BOSTON PUBLIC HEALTH COMMISSION
BIOLOGICAL LABORATORY REGULATIONS

FREQUENTLY ASKED QUESTIONS

1) When were the regulations put in place and what do they cover?
   The biological laboratory regulations were adopted on September 19, 2006 and require anyone operating or planning to operate a Biosafety Level 3 or Level 4 biological research laboratory within the City of Boston to apply for and receive a permit to operate from the Boston Public Health Commission. Laboratories using rDNA technology have been regulated by BPHC/DHH since the early 1980s.

2) What does Level 3 and Level 4 mean and what is the difference?
   The Centers for Disease Control and Prevention have defined four levels of Biosafety requirements (BSL-1 through BSL-4) based on the types of biological agents (bacteria, viruses, etc.) and the containment precautions needed for them. These levels are:

   **BSL-1:** This level is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory does not have to be separated from the rest of the building, work is usually done on open bench tops, and safety precautions are generally minimal – gloves, face mask, hand washing, disinfecting of surfaces after work. Many high school biology classes do laboratory projects at the equivalent of BSL-1.

   **BSL-2:** This level is similar to BSL-1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. BSL-2 is for work with bacteria and viruses that cause only mild disease to humans, or are difficult to contract via aerosol in a lab, such as Lyme disease, Salmonella, mumps, measles, and MRSA. At BSL-2, lab personnel have to have specific training (and may be vaccinated or receive medical monitoring) and be supervised by scientists with advanced training; access to the lab is restricted when work is being done; extreme caution is taken in handling and disposing of contaminated sharps; and some procedures may be done in special biological safety cabinets (an enclosed ventilated table) to reduce the risk of splashes and aerosols that may be infectious. Workers wear smocks/gowns as well as gloves and goggles/face masks.
BSL-3: This level 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. At this level, lab personnel have specific training and are supervised by scientists with experience with the specific agents. The laboratory is separated from the rest of the facility by a double set of self-closing locking doors. Lab windows are sealed and ventilation draws air from outside into the lab and exhausts air to the outside through a HEPA filter. At BSL-3, all procedures involving work with infectious materials are done within biological safety cabinets or other containment systems. Staff wear personal protective clothing including smocks/scrubs/coveralls, gloves, and goggles/eye shields. Respiratory protection may be required.

BSL-4: This level is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted 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. Workers in BSL-4 labs wear special enclosed suits with outside air provided into the suit to completely separate them from the lab environment. BSL-4 laboratories are either a separate building or a highly controlled secure area within a building with separate filtered air and water service, security doors, and self-closing and locking airlock style entrance systems containing multiple showers, dedicated vacuum, and decontamination systems and other safety precautions to completely remove and destroy any traces of biohazard from staff leaving the lab. Staff at this level have a very high degree of specialized training in hazardous infectious agents and laboratory access is stringently controlled by the laboratory director.

3) How many level 3 and 4 labs operate in Boston?
   There are currently 7 laboratories working at BSL-3 in Boston operated by 5 different institutions. There is one BSL-4 facility currently in the planning/permitting process but it is not in use for BSL-4 projects. Permitting approval has not been granted by BPHC or Centers for Disease Control.

4) Are there any absolute prohibitions or activities that are banned at labs in Boston?
   Weaponization research is explicitly banned in the City of Boston. This includes a ban on any research that has the potential to make a high risk agent suitable for use in a biological weapon (or significantly aid in the construction of a biological weapon) by increasing the agent’s pathogenicity, increase its resistance to treatment, alter its transmission, or is otherwise not for the peaceful purposes of prevention, treatment, or protection.

   Similarly, there is a ban on work in the City of Boston that involves “High Risk Agents, designated by Presidential Executive Order 12958 or any other federal rule, regulation or law, as 'Top Secret', 'Secret', 'Confidential', or any other classification or requirement...that would prohibit the Boston Public Health Commission’s complete knowledge of the research”. This


means that no laboratory in Boston may refuse to provide the Commission information on the work being done in the lab on the grounds of it being ’classified’ or ’secret’ and any lab that refuses to allow the Commission access will have its permit revoked.

Use of rDNA technology or rDNA research requiring containment defined by the National Institutes of Health Guidelines (latest version, October 2011) as "BSL-4" is not permitted in the City of Boston.

5) What is rDNA research?
rDNA stands for recombinant DNA. Recombinant DNA molecules are DNA (the genetic code inside all cells) sequences that result from the use of laboratory methods first developed in the 1970s to bring together genetic material from different sources to make pieces of DNA that would not naturally be found in a living organism. This can be done because DNA molecules from all organisms share the same chemical structure and can easily be combined. rDNA techniques are used in basic research to mark and sequence genes and to research genetic diseases. Some practical applications of rDNA technology have involved using rDNA to produce medically necessary products such as insulin which is now produced by genetically modified *E. coli* bacteria instead of recovery from the pancreases of many pigs and cows.

6) What is required to get a BPHC permit to operate a biological laboratory?
There are two types of permits that an institution wishing to operate a biological laboratory in the City of Boston may need. If doing work at BSL-3 or BSL-4, the laboratory will need a permit under the Biological Laboratory Regulations. Facilities working with rDNA technology at BSL-2 or BSL-3 must also receive a permit under the Recombinant DNA Technology Use Regulations. Use of rDNA technology is prohibited at BSL-4.

The first step to receiving a Biological Safety Laboratory Permit is to apply and submit the following documentation for thorough review:

- Roster and bios of the Institutional Biosafety Committee which must include at least two community representatives, one of which must be approved by BPHC
- Biosafety/lab safety manual
- Hazard evaluation plan or risk management plan
- Disease surveillance plan
- Evacuation and emergency response plans
- Waste disposal plan
- Security plan
- Transportation plan
- Training policy/plan for all employees, visitors, students and first responders
- Laboratory inspection procedures
- Chemical hygiene plan
- Strain verification policy/procedure
- Commissioning/Decommissioning plan
- Decontamination plan
- Management commitment and employee participation plan
- Termination of work with agents plan
- Boston Fire Department Laboratory Registration Permit
- Certificate of Use and Occupancy
- National Pollutant Discharge Elimination System (MPDES) Discharge Permit (issued by MWRA, DEP, and BWSC)

Once the documents submitted with the application are reviewed and accepted by BPHC, an application for a BSL-4 laboratory must be reviewed and approved by the following additional agencies:
- Boston Biosafety Committee
- Boston EMS
- Boston Inspectional Services
- Boston Fire Department
- Boston Police Department

The final step before a permit is issued is an inspection of the laboratory space itself by a team from the BPHC. Once the application is approved and the inspection passed, a permit may be issued which is valid for 3 years.

7) **How often are labs inspected?**

Boston Public Health Commission inspects BSL-3 labs at least once a year and BSL-4 labs at least twice per year. Any lab working at any biosafety level may be inspected additionally at any time in response to an incident or a safety concern. These inspections can be conducted without prior notification. The Boston Public Health Commission also has the authority to review any and all documentation related to the operation of a permitted laboratory.

In addition to inspections, each permitted lab must submit an annual report to the BPHC that includes copies of all minutes from the IBC meetings and a complete roster of the IBC’s members, a report on any quality assurance and quality improvement efforts during the year, and updated information from the permit application. The institution must also notify the BPHC each time a new project or program in the lab is approved by the IBC at least thirty days before the project begins.

Finally, the regulations require the immediate reporting of any laboratory incidents. Any of these may trigger an inspection or other investigative action. These including:
- Any employee or other individual with access to the lab who has been exposed to high risk agents, shows symptoms of infection, or has been diagnosed with infection.
- Any employee absent from work due to illness for a period of two or more consecutive work days must be evaluated by the institution’s Occupational Health Officer before returning to work and, if the Officer suspects the illness may have been related to a lab exposure, the BPHC must be immediately notified.
- Any failure, malfunction, or renovation of any major mechanical or security system of the lab

8) **What other agencies/authorities are involved in the process?**
Federal
Federal manuals such as the NIH Guidelines and Biosafety Microbiological and Biomedical Laboratories (BMBL) establish requirements regarding federally funded biological laboratories. The EPA regulates deliberate or accidental releases to the environment. The CDC, USDA, and FBI regulate select agents while others (DOT, CDC) govern transportation.

State
The MWRA issues a wastewater discharge permit as part of the permitting process.

Local
On the local level, the Boston Public Health Commission, Boston Fire Department, Boston EMS, Boston Inspectional Services Department, and Boston Police Department are all involved in the permitting process.

9) What oversight is given to transport and/or transfer of biological agents?
A number of federal agencies and regulations govern transport of biological agents to and from all laboratories in America:
- Centers for Disease Control and Prevention (42 CFR 72: Interstate Shipment of Etiologic Agents)
- Department of Transportation
- Occupational Safety and Health Administration
- International Air Transport Association (air transport)
- US Post Office (US mail)

10) What happens if there is a violation?
If a violation of the regulations is found, the institution responsible for the lab faces a fine of $1,000 per day per violation found. In addition, labs in violation face the possibility of suspension of their permit or may have their permit immediate suspended and corrective action ordered if the violation is an immediate threat to public health.

11) What is the IBC? What is its role?
IBC stand for the Institutional Biosafety Committee. These were originally required by the NIH Guidelines for all institutions using rDNA technology that were recipients of federal money. Local regulations enacted by some communities extended this requirement to all institutions within their jurisdiction regardless of institutional funding sources. An IBC is a committee of experts in the institution that has biosafety oversight and authority over all regulated rDNA projects at their institution and at many institutions their oversight extends to all biosafety issues, regardless of the use of rDNA. BPHC Biological Laboratory Regulations require that IBCs be established and have authority over all research laboratories working at BSL-3 or BSL-4, regardless of the work being done. The IBC at each institution reviews and approves each project in the lab before it begins.
12) **What is the Boston Biosafety Committee (BBC)? What is its role?**
The Boston Biosafety Committee (BBC) is composed of both scientific and community representatives appointed by the Mayor and chaired by the Executive Director of the BPHC to assist in regulating biological laboratories at BLS-3 and BSL-4. The BBC reviews, and must approve, every research project conducted at BSL-4 in the city before it begins. The BBC also periodically provides review and recommendation on the effectiveness of the rDNA and Biological Laboratory regulations and advises and/or deliberates as needed about technical issues arising out of permits and applications under the regulations.