Watertown Biotechnology Regulation FAQ

Regulation: *Biotechnology and the use of Recombinant DNA Molecule Technology*

Q1. What is the intent of this regulation?

The regulation requires that all applicable companies within the Town of Watertown adhere to the *NIH Guidelines*, as well as to the biosafety levels (BSL) and containment measures outlined in the most recent version of *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. Additionally, the regulation forms a Watertown Biosafety Committee (WBSC) that will review registration and permit applications and make recommendations to the Watertown Board of Health (BOH).

Q2. Who makes up the Watertown Biosafety Committee (WBSC)?

The WBSC is composed of five members:

1. The Chair of the Board of Health and the Director of Public Health, or their designees.
2. An individual with knowledge of hazardous materials appointed by the Board of Health in consultation with the Fire Chief or his designee.
3. Two members of the public with experience in biotechnology and appointed by the Board of Health.

Q3. What type of work falls within the purview of this regulation?

The regulation covers work that utilizes biologic agents and/or work with recombinant DNA (rDNA) technology. The regulation prohibits work requiring BSL-4 containment within the Town of Watertown. Additionally, the regulation allows "Low-Risk Facilities" to register with the Town in place of seeking a permit.

Q4. What laboratory work is exempt from the regulation?

As stated in Section 7D of the regulation, medical facilities and clinical labs using commercially approved and/or established propriety protocols for diagnostic testing are exempt. Medical/clinical facilities that collect patient samples for testing at offsite laboratories are also exempt. However, clinical laboratories that are developing new diagnostic testing using rDNA and/or biologic agents must adhere to the regulation.

Additionally, as stated in the *Applicability and Statement of Purpose* section of the regulation: "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." This provision includes testing kits and products utilized by medical devices and manufacturing companies for quality control (QC) proposes. Companies that use QC protocols requiring the growth of biologic agents should reach out to the Watertown Health Department for further guidance.

Q5. When will the regulation go into effect?

The regulation has an effective date of July 1st, 2020. Companies already performing work within the Town of Watertown will have one year to come into compliance, as will companies that obtained Watertown building permits before July 1st, 2020.

After July 1st, existing companies wishing to make a significant protocol change such as work with a new BSL-3 organism, work with a new Select Agents or Toxins as defined by the Federal Select Agent Program, and/or new Large Scale activities as described in Appendix K of the *NIH Guidelines*, are required to seek a permit before the protocol change(s) can proceed.

Q6. How does a company know if it should register vs. apply for a permit?

Labs that are BSL-1 and are conducting work that is deemed exempt in Section III-F of the *NIH Guidelines*, and/or are not creating rDNA containing organisms but merely prorogating them, are considered to be "Low-Risk Facilities" and need only register. Labs that are BSL-2 or above, and/or are conducting non-exempt rDNA work as detailed in the *NIH Guidelines* must seek a permit. Companies applying for a permit do not need to register.

Q7. If a company is required to seek a permit, is their facility classified as "High-Risk"?

No. Companies required to seek a Biotechnology/rDNA permit in neighboring municipalities fall into this category.

Q8. Are there companies that require a biotechnology/rDNA permit in Watertown but do not need one in Cambridge or Boston?

BSL-2 facilities not working with rDNA, or only working with exempt rDNA materials, are required to seek a full Biotechnology permit in Watertown but are not required to do so in Cambridge or Boston. However, such facilities are required to obtain laboratory-specific permitting with the Boston or Cambridge Fire Departments, a permitting process not currently required in Watertown. Additionally, as detailed in Q4 of this document, exemptions are included in the Watertown regulation for certain medical, clinical, and manufacturing facilities.

Q9. What is involved in the permitting process?

1. A completed application, with all the required supporting materials, is submitted to the Director of Public Health.
2. A site inspection occurs.
3. An agent working on behalf of the Board of Health will review the inspection report and application to create a summary for the Watertown Biosafety Committee (WBSC).
4. The applicant presents an overview of the work to the WBSC (sample presentation can be found here).
5. The WBSC discusses the permit in question and votes on their recommendation.
6. The applicants' permit is scheduled for final review at an upcoming Watertown Board of Health (BOH) meeting.
7. The members of the BOH will discuss the WBSC recommendation and vote to issue or deny the permit.

Q10. What is the registration process?

The registration process is similar to the permitting process, though the requirements for inspection and/or presentation before the WBSC may be waved.

Q11. How long is a registration or permit valid?

Registrations and permits are valid for one year.

Q12. Are there new activities that would require an amendment to an active registration?

If you wish to move to a new location within the Town of Watertown, preform physical expansion of lab space within current facilities, create an additional lab space at another location in the Town of Watertown, and/or to perform Large Scale activities as defined in Appendix K of the *NIH Guidelines* you must apply for an amendment to the registration before the changes mentioned above can proceed.

Q13. Are there changes that would require a company with an active registration to seek a permit?

An increase in containment level above BSL-1 or the addition of non-exempt rDNA work, as detailed in the *NIH Guidelines*, requires a permit before the proposed changes can commence.

Q14. Are there new activities that would require an amendment to an active permit?

If you wish to move to a new location within the Town of Watertown, preform physical expansion of lab space within current facilities, create an additional lab space at another location in the Town of Watertown, and/or increase the containment level (BSL) for existing lab space you must first seek an amendment to the permit.

Also, a significant change of protocol such as work with a new BSL-3 organism, work with a new Select Agent or Toxin as defined by the Federal Select Agent Program, and/or new Large Scale activities as described in Appendix K of the *NIH Guidelines* require you seek an amendment to the permit before the change(s) can proceed.

Q15. What fees are associated with the regulation?

Registration requires an annual fee of $100. Permitting requires an annual fee of $500.

Q16. Are there any additional costs to applicants?

The Board of Health may retain a professionally competent person, agency, or institution to perform inspections and reviews at the permit holder's expense, as outlined in Section 8 of the regulation.

Q17. What constitutes "A plan for systematic monitoring of waste to assure that surviving organisms will not be released into the environment"?

Waste monitoring should be carried out according to a fixed protocol/system that adheres to the *NIH Guidelines* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. This system must conform to industry best practices. Examples include documented protocols containing the appropriate chemical agents and exposure times for the inactivation of specific organisms, appropriately marked waste receptacles that are not allowed to overflow, proper transportation of waste within the facility, and appropriate removal and disposal of waste from the facility.

Q18. What constitutes "systematic security of the premises"?

Site security should be carried out according to a fixed protocol/system that adheres to the *NIH Guidelines* and the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. This system must conform to industry best practices, which can include the use of employee ID badges, electronically keyed access to freight elevators that are located in spaces easily accessed by the public, and policies for visitors. For more recommendations, see the Boston Fire Department's Guidelines for Laboratory Safety and Security.

Work with organisms requiring BSL-3 level containment and/or work with "Select Agents" may require additional security measures as outlined in the *NIH Guidelines*, *BMBL*, and the Federal Select Agent Program.

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Q19. What is an Institutional Biosafety Committee (IBC)?

An Institutional Biosafety Committee is a committee internal to a company/institution responsible for assessing the biosafety containment level for research involving recombinant DNA and synthetic nucleic acid molecules. Their oversight can include, but is not limited to:

- Recombinant DNA and synthetic nucleic acid molecules (this includes Human Gene Transfer experiments)
- Infectious agents
- Biological toxins
- Human-derived tissues, fluids, cells
- Federally-regulated Select Agents, experiments with Dual Use Research of Concern potential, and research requiring BSL3 containment

The NIH has created an IBC self-assessment tool that can be found here.

Q20. How many members must make up an IBC, and who is qualified to do so?

IBC's must have a minimum of 5 members. In Watertown, **one*** of those members must be a non-affiliated induvial who serves on a volunteer basis. The NIH website "FAQs on Institutional Biosafety Committee (IBC) Administration (May 2019)", has detailed information about the make-up, function, and administration of an IBC.
* *The Watertown regulation takes precedence where different from the NIH Guidelines*

Q21. What type of individual is appropriate for the "non-affiliated member" of the IBC?

The "non-affiliated member" represents the interests of the surrounding community with respect to environmental and public health. Therefore, they should reside and/or work in Watertown, or reside in an adjacent municipality (Newton, Waltham, Cambridge, Allston-Brighton). The unaffiliated member of the IBC can have no relationship with the institution other than their volunteer service on the IBC.

Q22. What is a Select Agent or Toxin?

A Select Agent or Toxin is a biological agent or toxin that has been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. They are heavily regulated by the Federal Select Agent Program. A list of Select Agents and Toxins can be found here.

Q23. What constitutes Dual Use Research of Concern (DURC)?

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research (NIH Dual Use Research of Concern).

Detailed information on the U.S. Government Policy for Institutional Oversight of Life Sciences DURC can be found here.