



## ISSUE BRIEF

### PROPOSED AMENDMENTS TO BOSTON'S RECOMBINANT DNA AND BIOLOGICAL LABORATORY REGULATIONS

*Revised November 14, 2018*

#### Summary

In response to guidance from the United States Centers for Disease Control and Prevention (CDC), Boston University has proposed a project using rDNA technology to confirm the inactivation of Ebola and other similar viruses by inserting fluorescent genetic material into active virus cells. An amendment to the Boston Board of Health's local biosafety regulations is required to allow these safety enhancing techniques to be used.

#### Background

A key component of Boston's local regulatory oversight of biological laboratories is the regulation of recombinant DNA (or "rDNA"), which is DNA that has been created by combining genetic material from multiple sources. In response to safety and bioethics concerns arising from then-emerging recombinant DNA research, a 1981 Boston City Council Ordinance established the initial regulatory framework for rDNA research in Boston and prohibited the use of rDNA on agents requiring the highest level of containment (Biosafety Level 4, ("BSL-4"). The 1994 *Recombinant DNA Use and Technology Regulations* adopted by the Board of Health's successor – the Board of Trustees of Health and Hospitals – incorporated these provisions into a public health regulation that remains in effect. In 2006, BPHC's biological safety oversight responsibilities were expanded with the Board of Health's adoption of *Biological Laboratory Regulations*. At this time, seven BSL-3 laboratories and one BSL-4 laboratory are permitted and regulated under this regulation.

While the use of rDNA to genetically modify living organisms was controversial when the technology was initially developed, advancements in biological safety and the establishment of nationally-recognized standards for this research through National Institutes of Health (NIH) Guidelines and other standards has led to a more widespread acceptance and use of rDNA in laboratory research, and as a result rDNA is widely used in foods, medications, and consumer products. BPHC currently permits 33 BSL-2 and BSL-3 laboratories across Boston to use rDNA. Many other entities, including high schools and colleges, use rDNA on BSL-1 organisms, which generally does not require a permit as BSL-1 organisms present a significantly lower risk.

#### Proposal

In December 2017, BPHC issued the final operating permit for the city's only Biosafety Level 4 lab, located within BU's National Emerging Infectious Disease Laboratories (NEIDL). Boston University has proposed a research project for the NEIDL's BSL-4 lab that would include the use of recombinant DNA (rDNA), which is currently prohibited by the language of the existing *rDNA Regulation*.

As required by the *Biological Laboratory Regulation* and the NEIDL's BSL-4 lab permit, all new BSL-4 projects must first be reviewed by the Boston Biosafety Committee (BBC), an advisory group appointed by the BPHC Executive Director under the *Regulation* that is made up of scientific experts and community representatives.

The BSL-4 rDNA project, “*Generation and Use of Recombinant Filoviruses Expressing Fluorescent Proteins*,” was reviewed by the BBC on August 20<sup>th</sup>, 2018, resulting in generally favorable discussion about the merits of the project. The members highlighted the fact that project has been recommended by the CDC to create a more reliable method for confirming inactivation of Ebola and other similar viruses. Effective proof of inactivation is required under both the CDC and BPHC approval documents for the BSL-4 lab.

The BBC agreed that a subset of the BBC members would advise BPHC staff regarding potential regulatory changes to allow rDNA use on disease agents requiring BSL-4 containment and help determine the appropriate provisions and safeguards. This working group met on October 10<sup>th</sup> and members reiterated the point that while the use of rDNA to genetically modify disease agents was seen to be problematic in earlier decades, advancements in biological safety and establishment of nationally-recognized standards for this research through National Institutes of Health (NIH) Guidelines have made rDNA research acceptable, including in BSL-4 labs. The group also highlighted the fact that rDNA research is allowed and conducted in all other BSL-4 labs in the United States, and it was noted that Boston is now the only place where using this technology on some of the most significant research is prevented despite the recognition in the scientific community that it can be used to improve the safety of Boston’s researchers and citizens.

The working group recommended moving forward with eliminating the prohibition on rDNA research in BSL-4 labs, so long as each rDNA project proposed for the BSL-4 lab is required to undergo strict review by the BBC and BPHC, consistent with the *Biological Laboratory Regulations* to ensure appropriate consideration of any risk. The group deliberated about various approaches for incorporating this policy change, and recommended incorporating rDNA into the *Biological Laboratory Regulation*, repealing the 1994 *rDNA Regulation*, and addressing other provisions of the *Biological Laboratory Regulation* that are out of date.

#### Process:

Boston’s Board of Health is authorized to adopt, amend, and enforce reasonable health regulations under the state law pertaining to local boards of health (G.L. c. 111 § 31), and BPHC’s enabling statute (G.L. c. 111 App. § 2-7). All regulations must allow for public presentation to the Board, public comment period, public hearing, and vote. An initial presentation to the Board of Health is scheduled to take place on November 14<sup>th</sup> at 4pm at 1010 Massachusetts Avenue, 2<sup>nd</sup> floor.

If changes to the [rDNA Regulation](#) are found by the Board to be advisable, the public engagement process will include a public comment period, publication in a newspaper of general circulation followed by a public hearing additional public presentation to the Board, and vote. BPHC staff will take additional proactive steps to inform interested parties and solicit feedback on the proposed amendments to modernize and streamline the Board of Health’s biosafety regulations.

#### Conclusion:

In the decades since the adoption of the earliest rDNA laws, rDNA has become much more widely used, nationally regulated, and accepted. While it is appropriate to maintain local oversight of rDNA research, the prohibition on rDNA in BSL-4 labs now runs counter to established best practices and recommendations from the CDC for ensuring inactivation of the agents studied in these labs. There appears to be a consensus that researchers working in Boston should not be prevented from using safety techniques available to BSL-4 labs elsewhere in the country and BSL-2 and 3 labs across the city. A robust public comment process will allow opportunity for interested members of the community to provide feedback on the proposed amendments.