



**MINUTES OF THE MEETING OF THE BOARD OF THE
BOSTON PUBLIC HEALTH COMMISSION
Wednesday, November 14, 2018**

A meeting of the Board of the Boston Public Health Commission (“Commission”) was held on Wednesday, November 14th, 2018 in the Hayes Conference Room, 2nd floor, 1010 Massachusetts Avenue, Boston, MA 02118.

Board Members Present

Manny Lopes, Chair, Kate Walsh, John Fernandes, Rebecca Gutman

Also Present

Julien Farland, Gerald James, Jasmery Mejia, Mary Bovenzi, Heather Gasper, Gerry Thomas, Chimel Idiokitas, Erin Curran Serino, Robert Goldstein, Jennifer Tracey, Paul Shoemaker, Kate Donovan, Jennifer Jaeger, Jennifer Lo, Rita Nieves, Devin Larkin, Maya Saunders, Rebecca Shorin, Ted Myatt, Simon Muchoi, PJ McCann

Proceedings

At 4:07pm, Ms. Valdes Lupi welcomed Board members, staff, and attendees and welcomed Chief of Health and Human Services to offer remarks before the beginning of the Board meeting.

Mr. Martinez introduced himself to those present thanked the Board for the opportunity to be at the meeting, thank the board for their work and announced to the Board that Mayor Walsh has appointed Manny Lopes, to serve as Chair of the board, effective immediately. He noted that Mayor Walsh is appreciative of Mr. Lopes’ willingness to serve in this capacity.

Chairperson’s Comments

Mr. Lopes thanked the members of the Board, Ms. Valdes Lupi, Mr. Martinez and Mayor Walsh and remarked that it was an honor and privilege to serve, and that he looked forward to the opportunity to serve in this capacity. This work is from the heart and I look forward to supporting the great work that you all do.

Tonight, we will be focusing our agenda on Biological Laboratory Safety in Boston. I am pleased to welcome two key partners who will be joining us to present on this important issue.

First, we welcome a top-ranking federal official, Dr. Samuel Edwin, to give some context to the federal government’s oversight of lab safety. Samuel Edwin directs Division of Select Agents and Toxins, within the CDC’s Office of Public Health Preparedness and Response. Mr. Edwin is

also joined by Mr. James Holt, Senior Attorney at the US Department of Health and Human Services.

Also, we are thankful to have Dr. Alexander McAdam, who is here tonight as a representative of the Boston Biosafety Committee. Mr. McAdam is Director of the Infectious Diseases Diagnostic Laboratory at Children's Hospital and Associate Professor of Pathology at Harvard Medical School.

Thank you both for being here.

Executive Office Report: Monica Valdes Lupi, JD, MPH

I know we have a full agenda tonight, so I will forego a full update and provide any additional timely information in writing.

Ms. Valdes Lupi welcomed Dr. Edwin and Mr. James Holt, a senior attorney from US Department of Health and Human Services.

Presentation and Discussion: Boston Biosafety Update

Presenters:

- Samuel S. Edwin, Ph.D. Director, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention
- Simon Muchohi, PhD, MPH, CIH, CSP, CHMM, Director of Biological Safety, BPHC
- Alexander McAdam, MD, PhD, Member, Boston Biosafety Committee; Director, Infectious, Diseases Diagnostic Laboratory, Children's Hospital; Associate Professor of Pathology, Harvard Medical School
- PJ McCann, Esq., Deputy General Counsel, BPHC

Dr. Edwin presented the information in the attached presentation regarding the work of the Federal Select Agent Program to regulate 67 agents with severe public health threats. He emphasized the importance of collaboration with officials at the state and local levels in ensuring appropriate oversight.

Ms. Walsh asked whether entities tended to be public or private. Dr. Edwin replied that the entities range from public, private and non-profit, and that in certain regards, BSL-2 work can be riskier than work at BSL-3 or BSL-4 because of the heightened oversight of level 3 and 4 labs.

Dr. Edwin highlighted that the relevant agencies had ensured Congress that in-house methods to inactivate toxins would be required, and that guidance is on the agency website. He noted that since 2003 there have been no thefts or deaths in FSAP-regulated laboratories.

An additional question was raised by Ms. Walsh about incident reporting at the local level as compared to the federal level. BPHC staff responded that all events that are required to be reported to the CDC must also be reported to BPHC.

Ms. Walsh noted that because we are more likely to know about incidents in level 3 and 4 labs, we should think more broadly about risk at all levels.

Mr. Muchoi presented an overview of the regulation and oversight of biosafety in Boston. He highlighted collaboration with BPHC's Infectious Disease Bureau and other City agencies to ensure coordination, as well as the role of the Boston Biosafety Committee in providing subject matter expertise.

Muchoi then outlined the biosafety classifications, the roles and responsibilities of BPHC's Biosafety Program, goals of local oversight, incident reporting provisions, and specific prohibitions in existing regulations, which include recombinant DNA work in BSL-4 labs.

Mr. Lopes asked about coordination between the City and Federal government around inspections and incident reporting. Mr. Edwin outlined coordination at the Federal level and said that CDC encourages regulated labs to report to state and local officials.

Mr. McAdam outlined his background and noted that he was here to represent the Boston Biosafety Committee. He outlined the role of the Boston Biosafety Committee in general, and the specific revitalized role the advisory group played in reviewing the BSL-4 lab at Boston University's National Emerging Infectious Disease Laboratory (NEIDL), and specific research projects for the BSL-4 lab.

He noted that the BBC met in August 2018 to review updated protocols and two new BU BSL-4 research protocols, one of which included rDNA with BSL-4 agents Ebola and Marburg. The CDC proposed that the most accurate way to determine whether the virus had been inactivated was to use incorporated fluorescent protein into the virus so that they would glow when active.

The BBC supported that project and there was strong consensus that a policy recommendation to allow for rDNA work on BSL-r agents should be developed by a working group of the BBC. That working group met in October and had a long and thoughtful discussion about appropriate safeguards. The conclusion was to change the regulation rather than create an exception.

The group recommended removing the prohibition on rDNA research on BSL-4 agents in Boston, under the specific conditions that any project would undergo rigorous approval process required of BSL-4 protocols, and that the BBC and BPHC review process would create an appropriate mechanism for presenting individual BSL-4 research protocols that present any unacceptable risk.

For the purposes of evaluating individual projects, and Mr. McAdam noted that established federal guidance documents give us a structure to evaluate risk in this context.

The BBC also recommended streamlining the regulatory framework by incorporating rDNA oversight into the Biological Laboratory Regulation and repealing the rDNA Regulation to simplify the regulatory structure.

Ms. Walsh noted that it seems as though the science has outpaced the regulation, and asked why, if the review process for individual BSL-4 projects is so rigorous, why additional language outlining the review process for rDNA BSL-4 projects is necessary.

Dr. McAdam agreed that rDNA research is more well established and advanced to the point where we have far less concern around safety than we once did. He further responded that the

requirement is in the context of the requirements for BSL-4 labs, and underscores that these projects, if the Regulation were amended to allow them, would undergo strict individualized rigorous review.

Mr. Lopes asked why other jurisdictions are not regulating the way we have. Dr. McAdam noted that some others to, including Cambridge and Newton, though the provisions differ.

Mr. McCann outlined the proposed amendments. He noted that the working group of the BBC worked on a first draft of proposed amendment language, which has been provided to the Board, including:

- Rescind rDNA Regulation, clarify that Biological Lab Regulation supersedes the 1994 rDNA Regulation and 1981 Ordinance (2.06(a))
- Add: “Research projects using rDNA in BSL-4 laboratories must apply for a permit pursuant to this regulation and will be subject to review by the Boston Biosafety Committee and approval by the Executive Director” (2.06(b))
- Throughout, add “rDNA at BSL 2, 3, or 4” to work that is covered
- Revise definitions and citations to align with updated guidance
- Incorporate requirement from permit docs that each individual BSL- 4 project undergo review by BBC and approval by BPHC

Ms. Walsh asked if the language about rDNA at 2, 3, and 4 is consistent with existing practice.

Mr. McCann said that generally it was, and that it was already included in the existing rDNA Regulation.

Mr. McCann then outlined regulatory process, requirements, and steps.

Mr. Fernandez asked if any negative comments were expected.

Mr. McCann noted that the BSL-4 lab has been a controversial issue and that groups who were interested in the permitting process for the BSL-4 lab may take interest in this, but the response is along the lines of what we have presented; if work is going to be allowed in the BSL-4 lab, it should be allowed to use technology to allow it to be done safely. There is an issue brief with more points in support.

Mr. McCann said that it is custom to take a voice vote of the Board prior to moving forward with a public comment period.

Mr. Fernandez moved to approve moving forward with a public comment process, Ms. Walsh seconded, and the vote to move forward was unanimous.

Mr. Lopes said while this is not the public hearing, if any members of the public would like to make a brief comment at this time, I would open the floor.

At 5:10pm, Mr. Lopes asked for a vote to enter into executive session for the purposes of discussing litigation strategy and contract negotiations.

The Board voted to return to public session and Mr. Lopes began by reporting that a performance evaluation for Executive Director Monica Valdes Lupi had been conducted by a subcommittee of the Board and shared that he was pleased to announce a satisfactory performance evaluation, and the current Board has reviewed and agreed with this finding.

Mr. Lopes asked for a vote that included a vote to extend the employment contract for one year that will expire on January 31, 2020. The Board voted unanimously in favor of the contract extension.

At 5:45pm, a motion to adjourn was taken and approved unanimously.