Massachusetts cities and towns, with the support of state government, have sought to create local policies that more easily support renovation or new construction of biotech laboratory and manufacturing facilities.

There are 84 communities within the Commonwealth that are BioReady with ratings between Platinum to Bronze. Watertown is a BioReady Community at a Gold level. There are 22 communities at the Gold level and another 29 communities at the Platinum level. The 2011 Strategic Framework for Economic Development and the 2015 Comprehensive Plan identified a goal to support key industry clusters including life sciences and to seek a platinum rating to continue to support a favorable municipal environment for laboratories and be consistent with the surrounding communities' platinum ratings.

Bronze Municipalities at this level feature:

- Municipal water and sewer available in commercial and industrial areas.
- Zoning allows for biotech laboratory and manufacturing uses by special permit.
- Identified point of contact in town/city hall to assist biotech projects.

Silver Municipalities at this level feature Bronze Criteria plus:

- Municipality allows biotech laboratory and manufacturing uses by right.
- Has identified buildings and/or land sites for biotechnology uses in municipal plans.

AND

- Municipality convenes site plan review meetings, bringing together all pertinent departments, to provide an overview of the local approvals process for significant commercial and industrial projects.
- Has land sites and/or buildings included in MassEcon BioSites Inventory

OR

- Community has identified Priority Development Sites per Chapter 43D.
- Municipality has a site designated as a Massachusetts Growth District.

Gold Municipalities at this level feature:

- Silver Criteria plus
- Municipality has sites or buildings pre-permitted for biotechnology laboratory or manufacturing use

OR

- Municipality has existing buildings in which biotech laboratory or manufacturing activities are taking place.

Platinum Municipalities at this level feature:

- Gold Criteria plus
- Municipality's Board of Health has adopted the National Institutes of Health guidelines on rDNA activity as part of its regulations.
- Municipality includes a building or buildings that are already permitted for biotech uses and have 20,000 square feet or more of available space for biotech uses.

OR

- Municipality has a shovel-ready pre-permitted land site with completed MEPA review and municipal water and sewer capacity to meet additional demand.