# Appendix 1

## MEPA CERTIFICATES

The Commonwealth of Massachusetts
Executive Office of Environmental Affairs
100 Cambridge Street, Boston, MA 02202

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October 8, 1999

CERTIFICATE OF THE SECRETARY OF ENVIRONMENTAL AFFAIRS
ON THE
ENVIRONMENTAL NOTIFICATION FORM

| | |
|---|---|
| PROJECT NAME | : BioSquare Project Phase II |
| PROJECT MUNICIPALITY | : Boston (South End) |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : University Associates Limited Partnership |
| DATE NOTICED IN MONITOR | : September 8, 1999 |

Pursuant to the Massachusetts Environmental Policy Act (G. L. c. 30, ss. 61-62H) and Section 11.03 of the MEPA regulations (301 CMR 11.00), I hereby determine that this project **requires** the preparation of an Environmental Impact Report.

As described in the Environmental Notification Form (ENF), the Bio Square Phase II project includes 540,500 square feet of research space, 1,140 net new parking spaces (including 30 surface spaces), a small amount of street level retail space, a helipad for emergency medical transport, a bike path, landscaping, and associated infrastructure on an 8.5 acre site bounded by Albany Street and the Massachusetts Avenue Connector. Phase I of the project completed MEPA review in 1991, and consisted of 340,000 square feet of medical office/research space, a 230 room hotel, 1,000 parking spaces, and two additional research/office buildings. Phase I is now partially operational. As stated in an earlier Certificate, for purposes of MEPA review, I also consider the Medical Services Center (EOEA #11883) to be part of the proposed project. (The Medical Services Center consists of an 111,000 square foot outpatient care center and 22 new parking spaces, the demolition of four buildings, and the renovation of two other buildings.) I deferred a stand-alone EIR on the Medical Services Center in favor of allowing a single document for the Bio Square Phase II project that would address the cumulative impacts of both projects.

The project is undergoing MEPA review pursuant to section 11.03 (5)(b)(4)(a), because the project requires a Sewer Connection Permit from the Department of Environmental Protection (DEP) and results in the discharge of greater than 100,000 gallons per day to a sewer system. The project is undergoing review and requires the preparation of a mandatory EIR pursuant to section 11.03 (6)(a) (6) and (7) of the MEPA regulations, because the project requires an access permit from the Massachusetts Highway Department (MHD) and involves the generation of greater than 3,000 new vehicle trips per day and provision of greater than 1,000 new parking spaces at a single location. The project will also require a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA), and review by the Massachusetts Historical Commission. The proponent is seeking financial assistance from the Commonwealth for the Medical Services Center portion of the project. MEPA jurisdiction therefore extends to all aspects of the project that may have significant environmental impacts.

## SCOPE

### General

The proponent should prepare the EIR in accordance with the general instructions for outline and content found in section 11.07 of the MEPA regulations, as modified by this Certificate. The proponent should circulate the EIR to those parties who commented on the ENF or the ENF for EOEA #11883, and to any state agencies from which the proponent will seek permits, approvals, or financial assistance. The proponent should also circulate a copy of the EIR to the Central Artery/Tunnel project, and should provide a reasonable number of copies free of charge on a first come, first served basis. The EIR should include a copy of this Certificate and each comment letter received. The EIR should respond to all substantive comments received. M.1

### Joint Review

The BRA is reviewing the project pursuant to Article 80 of the Boston Zoning Code, and will soon issue its own scope for a Project Impact Report (PIR). I anticipate that the BRA scope will include a requirement to analyze project impacts on traffic, parking, transit, wind, shadow, daylight, air quality, noise, water quality, stormwater, solid and hazardous wastes, geotechnical issues, groundwater, construction impacts, historic resources, and infrastructure. The proponent has indicated its

intent to submit one document that satisfies the requirements of both MEPA and Article 80. The MEPA regulations allow for such coordinated review, and I hereby allow the proponent to submit a joint EIR/PIR document.

Alternatives

The EIR should analyze the proponent's preferred build alternative. In addition, the EIR should analyze the no-build alternative to establish baseline conditions. The EIR should also analyze alternative site layouts to arrive at a site layout that minimizes overall impacts. In particular, the EIR should investigate alternative internal circulation patterns that would minimize traffic impacts on the adjacent residential areas of the South End, while still attempting to meet the urban design goal of extending the existing South End block pattern across the site. The EIR should investigate methods of maximizing the efficiency of traffic flow to and from the site while minimizing the potential for increasing cut-through traffic on residential streets. The EIR should also ensure full consideration of pedestrian and bicycle access in all roadway and landscaping design improvements. The EIR should fully explain any trade-offs involved with the various access schemes. M.2

The current proposal locates 30 surface parking spaces in the general location of the helipad. The EIR should investigate reducing or eliminating the number of surface parking spaces, and increasing the amount of landscaped open space on site. M.3

Project Description and Permitting

The EIR should include a description of the project and a brief description of each state permit or agency action required for the project. The EIR should document how the project meets the performance standards of the applicable state permits. The EIR should contain sufficient information for the permitting agencies to evaluate the environmental impacts of their permitting decisions relative to the project. M.4

Cumulative Impacts

The EIR should explain the relationship of the Bio Square Phase II project to the proponent's other projects in the vicinity (i.e., Bio Square phase I, the Medical Services Center, and the proponent's other activities in the South End Medical Area). The EIR should fully explain any cumulative impacts, particularly on traffic, transit, parking, and air quality. M.5

The proponent is currently preparing a Planned Development Area Master Plan for the projects southeast of Albany Street and an Institutional Master Plan for the main campus northwest of Albany Street, both to satisfy requirements of the BRA. The EIR should include as much summary information from the Master Plans as necessary to understand the cumulative impacts of the Bio Square Phase II project and the proponent's other projects in the South End Medical Area. M.6

Traffic

The EIR should include a traffic study that conforms to the *EOEA/EOTC Guidelines for Traffic Impact Assessment* as modified by this scope and the comments from MHD. The EIR should identify appropriate mitigation measures for areas where the project will have a significant impact on traffic operations. The EIR should include clear commitments to implement the mitigation, and describe the timing and any phasing of the mitigation. The EIR should include capacity analyses and a summary of average and 95th percentile vehicle queues for each intersection in the study area. The EIR should identify the discrete traffic impacts of Bio Square Phase II, but should also include analysis of the cumulative impacts, as discussed above.

The study area should include the following intersections under state control: M.7A

- -the intersection of Frontage Road with the BioSquare site drive
- -the intersection of the Massachusetts Avenue Connector with the East Concord Street extension
- -the intersection of the Massachusetts Avenue Connector with Massachusetts Avenue and Melnea Cass Boulevard
- -the intersection of Frontage Road with Albany Street

The study area should include the following intersections under local control:

- -the intersection of Albany Street with East Concord Street and the east Concord street extension
- -the intersection of East Brookline Street with Albany Street
- -the intersection of Albany Street with Massachusetts Avenue
- -any other local intersection identified in the BRA scope

The EIR should also discuss any construction period traffic impacts, and should identify the number of truck trips associated with various construction phases. The EIR should also identify any coordination necessary with the ongoing Central Artery/Tunnel construction activities in the project area. M.7B

Parking

The EIR should include a parking needs assessment. The proponent should explain the nature of the on-site parking (i.e., quantify how many employee spaces and how many commercial/visitor spaces are proposed); identify turnover rates for employees and other parkers; and include an analysis of parking supply and demand in the project area, and current parking prices. The EIR should demonstrate that the parking supply is the minimum necessary to accommodate project demand without encouraging employee commuting by single occupant vehicles. The parking needs analysis should include an overall assessment of the parking needs and supply in the South End Medical Area. M.7C

Transportation Demand Management

The transportation analysis should develop a thorough Transportation Demand Management (TDM) program that capitalizes on the transit accessibility to the site. The EIR should specifically discuss whether the proponent intends to subsidize transit use by employees, and should explain whether any employee parking subsidies are proposed. The EIR should discuss the proponent's existing TDM program, and whether any additional TDM measures are proposed as part of the Bio Square II project. M.7D

I note that the project will have to comply with the DEP ridesharing regulation (310 C.M.R. 7.16). I encourage the proponent to include information on compliance strategies in the EIR. M.7E

Air Quality

The EIR should contain a mesoscale air quality analysis for emissions of Volatile Organic Compounds prepared in accordance with guidance from the DEP Division of Air Quality. The EIR should consider various Transportation Demand Management (TDM) measures as a method of reducing mesoscale emissions. M.8

The project will also require a microscale air quality analysis for carbon monoxide (CO), pursuant to the CO maintenance strategy adopted by the Commonwealth. The EIR should include a microscale analysis prepared in accordance with DEP Division of Air Quality guidance.

Historic/Urban Design

The EIR should analyze potential impacts on historic resources, particularly on the nearby South End Landmark District. The EIR should include a quantitative analysis of potential for new shadows on portions of the district. The EIR should also discuss the urban design of the project, including building heights and massing, the consistency of project design with City planning goals for the area, and any potential impacts on the historic district. I recommend that the proponent consult with the Massachusetts Historical Commission and the South End Landmark District Commission on this issue. M.9

The ENF proposes to incorporate a segment of the "Bike to the Sea" trail that will link the Fort Point Channel area and Boston Harbor to Boston neighborhoods. The EIR should develop the public open space elements in more detail, and describe coordination with adjoining sites and street crossings. M.10

Wastewater

The EIR should include estimates of project water use and wastewater generation. The EIR should analyze whether the existing sewer infrastructure has the capacity to accommodate the increased sewer demand, and whether any additional wastewater infrastructure will be required to serve the project. The EIR should also include a water conservation plan, and should respond to the comments concerning wastewater from DEP and the Boston Water and Sewer Commission. M.11

Mitigation

The EIR should include a summary of all mitigation measures to which the proponent has committed. The mitigation summary should form the basis of the Proposed Section 61 Findings and Commitment Letter to be presented in the Final EIR. M.12

October 8, 1999
Date

Bob Durand

Comments received (continues on next page):

9/24/99 Boston Redevelopment Authority
9/27/99 Boston Environment Department
9/27/99 Boston Water and Sewer Commission

Comments received (continued):

9/29/99 Massachusetts Highway Department
9/30/99 Massachusetts Historical Commission
9/30/99 Department of Environmental Protection NERO
9/30/99 Department of Environmental Protection Boston

BAD/ASP/asp

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December 1, 2003

CERTIFICATE OF THE SECRETARY OF ENVIRONMENTAL AFFAIRS
ON THE
DRAFT ENVIRONMENTAL IMPACT REPORT

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT MUNICIPALITY | : Boston (South End) |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : University Associates Limited Partnership |
| DATE NOTICED IN MONITOR | : October 7, 2003 |

As Secretary of Environmental Affairs, I hereby determine that the Draft Environmental Impact Report (Draft EIR) submitted on this project **adequately and properly complies** with the Massachusetts Environmental Policy Act (G. L. c. 30, ss. 61-62H) and with its implementing regulations (301 CMR 11.00).

Project Description

As described in the Draft EIR, the proposed project involves development of 457,700 square feet of medical research space, 1,400 parking spaces, and associated infrastructure on a 14.5-acre site along Albany Street. The project includes a 223,000 square foot building that will contain a "Level 4 Biocontainment" national research facility. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EOEA #7034), which completed the EIR review process in 1991. The Draft EIR also includes a cumulative traffic impact analysis that incorporates analysis of the Moakley Services Center Project (EOEA #11883), in accordance with the 1999 Certificates on the Moakley Services Center Project and BioSquare Phase II Project.

Standard and Purpose of MEPA Review

Aspects of the project, in particular the biocontainment facility, have generated substantial concerns in the comments received. As part of the MEPA process, I will not make substantive judgments as to the proposed land use, nor will I act as an agent of appeal or affirmation of local land use decisions. MEPA is not a zoning process, nor is it a permitting process. MEPA review does not in itself result in any formal adjudicative decision approving or disapproving a project. The purpose of MEPA review is to ensure that a project proponent studies feasible alternatives to a proposed project; fully discloses environmental impacts of a proposed project; and incorporates all feasible means to avoid, minimize, or mitigate Damage to the Environment as defined by the MEPA statute. After completion of the EIR process, the state permitting agencies must then issue substantive decisions on whether or not to permit those aspects of the project within their respective jurisdictions. If permits are issued, the state agencies must incorporate the information in the EIR process into their required Section 61 Findings, thus formalizing the mitigation commitments contained in the EIR.

Section 11.08(8)(b) of the MEPA Regulations requires me to find a Draft EIR adequate even if certain aspects of the project or issues require additional technical or descriptive analysis, so long as I find that "the draft EIR is generally responsive to the requirements of 301 CMR 11.07 and the Scope." I have fully examined the record before me, including but not limited to the Scope that my predecessor issued on October 8, 1999; subsequent Certificates on related Notices of Project Change and correspondence between the proponent and the MEPA Office; the Draft EIR filed in response to the October 8, 1999 Certificate; and the written comments entered into the record. I find that the Draft EIR is sufficiently responsive to the requirements of the MEPA regulations and the Scope to meet the regulatory standard for adequacy. The project review may therefore proceed to the stage of a Final EIR. Below I have specified the remaining issues that require additional analysis in the Final EIR.

Thresholds and Jurisdiction

The project is undergoing review and requires the preparation of a mandatory EIR pursuant to section 11.03 (6)(a)(6) and (7) of the MEPA regulations, because the project requires an access permit from the Massachusetts Highway Department (MHD) and involves the generation of greater than 3,000 new vehicle trips per day and provision of greater than 1,000 new parking spaces at a single location. The project will also require a

Sewer Connection Permit from the Department of Environment Protection (DEP). The project will also require a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA), and review by the Massachusetts Historical Commission. The proponent is seeking financial assistance from the Commonwealth for the Moakley Services Center portion of the project. MEPA jurisdiction therefore extends to all aspects of the project that may have significant environmental impacts.

General

The Final EIR should contain a copy of this Certificate and a copy of each comment received. The Final EIR may incorporate by reference those portions of the Draft EIR that do not require further analysis. 1

At a minimum, the proponent should circulate the Final EIR to those parties submitting individual written comments on the ENF and/or the Draft EIR, and to any state agency from which the proponent will seek permits. The proponent should also make a reasonable number of hard copies of the Final EIR available on a first come, first served basis. 2

Biocontainment Building

The Draft EIR does not include a detailed discussion of the potential environmental impacts of the biocontainment building. The Final EIR should include more detail on the proposed use of this building and any potential environmental impacts from the proposed use. 3

The Final EIR should address the concerns raised regarding the safety of the proposed biocontainment building. The Final EIR should discuss the design features that the biocontainment building will employ to enhance safety. The Final EIR should document how the facility would meet any applicable state and federal regulations regarding safety of the facility. The Final EIR should evaluate a "worst case" safety event involving the loss of the physical integrity of the containment systems. The Final EIR should also address safety considerations related to any transport of potentially hazardous biological agents to and from the biocontainment facility. 4 5 6 7

Transportation

The Draft EIR includes a cumulative traffic analysis for the

Transportation

The Draft EIR includes a cumulative traffic analysis for the Medical Center campus and specific analysis of impacts associated with BioSquare Phase II. The analysis of both project-specific and cumulative traffic impacts is generally adequate. However, the proposed median break access point along the Massachusetts Avenue Connector and creation of a new signalized intersection has raised significant concerns about traffic safety and potential impacts on Phase 2 of the Urban Ring project under study by the Massachusetts Bay transportation Authority (MBTA). The Final EIR should investigate alternatives to the proposed access point and intersection. The Final EIR should demonstrate that any alternative access arrangement would meet safety standards for effected roadways and would avoid or absolutely minimize impacts on the Urban Ring project. The Final EIR should also disclose any other impacts of alternative access, including the potential for increased traffic in adjacent residential areas. 8

Wastewater

The project will generate approximately 34,525 gallons per day of sanitary sewage. Because the project is located in an area contributing to a Combined Sewer Overflow, the Department of Environmental Protection has indicated that it will likely require a minimum of 4:1 Inflow/Infiltration (I/I) removal as part of its permitting process. The Final EIR should include analysis of how the proponent would meet any applicable I/I removal requirements. 9

Comments

The Final EIR should respond to the comments received, in particular to the detailed comment letter submitted by Alternatives for Community and Environment. The Final EIR should present additional narrative or technical analysis as appropriate to respond to substantive concerns. 10

Mitigation

The Final EIR should contain a summary of all mitigation measures to which the proponent has committed. The Final EIR should include a draft Letter of Commitment for use by MHD in 11 12

preparing its Section 61 Findings. The Final EIR should also include proposed Section 61 Findings for use by DEP.

December 1, 2003
Date

Ellen Roy Herzfelder

Comments received:

(10) 11/05/03 Boston Flower Exchange
(1) 11/07/03 Department of Environmental Protection NERO
(2) 11/07/03 Massachusetts Bay Transportation Authority
11/10/03 Massachusetts Historical Commission
(11) 11/24/03 Council for Responsible Genetics
7 11/24/03 Boston Redevelopment Authority
(7) 11/24/03 Massachusetts Water Resources Authority ?
8 11/24/03 Boston Water and Sewer Commission
12 11/24/03 Shirley Kressel
13 11/24/03 Deirdre Doran
14 11/24/03 Glen Berkowitz
15 11/24/03 Alternatives for Community and Environment
11/25/03 Massachusetts Highway Department
9 11/28/03 Boston Environment Department

ERH/ASP/asp

6 11/26 CAIT, MHD

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November 15, 2004

CERTIFICATE OF THE SECRETARY OF ENVIRONMENTAL AFFAIRS
ON THE
FINAL ENVIRONMENTAL IMPACT REPORT

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT MUNICIPALITY | : Boston (South End) |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : University Associates Limited Partnership |
| DATE NOTICED IN MONITOR | : August 11, 2004 |

As Secretary of Environmental Affairs, I hereby determine that the Final Environmental Impact Report (FEIR) submitted on this project **adequately and properly complies** with the Massachusetts Environmental Policy Act (G. L. c. 30, ss. 61-62H) and with its implementing regulations (301 CMR 11.00).

Project Description

As described in the FEIR, the proposed project involves development of 428,700 square feet (sf) of medical research space, 1,400 parking space garage (approximately 496,000 sf), and associated infrastructure on a 14.5-acre site along Albany Street. The project includes a 194,000 sf building that will contain a "Level 4 Biocontainment" national research facility. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EOEA #7034), which completed the EIR review process in 1991 and the Moakley Services Center Project (EOEA #11883).

Standard and Purpose of MEPA Review

Aspects of the project, in particular the biocontainment facility, have generated substantial concerns in the comments received. As part of the MEPA process, I will not make substantive judgments as to the proposed land use, nor will I act as an agent of appeal or affirmation of local land use decisions. MEPA is not a zoning process, nor is it a permitting process.

MEPA review does not in itself result in any formal adjudicative decision approving or disapproving a project. The purpose of MEPA review is to ensure that a project proponent studies feasible alternatives to a proposed project; fully discloses environmental impacts of a proposed project; and incorporates all feasible means to avoid, minimize, or mitigate Damage to the Environment as defined by the MEPA statute. After completion of the EIR process, the state permitting agencies must then issue substantive decisions on whether or not to permit those aspects of the project within their respective jurisdictions. If permits are issued, the state agencies must incorporate the information in the EIR process into their required Section 61 Findings, thus formalizing the mitigation commitments contained in the EIR.

Section 11.08(8)(c) of the MEPA Regulations requires me to find an FEIR adequate even if certain aspects of the project or issues require additional technical or descriptive analysis, so long as I find that "the aspects and issues have been clearly described and their nature and general elements analyzed in the EIR…, that the aspects and issues can be fully analyzed prior to any Agency issuing its Section 61 Findings, and that there will be meaningful opportunities for public review of additional analysis prior to any Agency taking Agency Action on the Project." The MEPA Office has reviewed the FEIR submitted and the written comments from the permitting agencies and others. I find that the FEIR is sufficiently responsive to the requirements of the MEPA regulations and the Scope to meet the regulatory standard for adequacy. The project may proceed to permitting agencies.

Thresholds and Jurisdiction

The project requires the preparation of a mandatory EIR. It will need to obtain an Access Permit from the Massachusetts Highway Department (MHD). The project will require a Sewer Connection Permit, a Notification of Construction/Demolition, an Air Plan Approval Permit, and a Massachusetts Contingency Plan (if necessary) from the Department of Environment Protection (DEP). It will need to obtain an Industrial Wastewater Discharge Permit from the Massachusetts Water Resources Authority. The project will also require a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA), and review by the Massachusetts Historical Commission. The proponent is seeking financial assistance from the Commonwealth for the Moakley Services Center portion of the project. MEPA jurisdiction therefore extends to all aspects of the project that may have significant environmental impacts.

Review of the FEIR

The FEIR contained a copy of the DEIR Certificate and a copy of each comment received. The proponent circulated the FEIR to those parties submitting individual written comments on the DEIR, and to any state agency from which the proponent will seek permits.

The FEIR included more detail on the proposed use of the biocontainment building and any potential environmental impacts from the proposed use. It addressed, to a level sufficient for MEPA purposes, the concerns raised regarding the safety of the proposed biocontainment building. The FEIR identified the design features that the biocontainment building will employ to enhance safety. It documented how the facility would meet any applicable state and federal regulations regarding the safety of the facility. As required, the FEIR evaluated a "worst case" safety event involving the loss of the physical integrity of the containment systems. It addressed safety considerations related to any transport of potentially hazardous biological agents to and from the biocontainment facility. All federal and state requirements will be adhered to during the transportation of potentially hazardous biological agents. I note that the BRA is reviewing the project and will address the project's consistency with the City of Boston's zoning and other rules and regulations. Also, the National Institute of Health (NIH) is conducting a review under NEPA and will further analyze aspects of the project, particularly as it relates to the storage, safety, and containment design requirements of the federal government.

The proponent examined alternatives as required in the initial scope and the MEPA regulations. The FEIR investigated two alternatives to the proposed access point and intersection at the Massachusetts Avenue Connector. The project will now have access from the Frontage Road-South and from existing streets that connect to Albany Street. The proponent has abandoned the previously proposed access to the Massachusetts Avenue Connector due to concerns raised by MHD. The project will work to avoid or minimize impacts on the Urban Ring project. Furthermore, nothing in the project design will preclude the Massachusetts Avenue Connector access from being constructed in the future, if needed and the concerns of MHD are addressed. There is some potential for increased traffic in adjacent residential areas.

In the FEIR, the proponent has committed to undertake a minimum of 4:1 Inflow/Infiltration (I/I) removal as part of its permitting process with DEP to enter the Boston Water and Sewer Commission (BWSC) wastewater system.

The FEIR responded to the comments received on the DEIR and provided additional narrative or technical analysis as appropriate. The proposed project has received significant City of Boston review, and is now undergoing federal environmental review.

Mitigation

In the FEIR, the proponent committed to the following mitigation measures:

- Provide 4:1 I/I removal program (approximately $480,000);
- Create a pocket park along Albany Street (approximately $246,000);
- Modify the East Newton Street/Albany Street intersection as a four-way intersection (approximately $100,000 to $200,000);
- Provide a traffic and parking management plan for Albany Street between East Newton Street and Union Park Street;
- Rebuild Albany Street sidewalks and provide pavement markings along Albany Street including lane striping and crosswalks (approximately $35,000 to $60,000);
- Install fiber optic cables along Albany Street (approximately $20,000 to $25,000);
- Provide the City of Boston with up to two variable message boards for real time traffic information (approximately $52,000);
- Install directional signage at site (approximately $25,000);
- Institute a Transportation Demand Management (TDM) Program that includes membership in Transportation Solutions for Commuters (TMA);
- Provide a transit pass subsidy program (25 percent) for Boston Medical Center employees;
- Provide a ridesharing program, preferential parking, a guaranteed ride home, direct-deposit payrolls, shuttle bus service to Orange and Red Lines, Zipcar, and flextime and telecommuting as part of its TDM program; and
- Provide safe and secure bicycle storage areas (up to 140 bicycles in the parking garage and around the site) (approximately $20,000) and shower facilities for employees.

EOEA #12021 FEIR Certificate November 15, 2004

The FEIR included a draft Section 61 Findings for the Massachusetts Highway Department, the Department of Environmental Protection, and the Massachusetts Water Resources Authority in Appendix 7 of the FEIR.

Based on a review of the ENF, the DEIR, the FEIR and the many comments submitted on this project, I hereby find that the FEIR adequately and properly complies with the MEPA regulations. I am confident that any outstanding issues can be addressed in the federal, state and local permitting process and that additional mitigation measures can be developed to further ensure that this facility is operated in a manner that protects public health and the environment. No further MEPA review is required at this time.

November 15, 2004
Date

Ellen Roy Herzfelder

Comments received:

Oxxon Therapeutics, 8/20/04
MA Biologic Laboratories, 8/31/04
COBTH, 9/7/04
Conservation Law Foundation (CLF), 9/8/04
BU School of Public Health, 9/9/04
Fort Point Assoc. (FPA), 9/20/04
Lawrence S. Blaszkowski (MGH), 9/20/04
Christopher Brayton, 9/21/04
FPA, 9/24/04
Univ. of Maryland School of Medicine, 9/27/04
Kenneth Olken, 9/29/04
President, Boston City Council, 9/29/04
Long Bay Management Co., 9/29/04
Kevin C. Peterson, 9/29/04
Novo Biotic Pharmaceuticals, 9/30/04
Taylor Smith Realty, 10/1/04
Michael E. Capuano, U.S. House of Representatives, 10/6/04
CLF, 10/7/04
FPA, 10/8/04
South Boston Community Health Center, 10/12/04
Sheila Grove, 10/12/04
DEP/NERO, 10/13/04

Inner Core Committee, 10/19/04
Virginia Pratt, 10/19/04
Paul Zigurds Rinkulis, 10/21/04
CUH2A, 10/22/04
The Ellis South End Neighborhood Assoc., 10/22/04
Boston Environmental Hazards Program, 10/22/04
MWRA, 10/25/04
CLF, 10/25/04
Hemisphere, 10/25/04
David S. Mundel, 10/25/04
CUH2A (J. Crane), 10/27/04
Pam Kennedy, 10/28/04
John E. Mann, 10/28/04
Patricia Glynn, 11/2/04
Jessie Partridge, 11/3/04
William J. Santoro, 11/3/04
Susan Gracey, 11/3/04
Neighborhood of Affordable Housing, 11/4/04
Cambridge Health Alliance, 11/4/04
Dorothy Woelfel, 11/4/04
Miriam Shenitzer, 11/4/04
Phoebe Knopf, 11/5/04
Vicky Steinitz (UMASS), 11/5/04
BWSC, 11/5/04
Watertown Citizens for Environmental Safety, 11/5/04
William S. Grenzebach, 11/5/04
Robina E. Folland, 11/5/04
Safety Net/Alternatives for Community & Environment (ACE), 11/5/04
Joan Ecklein, 11/5/04
Newton Dept. of Planning & Development, 11/5/04
Helaine Simmonds & Cinda Stoner, 11/7/04
ACE, 11/8/04
MAPC, 11/8/04
Shirley Kressel, 11/8/04
Old Dover Neighborhood Association, 11/8/04
Marc Pelletier, 11/9/04
Fort Point Assoc., 11/9/04
MHC, 11/9/04
EOTC, 11/9/04

Form Cards Supporting Project (approximately 476)
Form Letters Supporting the Project (approximately 157)
Form Letters Opposed to the Project (approximately 12)

f12021
ERH/WTG

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# CERTIFICATE OF THE SECRETARY OF ENVIRONMENTAL AFFAIRS FOLLOWING REMAND ON THE FINAL ENVIRONMENTAL IMPACT REPORT

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT MUNICIPALITY | : Boston (South End) |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : University Associates Limited Partnership |
| DATE NOTICED IN MONITOR | : August 8, 2004 |

As the Secretary of Environmental Affairs, I hereby issue the following Scope for a Supplemental Final Environmental Impact Report (SFEIR).

## Background

On August 11, 2004, a Certificate on the Final Environmental Impact Report (FEIR) was issued that determined the FEIR to have adequately and properly complied with the Massachusetts Environmental Policy Act (G. L. c. 30, ss. 61-62H) and with its implementing regulations (301 CMR 11.00). Following the issuance of that Certificate, litigation was commenced in Superior Court involving the proponent and other parties[1]. Among other things, the plaintiffs challenged the adequacy of the FEIR. In a Memorandum and Order dated July 31, 2006, the Court vacated the certification of the FEIR and remanded the matter to me for further administrative action in light of the Court's decision. The Scope that follows for the SFEIR is intended to address the specific information and analyses identified regarding the FEIR in the Court's Memorandum and Order.

[1] Ten Residents of Boston v. University Assoc. Limited Partnership, et al., Suffolk Sup Ct. C.A. No. 05-0109-BLS2. This office was not a party to that litigation.

Project Description

As described in the Draft EIR, the proposed project involves development of 457,700 square feet of medical research space, 1,400 parking spaces, and associated infrastructure on a 14.5-acre site along Albany Street. The project includes a 223,000 square foot building that will contain a "Level 4 Biocontainment" national research facility. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EOEA #7034), which completed the EIR review process in 1991. The Draft EIR also includes a cumulative traffic impact analysis that incorporates analysis of the Moakley Services Center Project (EOEA #11883), in accordance with the 1999 Certificates on the Moakley Services Center Project and BioSquare Phase II Project.

Thresholds and Jurisdiction

The project is undergoing review and requires the preparation of a mandatory EIR pursuant to section 11.03 (6)(a) (6) and (7) of the MEPA regulations, because the project requires an access permit from the Massachusetts Highway Department (MHD) and involves the generation of greater than 3,000 new vehicle trips per day and provision of greater than 1,000 new parking spaces at a single location. The project will also require a Sewer Connection Permit from the Department of Environment Protection (DEP). The project will also require a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA), and review by the Massachusetts Historical Commission. The proponent is seeking financial assistance from the Commonwealth for the Moakley Services Center portion of the project. MEPA jurisdiction therefore extends to all aspects of the project that may have significant environmental impacts.

## SCOPE

General

The form and content of the Supplemental Final EIR should conform to the requirements of the MEPA regulations at 11.07(6) except as otherwise directed by this Scope.

At a minimum, the proponent should circulate the SFEIR to those parties submitting individual written comments on the ENF, Draft EIR, and/or the Final EIR, and to any state agency from which the proponent will seek permits. The proponent should also make a reasonable number of hard copies of the Final EIR available on a first come, first served basis.

Biocontainment Building

In response to the Certificate on the Draft EIR, which requested an evaluation of a "worst case" safety event involving the loss of the physical integrity of the containment systems, the FEIR provided an analysis of a release of airborne anthrax spores. The

SFEIR should evaluate an additional "worst case" scenario that involves the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. I note that the Court's Memorandum and Order references smallpox, SARS, and the Ebola virus as potentially representative "worst case" contagious pathogens. The SFEIR should incorporate the analysis of anthrax from the FEIR to facilitate comparison and review. The analyses of a "worst case" scenario should quantify, to the extent possible, the magnitude of the impacts in terms of actual or probable damage to the environment, including the probability of the risk of the "worst case" scenario over the life of the project.

Alternatives

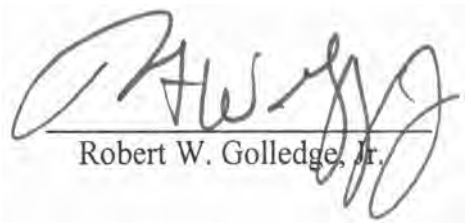
The SFEIR should identify feasible alternative locations for the biocontainment building, including at least one feasible alternative location located in an area less densely populated than the proposed location in Boston's South End. The SFEIR should evaluate whether the potential public impacts due to the release of a contagious pathogen, including a "worst case" scenario, would be materially different if the biocontainment building were located in a feasible alternative location in a less densely populated area.

Mitigation

The SFEIR should demonstrate that such impacts have been avoided to the maximum extent feasible, identify measures to minimize those potential impacts that cannot be avoided, and identify appropriate mitigation for any potential impacts upon the public, such as due to the release of a contagious pathogen, that may be identified through the analyses required above. The SFEIR should contain a summary of the mitigation measures committed to by the proponent. Revised Draft Section 61 findings should be included in the SFEIR for any state agency issuing a permit or approval for the project.

Response to Comments

The SFEIR should respond to the comments received on the FEIR to the extent that they are within the Scope of the SFEIR. The SFEIR should include a copy of each comment letter received. The SFEIR need not reproduce every form letter received but should include one template and any form letters that included additional individual comments. The SFEIR should present any additional narrative or quantitative analysis necessary to respond to the comments received.



September 5, 2006
Date

Robert W. Golledge, Jr.

RWG/dbb

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December 2, 2011

CERTIFICATE OF THE SECRETARY OF ENERGY AND ENVIRONMENTAL AFFAIRS
ON THE
NOTICE OF PROJECT CHANGE

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT MUNICIPALITY | : Boston |
| PROJECT WATERSHED | : Boston Harbor |
| EEA NUMBER | : 12021 |
| PROJECT PROPONENT | : Boston University and Boston Medical Center |
| DATE NOTICED IN MONITOR | : September 7, 2011 |

Pursuant to the Massachusetts Environmental Policy Act (MEPA) (G.L.c.30, ss. 61-62I) and Section 11.10 of the MEPA regulations (301 CMR 11.00), I have reviewed the Notice of Project Change (NPC) for this project. The NPC requests that the proponent be allowed to conduct two levels of research in the National Emerging Infectious Disease Laboratories (NEIDL) Building[1] prior to the submission of the Supplemental Final Environmental Impact Report (SFEIR) and the court required risk assessment. The NEIDL Building is one component of the larger BioSquare Phase II project. The proponent has identified the levels of laboratory research as Biocontainment Safety Level (BSL) laboratories, known as BSL-2 and BSL-3[2]. In accordance with the Certificate Following Remand on the FEIR dated September 5, 2006, the project as a whole continues to require the preparation of an SFEIR that will address the question

1 The BioSquare Phase II property is jointly owned by Boston University and Boston Medical Center. It was formerly held under the University Associates Limited partnership and is now held through the BioSquare Realty Trust. The NEIDL Building is a Boston University Project. The NEIDL Building is not located on the parcel of land transferred from the then Massachusetts Highway Department that was part of the entire BioSquare Phase II MEPA filing.

2 For a description of the classification of containment levels, as established by the Centers for Disease Control and Prevention, please see the "Review of the NPC" Section of this Certificate.

of risk assessment and "worst case" scenarios that involve the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The Scope for the SFEIR issued on September 5, 2006 remains in effect.

I hereby determine that the NPC, as it pertains to BSL-2, **does not require** the preparation of an additional Environmental Impact Report (EIR). However, I am legally precluded from waiving the risk assessment for those contagious pathogens that were the subject of concern by the Superior and Supreme Judicial Courts and proposed for study by the National Institutes of Health ("NIH"), until I have been afforded the opportunity to review the risk assessment for those contagious pathogens currently being studied by NIH. The proponent should accordingly submit its completed SFEIR with its risk assessment prior to conducting BSL-3 and BSL-4 laboratory research in the NEIDL Building. Alternatively, the proponent may file a future NPC and waiver request on BSL-3 activities after NIH completes its review and BU provides sufficient information on BSL-3 to meet the requirements of the SFEIR, should the proponent still wish to proceed with BSL-3 prior to BSL-4 research.[3] In a separate Draft Record of Decision (DROD), also being issued today, I am proposing to grant a Phase 1 Waiver, allowing the proponent to conduct lower level BSL-2 laboratory research within the NEIDL Building in advance of the SFEIR for the project.

NPC Project Change Description

According to the NPC, the project change consists of the utilization of approximately 65,280 square feet (sf) of BSL-2 and BSL-3 laboratory space within the completed 192,000 sf NEIDL Building prior to the completion of the additional risk assessment/SFEIR. The proponent is currently utilizing approximately another 96,000 sf of support space for offices, clinical research and lab support. According to the proponent, BSL-2 space would occupy approximately 40,320 sf. Nearly three years after the building has been completed, the NIH's risk assessment has not yet been completed. The proponent estimates that it may take as much as a year before the risk assessment is completed and the SFEIR is subject to my review. Before the NEIDL Building is approved for 30,720 sf of BSL-4 laboratory use, the highest BSL level for a research laboratory, the general public will be provided with an opportunity to review and comment on the risk assessment and the SFEIR, and state and federal agencies will take action approving, denying, or conditioning the BSL-4 laboratory use. Additionally, the proponent estimates that six to nine months will be needed for any applicable administrative and/or judicial review. The proponent's best estimate is that BSL-4 research would begin no earlier than October 2013.

3 It is important to note that the NPC filed on behalf of Boston University does not request a waiver from the requirements of the SFEIR for BSL-4. Only after I have completed my review of the SFEIR and I have determined it to be adequate, will Boston University be allowed to seek its state permits to begin any BSL-4 laboratory research work.

The proponent would like to access the building for lower level biological research prior to the completion of the administrative and judicial reviews of the BSL-4 activities. The proponent has also stated that it will not commence actual BSL-3 level research until the risk assessment has been completed and considered by NIH. The proponent is accordingly seeking a "conditional approval" under MEPA. The proponent initially requested approval operate the laboratory at the BSL-2 level starting this winter and would seek additional City and State regulatory approvals necessary for BSL-3 level operations so that BSL-3 research can begin immediately following the completion of the risk assessment by NIH, without my further review of the assessment. However, on October 24, 2011, the proponent sent a clarifying letter stating that the Waiver request is not conditioned upon any other action being taken by any other agency and is not a request that I improperly delegate any of my responsibilities under MEPA to other agencies.

Project History

In 1999, an Environmental Notification Form was submitted for the proposed project. The project required a mandatory EIR. In 2003, the DEIR was determined to be adequate. In the FEIR, the proposed project consisted of the development of 428,700 sf of medical research space, a 1,400 space parking garage (approximately 496,000 sf), and associated infrastructure on a 14.5-acre site along Albany Street in Boston. The project included the 192,000 sf NEIDL Building. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EEA #7034), which completed its EIR review process in 1991 and the Moakley Services Center Project (EEA #11883). On August 11, 2004, the FEIR for the BioSquare Phase II was determined to be adequate.

Following the issuance of that FEIR Certificate, a group of ten citizens commenced litigation against the proponent and other parties, challenging, among other things, the adequacy of the FEIR. In a Memorandum and Order dated July 31, 2006, the Court vacated the certification of the FEIR and remanded the matter to the then Secretary of Environmental Affairs for further administrative action in light of the Court's decision. Soon thereafter, the proponents petitioned the Appeals Court, pursuant to G. L. c. 231, s. 118, for interlocutory relief from the Superior Court's decision, and the matter was subsequently transferred to the Supreme Judicial Court (SJC). On December 13, 2007, the SJC rendered its decision in Allen v. BRA, et al, 450 Mass. 242 (2007), affirming the Superior Court decision and holding that: the decision on the adequacy of the final EIR was arbitrary and capricious (1) in failing to consider likely damage to the environment caused by the release of a contagious pathogen, and (2) due to the developer's failure to address alternative locations for the project. In its decision, the SJC noted that the decision on the adequacy of the final EIR was arbitrary and capricious in that the "worst case scenario put forth by the proponent inadequately addressed the consequences of a release of contagious pathogens from the BioLab, potentially denying State Agencies the opportunity to meaningfully review the environmental impact of such a release and consideration of the measures that would be necessary to mitigate environmental damage." Id. at 257.

As a result of the remand order from the Superior Court, the then Secretary issued a Certificate Following Remand on the FEIR on September 5, 2006, that required a Supplemental Final Environmental Impact Report (SFEIR). That certificate was not modified after the December 13, 2007 SJC affirmation of the Superior Court's remand[4].

The project has also undergone review under the National Environmental Policy Act (NEPA), and the National Institutes of Health (NIH) completed a Final Environmental Impact Statement and issued a Record of Decision in February, 2006. In response to issues raised in a federal court proceeding regarding the NIH Final Environmental Impact Statement (FEIS), the NIH completed additional reviews of the potential impacts of the BSL-4 Biolab, including a report entitled the *Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University* (DSER)[5], which was developed, in part, to address the Superior Court and SJC directive that the SFEIR provide additional worst case scenario analysis and evaluate the comparative levels of risk associated with alternative locations for the BSL-4.

In 2007, former Secretary Ian Bowles requested that the National Research Council (NRC) convene an expert committee to provide technical input on the DSER. Secretary Bowles asked that the Committee evaluate only the DSER, and not mitigation. The Committee was asked to review the DSER and meet to discuss the methodologies and analyses therein and to address the following specific questions pertaining to the scientific adequacy of the NIH Study:

- Determine if the scientific analyses in the NIH Study are sound and credible;
- Determine whether the proponent has identified representative worst case scenarios; and
- Determine, based on the study's comparison of risk associated with alternative locations, whether there is a greater risk to public health and safety from the location of the facility in one or another proposed location.

The parties agreed that the Committee 's report would be limited to a technical review of the DSER, and that the Contractor, the National Research Council (NRC), would not make any findings or recommendations regarding the adequacy of any determinations or decisions made by any agency or department of the U.S. Government or the Commonwealth under NEPA or MEPA. Furthermore, NRC would not be responsible in any way for any such decisions or

4 The 2006 Certificate required the SFEIR to evaluate an additional "worst case" scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The 2006 Certificate further stated that, in light of the Superior Court suggestion that smallpox, SARS, and the Ebola virus as potentially representing "worst case" contagious pathogens, the SFEIR should incorporate the analysis of anthrax from the FEIR to facilitate comparison and review. The 2006 Certificate also noted that the SFEIR should identify a feasible alternative location for the biocontainment building in a less densely populated area.

5 The DSER was intended to form the scientific basis of the SFEIR, which Boston University has not yet filed for MEPA review.

determinations. Thus, the questions addressed by the Committee solely pertain to the scientific adequacy of the risk assessment and other analytical methodologies used in the DSER and whether the report responds to former Secretary Bowles' questions in a scientifically sound and credible manner.

The committee's assessment was critical of the DSER, finding that it was not sound and credible, did not adequately identify and thoroughly develop worst-case scenarios, and did not contain the appropriate level of information to compare the risks associated with alternative locations. The report also raised specific concerns about agent selection, scenario development, modeling methodology, environmental justice issues, and risk communication.

As a result of the concerns raised by the NRC, NIH established its Blue Ribbon Panel (BRP) in March, 2008, to provide scientific and technical advice to NIH. This process culminated in the NRC committee delivering its third report in April, 2010, which found the proposed approaches to conducting the risk assessment suitable and well planned. Additionally, the NRC committee determined that the 13 pathogen agents selected for analysis were appropriate and comprehensive, and the expertise available on and to the assessment team seemed strong. The committee encouraged NIH and its contractor (Tetra Tech) to develop qualitative analyses (an explanation of the safety and risk profile) of all 13 pathogens in a manner that is clear and accessible to the public. The committee also suggested that the qualitative analyses in the body of the assessment be supplemented with results of quantitative modeling planned for five pathogens, with details provided in appendices. Further, the committee encouraged NIH to rely on data available from existing case studies, public health surveillance of the surrounding communities, and release incidents, not only to support its models but also to provide a complete and understandable picture for the public. The NRC committee again emphasized that the final risk assessment serve as an effective risk communication tool.

On September 22, 2010, NIH submitted and presented supplemental materials to the NRC committee, and after reviewing the material, the NRC committee concluded that it could not endorse NIH's supplemental materials and illustrative analyses. In summary, the results presented on September 22 were insufficient for the committee to find that the analyses presented thus far will lead to a scientifically and technically sound risk assessment. The illustrative results presented to date were not sufficiently documented and supported to convince the committee that the contractors are on track to completing a comprehensive risk assessment for the NEIDL facility. The committee also noted that based on the limited information provided by NIH's contractor, the information was not responsive to the committee's recommendation that qualitative analyses addressing the three questions raised in its 2008 letter report be prepared first and that these qualitative analyses then be supplemented by quantitative analysis through modeling using available data on the agents in question. The NRC committee also found that any modeling should be used in a context that reflects scientific knowledge and experience. The committee reiterated the need to include actual data based on published results in the models

where possible, and that the models be transparent and couched in the context of the risk assessment and address appropriate uncertainties. As it currently stands, BU has yet to complete its risk assessment of the 13 pathogens that are under review by the NRC committee.

Against this backdrop it is important to note two important aspects of the pending Superior Court decision: (1) the inclusion of "contagious pathogens" in its requirement for an SFEIR and (2) strong litigation language in a footnote relative to the Secretary's inability to delegate his authority under MEPA to a federal agency. First, the Superior Court found that "no EIR regarding the Biolab project can rationally be found to comply with MEPA that failed to consider any 'worst case' scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen..." The NPC does not outline or examine the differentiation between the BSL-3 and BSL-4 risk assessment being undertaken by NIH. What is clear is that a risk assessment is being carried out on BSL-3 pathogens. Some comment letters have pointed out that certain BSL-3 agents may present more serious potential risks than BSL-4 agents and may be described as contagious pathogens[6].

Secondly, the Superior Court has required a risk assessment for the more serious contagious pathogens and has emphasized that the Secretary may not delegate his requirement to examine the issues before MEPA to a federal authority. Specifically, the Court states: "all parties acknowledge that the Secretary may not properly delegate her responsibility to ensure an adequate Final EIR to any federal agency. Nor may she certify an inadequate EIR based on her expectation that the issues inadequately analyzed will later be adequately analyzed in a federal EIR." Ten Residents vs. Boston Redevelopment Authority, 24 Mass. L. Rep. 324, fn10 (2006). This judicial edict continues to govern my ability to render MEPA decisions with respect to the Biolab. The ongoing risk assessment development brought about by both federal and state court decisions contains some BSL-3 pathogens, as well as BSL-4 pathogens. Therefore, in spite of the proponent's clarifying letter, I am legally barred from acting on the proponent's waiver request for BSL-3 level research until I am able to independently review the risk assessment for the contagious pathogens proposed for study by BU at the Biolab. I have reached this conclusion after consultation with counsel, including the Office of the Attorney General. In addition, I have requested that the Office of the Attorney General submit this Certificate to the Court as an informational filing.[7]

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6 In the November 7, 2007 report prepared by an expert committee that was convened by the National Research Council to review the *Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University* (DSER) that was prepared in connection with the National Environmental Policy Act, the NRC committee noted that: "Agents such as *Yersinia pestis* (pneumonic plague), influenza virus (including virulent strains), SARS virus, and highly pathogenic avian influenza virus are often studied in BSL-3 and other lower-level containment facilities." See NRC Report, page 8. The Committee also noted that "the selection of agents for the worst case scenario was appropriately not limited to BSL-4 agents as some agents handled in BSL-3 facilities may present more serious potential risks than BSL-4 agents. Agents are categorized for BSL-4 containment because they cause deadly disease for which there is no treatment, not because they are highly infectious and cause widespread disease." Id.

7 To differentiate BSL-3 and BSL-4 from BSL-2, I note that none of the 13 pathogens being studied in the NIH risk

Jurisdiction and Permitting

The project as a whole is subject to a mandatory EIR pursuant to Section 11.03(6)(a)(6) and (7) of the MEPA regulations because it will (1) require State Agency Permits (2) generate 3,000 or more new vehicle trips per day and 3) provide greater than 1,000 new parking spaces at a single location. It required a Vehicular Access Permit from the Massachusetts Department of Transportation (MassDOT). After it has received all the necessary reviews and approvals for lower level research operations, the proponent must obtain a Sewer Use Discharge Permit from the Massachusetts Water Resources Authority (MWRA). The project required a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA). The proponent was required to comply with the National Pollutant Discharge Elimination System (NPDES) General Permit for stormwater discharges from a construction site.

Because the proponent has received a transfer of state land for a portion of the project[8], MEPA jurisdiction over this portion of the project subject to the land transfer is broad and extends to all aspects of the project that are likely, directly or indirectly, to cause Damage to the Environment, as defined in the MEPA regulations. In relation to this NPC and the NEIDL Building, the State Agency Action involved is a Sewer Use Discharge Permit from the MWRA.

## REVIEW OF THE NPC

The NPC presented a description of the uses proposed for the NEIDL Building. Because the NEIDL Building is completed, the proponent has identified few environmental impacts. Traffic and parking impacts, drainage, and permitting issues were fully evaluated in the DEIR and the FEIR. The remaining issues to be reviewed, such as the risk assessment, will be addressed in the SFEIR.

As noted above, the review of the NPC is unavoidably linked to the governing court ruling as it pertains to contagious pathogens. The Centers for Disease Control and Prevention (CDC) has established standards for the classification of containment levels for biological research laboratories, known as Biocontainment Safety Levels (BSL) 1-4. BSL-1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and that pose minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the building's general traffic patterns and work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment and/or facility design is not required. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised

assessment are BSL-2 agents. While the Superior Court decision did not specifically remove BSL-2 from its risk assessment requirements, it is clear that the Court was asking that highly dangerous pathogens be examined, not the more moderate BSL-2 pathogens.

8 The plaintiffs have challenged the efficacy of the transfer of land in the litigation now pending before the Superior Court, and that matter remains before the Court as well.

by a scientist with general training in microbiology or a related science. BSL-2 is similar to BSL-1 for work involving agents of moderate potential hazard to personnel and the environment. These labs have personnel with specific training in the handling of pathogenic agents, and access to the laboratory is limited when work is being conducted. Within the facility, extreme precautions are taken with contaminated sharp items. Biological safety cabinets or other physical containment equipment are used in certain procedures where aerosols or splashes may occur. No BSL-2 agents are involved in the risk assessment currently being developed by the NIH.

BSL-3 is used for clinical, diagnostic, teaching, research or production facilities where work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by inhalation, absorption, ingestion, or injection. The lab has special engineering and design features, and laboratory personnel have specific training in the handling of pathogens and potentially lethal agents. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other containment devices. Personnel may have additional personal protective equipment requirements, possibly including respiratory protection in some labs. Access is restricted to only those that have proper training and security access to work in the facility.

BSL-4 is required for work with dangerous and exotic agents that pose a high individual risk of lab infections and life-threatening disease and for which there is no vaccine and no cure. The lab staff has specific and thorough training in the handling of extremely hazardous infectious agents, the use and function of primary and secondary containment, and the standard lab practices and procedures. The lab director strictly controls access to the lab, which is either in a separate building or in a controlled secured area within a building completely isolated from all of the building areas. A special training program for staff is required, including training on personal protective equipment (positive pressure suit). A specific facility operations manual is prepared or adopted.

Upon issuance of a Final Record of Decision, granting BU's waiver request for BSL-2 activities, the MWRA can issue a Sewer Use Discharge Permit to the proponent for BSL-2 activities at the laboratory. All research proposals at the NEIDL Building will be reviewed and approved in advance by the Boston University Institutional Biosafety Committee (IBC). The IBC has two community representatives on it. There is an NEIDL Community Liaison Committee (CLC) with six community representatives serving on it for the research laboratory. The CLC will review all work proposed at the facility and advise the community on planned research activities.

Waiver Request

As noted above and as set forth more fully in the DROD also being issued today, the proponent has requested a Waiver to allow for the utilization of approximately 65,280 sf of low level laboratory research space within the 192,000 sf NEIDL building prior to completion of the

risk assessment/SFEIR. Based upon my review of the NPC and the comments received, I have proposed to grant the Waiver, but only for BSL-2 laboratory research activities containing approximately 40,320 sf. The proponent currently utilizes 96,000 sf of space within the building for support service, such as office, clinical research, and lab support. The DROD will be noticed for public comment and contains conditions to ensure that the impacts from utilization of the low level laboratory research space are avoided, minimized, and mitigated to the maximum extent feasible. The cumulative impacts of the project and the utilization of BSL-3 and BSL-4 laboratory research space will be further addressed in the risk assessment/SFEIR.

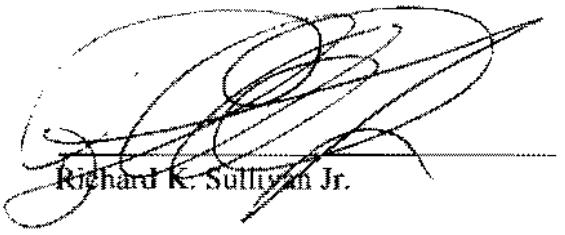
I acknowledge the comments and concerns expressed by many commenters. However, I do not believe that the impacts from the utilization of BSL-2 laboratory research space warrants the preparation of an EIR under the applicable provisions of the MEPA regulations, or under the requirements of the Superior Court decision as upheld by the SJC. I am also confident that the risk assessment for the project can be fully reviewed in the context of the SFEIR. The proponent has represented that the only risks associated with the project lie in the research that will be performed in BSL-4 laboratories. After reviewing the SJC and Superior Court decisions, I note that the SFEIR includes laboratory research that may qualify as BSL-3 and BSL-4. The threat or risk from laboratory research will be from research on extremely contagious biological agents that could pose serious harm to an already compromised Environmental Justice community in Boston's South End neighborhood. The proponent should continue to work with community members to address their ongoing concerns.

The SFEIR should also address the Metropolitan Area Planning Council's concern regarding the transport of hazardous materials to and from the project site.

Conclusion

Based upon a review of the NPC and the comments received, I have proposed in a separate DROD issued today to grant a Phase 1 Waiver for utilization of the NEIDL building for BSL-2 low level research prior to the completion of a risk assessment by the NIH and the subsequent submittal of the SFEIR.

December 2, 2011
Date



Richard K. Sullivan Jr.

Comments received:

Boston Public Health Commission, 8/31/11
Association of Independent College and Universities in Massachusetts, 8//31/11
Fort Point Associates, 9/1/11
Joanie Parker, 9/1/11
Lynn Klotz, 9/1/11
Conference of Boston Teaching Hospitals, 9/2/11
Michele D. Maniscalco, 9/2/11
MassBio, 9/6/11
Elizabeth Glenn, 9/6/11
John Saylor, 9/6/11
Chris Knighton, 9/6/11
Nathan Seavey, 9/6/11
Monica Spicher, 9/6/11
Elizabeth Glenn, 9/6/11
Kyla Neilan, 9/6/11
Associated Industries of Massachusetts, 9/7/11
Dr. David Waxman, 9/7/11
Diana M. Nugent, 9/8/11
Ara Tahmassian, 9/8/11
Robina E. Folland, 9/8/11
Robert Donahue, 9/8/11
Donna M. Ambrosino, MD, 9/8/11
Eleanor MacLellan, 9/8/11
Louis M. & Christina S. Abbey, 9/8/11
Elizabeth Claggett-Borne, 9/8/11
Paul Saint-Amand, 9/8/11
Daniel Verinder, 9/8/11
Michael Bleiweiss, 9//9/11
Phyllis J. Miller, 9/9/11
Greater Boston Chamber, 9/9/11
Kenneth Ryan, 9/9/11
Dana–Farber/Harvard Cancer Center, 9/9/11
John Tonkiss, 9/9/11
Rebecca Gloe, 9/9/11
Jonathan Freedman, 9/9/11
Constance Phillips, 9/9/11
S. Sherill Ashe, 9/9/11
Benjamin Tocchi, 9/9/11
Rachel Mia Leone, 9/10/11
Boston University School of Public health, 9/12/11

Patty Kellogg, 9/12/11
Mark Lohsen, 9/12/11
Mary Hart, 9/12/11
Lehigh University, 9/13/11
Brigham and Women's Hospital, President, 9/13/11
Terence M. Keane, 9/13/11
Barbara McKinley, 9/13/11
Shirley Kressel, 9/13/11
Polly Wynn Allen, 9/13/11
Elizabeth B. Gerlach, 9/14/11
Patricia Aron, 9/14/11
Brenda M. Steinberg, 9/14/11
Dot Walsh, 9/14/11
Cat Bryant, 9/15/11
Nancy Seymour, 9/15/11
Joan Figler, 9/15/11
Tufts School of Medicine, Harris A Berman, 9/15/11
Tufts University, Peggy Newell, Provost & Senior Vice President ad interim, 9/15/11
James Levin, 9/15/11
Ellen N. Jamieson, 9/15/11
Annemarie Baldyga, 9/15/11
John D. Nash, 9/15/11
Alan Weinberger, 9/15/11
William S. Grenzebach, 9/15/11
Gary L. Gottlieb, President/CEO, Partners Healthcare, 9/15/11
Alexis Brubaker, 9/15/11
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Carolyn Cotsonas Finn, 9/15/11
Gustavo Mostoslavsky, 9/15/11
Maureen E, Feeney, Boston City Councillor, 9/15/11
Marcia Davis, 9/15/11
Jennifer A Pleus, 9/15/11
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Kenmore Association, 9/16/11
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Julie B. Pinkham & Donna Kelly, Massachusetts Nurses Association, 9/20/11
Kenneth King, 9/20/11
Jeffrey W. Hunter, Dean of Boston University School of Dental Medicine, 9/20/11
Boston City Councilors, Arroyo, Jackson, Pressley & Yancey, 9/21/11
Alan M. Garber, Provost and Jeffrey S. Flier, Dean, Harvard Medical School, 9/21/11
Christopher J. Menard, 9/21/11
Kevin M. Tuohey, 9/21/11
Elizabeth Walsh, 9/21/11
David H. Farb, Professor & Chair, Boston University Department of Pharmacology..., 9/21/11

Pax Christi Western Massachusetts, 9/21/11
James Jennings, Tufts University, 9/21/11
Samuel M. Bauer, 9/21/11
Fort Point Associates, 9/22/11
Fort Point Associates, 9/22/11
Newmarket Business Association, 9/22/11
Alexander Norbash, MD, Boston Medical, 9/22/11
R.P.F. Security Associates, 9/22/11
Sherwood S. Hughes, 9/22/11
James F. English, 9/23/11
Maira E. English, 9/23/11
Alan B. Dittrich, 9/23/11
Massachusetts Water Resources Authority, 9/26/11
Thomas G. Robbins, 9/26/11
Willis G. Wang, 9/26/11
Sheila E. Grove, 9/26/11
Scott S. Pare', 9/26/11
John A. Porco, Professor of Chemistry, Boston University, 9/26/11
James P. Keeney, 9/26/11
Judith Olejnik, 9/26/11
Boston Imaging Core Lab, 9/26/11
Metropolitan Area Planning Council, 9/26/11
359 Signed Postcards Supporting Boston University's Waiver Request, 9/27/11
Council for Responsible Genetics, 9/27/11
Stephen P. Burgay, 9/27/11
South Boston Community Health Center, 9/27/11
Michael Welsh, 9/27/11
Karen H. Antman, 9/27/11
Conservation Law Foundation, 9/27/11
Watertown Citizens for Environmental Safety, 9/27/11
Anderson & Krieger, 9/27/11
3 Signed Postcards Supporting Boston University's Waiver Request, 9/28/11
Spillane & Spillane, 9/28/11
Karen Freund, 9/30/11
Representative Charles A. Murphy, 9/30/11
Representative Thomas A. Golden, Jr., 9/30/11
Linda K. Lukas, 9/30/11
Representative Harold P. Naughton, Jr., 9/30/11
Community Development Corporation of Boston, 10/3/11
Francisco Tapia, 10/4/11
Alliance Detective & Security Service, 10/4/11
Mass Housing, Director of Public Safety, 10/4/11

College Bound Dorchester, 10/4/11
Primitiva Tapia, 10/4/11
Mass Housing, Seline Moreno, 10/4/11
Kimberly K. Russell-Lucas, 10/4/11
Pat Augustine, 10/4/11
Constance Phillips, Boston University School of Medicine, 10/5/11
Jian Huan Wu, 10/5/11
Marisa Lopez, 10/5/11
Raysa Tapia, 10/5/11
Suzeth L. Dunn, 10/5/11
Senator Sonia Chang-Diaz, 10/6/11
Foley Hoag, 11/11/11
Representative Gloria L. Fox, 10/17/11
Anderson & Krieger, 10/19/11
Fort Point Associates, 10/24/11
Representative Byron Rushing, 10/25/11
6 Signed Postcards Supporting Boston University's Waiver Request, 11/2/11

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RKS/WTG

*The Commonwealth of Massachusetts*
*Executive Office of Energy and Environmental Affairs*
*100 Cambridge Street, Suite 900*
*Boston, MA 02114*

Deval L. Patrick
GOVERNOR

Timothy P. Murray
LIEUTENANT
GOVERNOR

Richard K. Sullivan, Jr.
SECRETARY

Tel: (617) 626-1000
Fax: (617) 626-1181
http://www.mass.gov/envir

December 2, 2011

DRAFT RECORD OF DECISION

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT LOCATION | : Boston |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : Boston University and Boston Medical Center |
| DATE NOTICED IN MONITOR | : September 7, 2011 |

Pursuant to the Massachusetts Environmental Policy Act (G. L., c. 30, s. 61-62I) and Sections 11.11 of the MEPA regulations (301 CMR 11.00), I have reviewed the Notice of Project Change (NPC) and request for a Phase I Waiver. I hereby propose to grant a waiver that will allow the proponent to conduct lower level research, known as Biocontainment Safety Level (BSL-2) in the National Emerging Infectious Disease Laboratories (NEIDL) Building prior to the submission of the Supplemental Final Environmental Impact Report (SFEIR) for the above project.

Project History

In 1999, an Environmental Notification Form (ENF) was submitted for the proposed project. The project required a mandatory EIR. In 2003, the DEIR was determined to be adequate. In the FEIR, the proposed project consisted of the development of 428,700 sf of medical research space, a 1,400 space parking garage (approximately 496,000 sf), and associated infrastructure on a 14.5-acre site along Albany Street. The project included the 192,000 sf NEIDL building. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EEA #7034), which completed its EIR review process in 1991 and the Moakley Services Center Project (EEA #11883). On August 11, 2004, the FEIR was determined to be adequate.

Following the issuance of that Certificate, litigation was commenced in Superior Court

involving the proponent and other parties. Among other things, the plaintiffs challenged the adequacy of the FEIR. In a Memorandum and Order dated July 31, 2006, the Court vacated the certification of the FEIR and remanded the matter to the Secretary for further administrative action in light of the Court's decision. On September 5, 2006, the then Secretary issued a Certificate that required an SFEIR. The SFEIR should evaluate an additional "worst case" scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The Superior Court suggested smallpox, SARS, and the Ebola virus as potentially representing "worst case" contagious pathogens. The SFEIR should incorporate the analysis of anthrax from the FEIR to facilitate comparison and review. It should identify a feasible alternative location for the biocontainment building in a less densely populated area.

NPC Project Change Description

According to the NPC, the project change consists of the utilization of approximately 65,280 square feet (sf) of BSL-2 and BSL-3 laboratory space within the completed 192,000 sf NEIDL Building prior to the completion of the additional risk assessment/SFEIR. The proponent is currently utilizing approximately another 96,000 sf of support space for offices, clinical research and lab support. According to the proponent, BSL-2 space would occupy approximately 40,320 sf.

Nearly three years after the building has been completed, the National Institute of Health's (NIH) risk assessment has not yet been completed. The proponent estimates that it may take as much as a year before the risk assessment is completed and the SFEIR is reviewed by me. Before the NEIDL Building is approved for BSL-4 laboratory use (30,720 sf), the public will be provided with an opportunity for review and comment, and state and federal agencies will have to take action approving, denying, or conditioning the BSL-4 laboratory use. BSL-4 involves the use of the highest BSL level (contagious pathogens) for a research laboratory. Additionally, six to nine months will be needed for federal and state court reviews. The proponent's best estimate is that BSL-4 research would not begin until October 2013 at the earliest.

The proponent would like to begin to use the building for lower level biological research pending the completion of the administrative and judicial reviews of the BSL-4 activities. The proponent has also agreed that it will not commence actual BSL-3 level research until the risk assessment has been completed and considered. The proponent would operate the laboratory at the BSL-2 level starting this fall and would seek additional City and State regulatory approvals necessary for BSL-3 level operations so that BSL-3 research can begin immediately following the completion of the risk assessment.

Jurisdiction and Permitting

The project as a whole is subject to a mandatory EIR pursuant to Section 11.03(6)(a)(6) and (7) of the MEPA regulations because it requires State Agency Permits and will generate 3,000 or more new vehicle trips per day and will provide greater than 1,000 new parking spaces

at a single location. It required an Access Permit from the Massachusetts Department of Transportation (MassDOT). After it has received all the necessary reviews and approvals for lower level research operations, the proponent must obtain a Sewer Use Discharge Permit from the Massachusetts Water Resources Authority (MWRA). The project required a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA). The proponent was required to comply with the National Pollutant Discharge Elimination System (NPDES) General Permit for stormwater discharges from a construction site.

Because the proponent has received a transfer of state land for a portion of the project, MEPA jurisdiction over this project is broad and extends to all aspects of the project that are likely, directly or indirectly, to cause Damage to the Environment, as defined in the MEPA regulations.

For the NPC and the NEIDL Building, the State Agency Permit is the Sewer Use Discharge Permit from the MWRA.

Summary of Potential Environmental Impacts

There is no identified increase in traffic generation, parking demand and stormwater flow from the NPC. The project has been designed to meet or exceed the performance standards in the Massachusetts Stormwater Policy. There is no alteration proposed on the project site that occurs in a wetland resource area or buffer zone. The project has access from the Frontage Road-South and from existing streets that connect to Albany Street.

The BioSquare Phase II project added 1400 structured parking spaces. On a typical weekday, the proponent has estimated that the total project will generate approximately 3,115 unadjusted weekday vehicle trips. The corresponding weekday morning and evening peak hour traffic volume increases are approximately 436 and 419 unadjusted weekday vehicle trips per hour respectively. The low level research portion of the NEIDL Building should have fewer trips than the total buildings utilization that was estimated at 491 adjusted weekday vehicle trips, 70 adjusted morning and 70 adjusted evening weekday vehicle trips. This amount of vehicle trips should have a minimal effect on area traffic.

The temporary environmental impacts resulting from the construction of the BioSquare Phase II include: noise, air quality (dust), water quality, and traffic. However, the NEIDL Building portion of the project has been completed for three years.

Summary of Proposed Mitigation Measures

The NEIDL Building must meet applicable city, state and federal safety regulations. For the entire BioSquare Phase II, the proponent has committed to provide 4:1 Infiltration/Inflow (I/I) removal from the wastewater system. To date approximately 60,000 gallons per day (gpd) of the 183,000 gallons of I/I removal required for the full operation of the NEIDL Building has been

accomplished. The remaining I/I removal will be accomplished through two projects which are awaiting engineering review by the Boston Water and Sewer Commission and will be implemented when the building becomes operational. The proponent created a pocket park along Albany Street. The proponent modified the East Newton/Albany Street intersection as a four-way intersection. It will provide a traffic and parking management plan for Albany Street between East Newton and Union Park Streets to the Boston Transportation Department as part of the MassDOT Access Permit, which has not been approved. The proponent rebuilt Albany Street sidewalks and provided pavement markings along Albany Street including lane striping and crosswalks and directional signing at the site. It installed fiber optic cables along a portion of Albany Street. The proponent will provide the City of Boston with up two variable message boards for real time traffic information as part of the MassDOT Access Permit.

The proponent has instituted a Transportation Demand Management (TDM) program that includes membership in Transportation Management Agency, Transportation Solutions for Commuters. The TDM program included a 25 percent transit pass subsidy program to Boston Medical Center employees, a ridesharing program, preferential parking, a guaranteed ride home, direct deposit payrolls, shuttle bus service to the Orange and Red Lines, Zipcar, flextime, and telecommuting. The proponent provided safe and secure bicycle storage/parking areas (up to 24 bicycle parking spaces in the garage 610 Albany Street) and approximately 170 bicycle parking spaces within a block of the site and shower facilities for employees.

Waiver Request

On August 25, 2011, the proponent requested a waiver that would allow it to proceed with the utilization of approximately 65,280 sf of BSL-2 and BSL-3 laboratory research space within the completed 192,000 sf NEIDL Building prior to the risk assessment/SFEIR. Based upon my review of the NPC and the comments received, I have proposed to grant the Waiver, but only for BSL-2 laboratory research activities containing approximately 40,320 sf. The proponent currently utilizes 96,000 sf of space within the building for support service, such as office, clinical research, and lab support. The NPC was submitted in conjunction with this waiver request that identified the environmental impacts for the project and described the measures to be undertaken by the proponent to avoid, minimize and mitigate project impacts.

Standards for All Waivers

The MEPA regulations at 301 CMR 11.11(1) state that I may waive any provision or requirement in 301 CMR 11.00 not specifically required by MEPA and may impose appropriate and relevant conditions or restrictions, provided that I find that strict compliance with the provision or requirement would:

(a) result in an undue hardship for the proponent, unless based on delay in compliance by the proponent; and

(b) not serve to avoid or minimize Damage to the Environment.

Determinations for a Phase I Waiver

The MEPA regulations at 301 CMR 11.11(4) state that, in the case of a partial waiver of a mandatory EIR review threshold that will allow the proponent to proceed with Phase I of the project prior to preparing an EIR, I shall base the finding required in accordance with 301 CMR 11.11(1)(b) on a determination that:

(a) the potential environmental impacts of Phase I, taken alone, are insignificant;
(b) ample and unconstrained infrastructure facilities and services exist to support Phase I;
(c) the project is severable, such that Phase I does not require the implementation of any other future phase of the project or restrict the means by which potential environmental impacts from any other phase of the project may be avoided, minimized or mitigated; and
(d) the agency action(s) on Phase I will contain terms such as a condition or restriction, so as to ensure due compliance with MEPA and 301 CMR 11.00 prior to commencement of any other phase of the project.

Findings

Based upon the information submitted by the proponent and after consultation with the state permitting agencies, I find that the Waiver Request for BSL-2 laboratory research has merit and that the proponent has demonstrated that the proposed project meets the standards for all waivers at 301 CMR 11.11(1). I find that strict compliance with the requirement to submit an SFEIR prior to the utilization of BSL-2 laboratory research space would result in an undue hardship for the proponent and would not serve to avoid or minimize Damage to the Environment. In accordance with 301 CMR 11.11(4), the latter finding is based on my determination that:

(a) the potential environmental impacts of Phase I (utilization of BSL-2 laboratory research), taken alone, are insignificant;

- Biological research at levels below BLS-3 is being safely conducted by the proponent at its other facilities and at many locations throughout the Commonwealth. Through the Boston Public Health Commission (BPHC) review and permitting, the proponent will be working closely with City officials in achieving a positive outcome for safety concerns and in improving health care research.

- The site on which the NEIDL Building has been constructed has no remaining areas of environmental impacts anticipated. Traffic impacts, associated with the utilization of the NEIDL Building have been analyzed in the DEIR and FEIR and mitigation has been developed. Considered by itself, the NEIDL Building with estimates of approximately 930 unadjusted trips and wastewater generation of approximately 17,600 gallons per day (gpd) does not require the preparation of an EIR.

(b) ample and unconstrained infrastructure facilities and services exist to support BSL-2 laboratory research at the NEIDL Building;

- The building has been constructed and has the entire infrastructure necessary to support the operation of the building. The infrastructure includes redundant water, sewer, electrical, and HVAC services, extensive security controls, and vehicle access and parking facilities. The existing driveways will continued to be used for ingress and egress. No additional infrastructure is necessary to make the building operational.

(c) the project is severable, such that BSL-2 laboratory research at the NEIDL Building does not require the implementation of any other future phase of the project or restrict the means by which potential environmental impacts from any other phase of the project may be avoided, minimized or mitigated; and

- The proposed interim use of the facility is completely separable from the future use of the project for BSL-3 and BSL-4 research use. While the building has been designed and constructed as an integral research facility, it has completely separate laboratories with independent supporting infrastructure to support the different BSL levels of research. Thus, the decision on the future use of the building for BSL-3 and BSL-4 research is not constrained or affected by the use of the balance of the building's research laboratories.

(d) the agency action(s) for the utilization of the BSL-2 research laboratories in the NEIDL Building will contain terms such as a condition or restriction, so as to ensure due compliance with MEPA and 301 CMR 11.00 prior to commencement of any other phase of the project.

- The utilization of BSL-2 research laboratory space will require an MWRA Industrial Wastewater Discharge Permit. This proposed work will be done in strict accordance with existing MWRA protocol and requirements. The proponent is merely requesting that the Secretary allow this aspect of the project to move forward in advance of the completion of the SFEIR. I hereby direct the MWRA to incorporate clear and enforceable language into the Sewer Use Discharge Permit to ensure that only BSL-2 work be conducted at the NEIDL.

Conclusion

I have determined that this waiver request has merit, and am issuing this Draft Record of Decision (DROD), which will be published in the next edition of the Environmental Monitor on

December 7, 2011, in accordance with 301 CMR 11.15(2), which begins the public comment period. The public comment period lasts for 14 days and will end on December 21, 2010. Based on written comments received concerning the DROD, I shall issue a Final Record of Decision within seven days after the close of the public comment period, in accordance with 301 CMR 11.15(6). I hereby **propose to grant** the waiver requested for this project, which will allow the proponent to proceed with all applicable permitting necessary for the utilization of BSL-2 research space in the NEIDL Building prior to preparing an SFEIR/risk assessment for the entire project, subject to the above findings.

December 2, 2011
DATE

Richard K. Sullivan Jr.

Comments received:

Boston Public Health Commission, 8/31/11
Association of Independent College and Universities in Massachusetts, 8//31/11
Fort Point Associates, 9/1/11
Joanie Parker, 9/1/11
Lynn Klotz, 9/1/11
Conference of Boston Teaching Hospitals, 9/2/11
Michele D. Maniscalco, 9/2/11
MassBio, 9/6/11
Elizabeth Glenn, 9/6/11
John Saylor, 9/6/11
Chris Knighton, 9/6/11
Nathan Seavey, 9/6/11
Monica Spicher, 9/6/11
Elizabeth Glenn, 9/6/11
Kyla Neilan, 9/6/11
Associated Industries of Massachusetts, 9/7/11
Dr. David Waxman, 9/7/11
Diana M. Nugent, 9/8/11
Ara Tahmassian, 9/8/11
Robina E. Folland, 9/8/11
Robert Donahue, 9/8/11
Donna M. Ambrosino, MD, 9/8/11
Eleanor MacLellan, 9/8/11
Louis M. & Christina S. Abbey, 9/8/11
Elizabeth Claggett-Borne, 9/8/11
Daniel Verinder, 9/8/11
Paul Saint-Amand, 9/8/11
Michael Bleiweiss, 9//9/11

Phyllis J. Miller, 9/9/11
Greater Boston Chamber, 9/9/11
Kenneth Ryan, 9/9/11
Dana–Farber/Harvard Cancer Center, 9/9/11
John Tonkiss, 9/9/11
Rebecca Gloe, 9/9/11
Jonathan Freedman, 9/9/11
Constance Phillips, 9/9/11
S. Sherill Ashe, 9/9/11
Benjamin Tocchi, 9/9/11
Rachel Mia Leone, 9/10/11
Boston University School of Public Health, 9/12/11
Patty Kellogg, 9/12/11
Mark Lohsen, 9/12/11
Mary Hart, 9/12/11
University of Massachusetts Medical School, Vice Provost for Research, 9/12/11
Lehigh University, 9/13/11
Brigham and Women's Hospital, President, 9/13/11
Terence M. Keane, 9/13/11
Barbara McKinley, 9/13/11
Shirley Kressel, 9/13/11
Polly Wynn Allen, 9/13/11
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Patricia Aron, 9/14/11
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Dot Walsh, 9/14/11
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Joan Figler, 9/15/11
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Kenneth King, 9/20/11
Jeffrey W. Hunter, Dean of Boston University School of Dental Medicine, 9/20/11
Boston City Councilors, Arroyo, Jackson, Pressley & Yancey, 9/21/11
Alan M. Garber, Provost and Jeffrey S. Flier, Dean, Harvard Medical School, 9/21/11
Christopher J. Menard, 9/21/11
Kevin M. Tuohey, 9/21/11
Elizabeth Walsh, 9/21/11
David H. Farb, Professor & Chair, Boston University Department of Pharmacology…, 9/21/11
Pax Christi Western Massachusetts, 9/21/11
James Jennings, Tufts University, 9/21/11
Samuel M. Bauer, 9/21/11
Fort Point Associates, 9/22/11
Fort Point Associates, 9/22/11
Newmarket Business Association, 9/22/11
Alexander Norbash, MD, Boston Medical, 9/22/11
R.P.F. Security Associates, 9/22/11
Sherwood S. Hughes, 9/22/11
James F. English, 9/23/11
Maira E. English, 9/23/11
Alan B. Dittrich, 9/23/11
Massachusetts Water Resources Authority, 9/26/11
Thomas G. Robbins, 9/26/11
Willis G. Wang, 9/26/11
Sheila E. Grove, 9/26/11
Scott S. Pare', 9/26/11
John A. Porco, Professor of Chemistry, Boston University, 9/26/11
James P. Keeney, 9/26/11
Judith Olejnik, 9/26/11
Boston Imaging Core Lab, 9/26/11
Metropolitan Area Planning Council, 9/26/11
359 Signed Postcards Supporting Boston University's Waiver Request, 9/27/11
Council for Responsible Genetics, 9/27/11
Stephen P. Burgay, 9/27/11
South Boston Community Health Center, 9/27/11
Michael Welsh, 9/27/11
Karen H. Antman, 9/27/11
Conservation Law Foundation, 9/27/11
Watertown Citizens for Environmental Safety, 9/27/11
Anderson & Krieger, 9/27/11
3 Signed Postcards Supporting Boston University's Waiver Request, 9/28/11
Spillane & Spillane, 9/28/11

Karen Freund, 9/30/11
Representative Charles A. Murphy, 9/30/11
Representative Thomas A. Golden, Jr., 9/30/11
Linda K. Lukas, 9/30/11
Representative Harold P. Naughton, Jr., 9/30/11
Community Development Corporation of Boston, 10/3/11
Francisco Tapia, 10/4/11
Alliance Detective & Security Service, 10/4/11
Mass Housing, Director of Public Safety, 10/4/11
College Bound Dorchester, 10/4/11
Primitiva Tapia, 10/4/11
Mass Housing, Seline Moreno, 10/4/11
Kimberly K. Russell-Lucas, 10/4/11
Pat Augustine, 10/4/11
Constance Phillips, Boston University School of Medicine, 10/5/11
Jian Huan Wu, 10/5/11
Marisa Lopez, 10/5/11
Raysa Tapia, 10/5/11
Suzeth L. Dunn, 10/5/11
Senator Sonia Chang-Diaz, 10/6/11
Foley Hoag, 11/11/11
Representative Gloria L. Fox, 10/17/11
Anderson & Krieger, 10/19/11
Fort Point Associates, 10/24/11
Representative Byron Rushing, 10/25/11
6 Signed Postcards Supporting Boston University's Waiver Request, 11/2/11

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RKS/WTG/wg

*The Commonwealth of Massachusetts*
*Executive Office of Energy and Environmental Affairs*
*100 Cambridge Street, Suite 900*
*Boston, MA 02114*

Deval L. Patrick
GOVERNOR

Timothy P. Murray
LIEUTENANT
GOVERNOR

Richard K. Sullivan, Jr.
SECRETARY

Tel: (617) 626-1000
Fax: (617) 626-1181
http://www.mass.gov/envir

December 23, 2011

FINAL RECORD OF DECISION

| | |
|---|---|
| PROJECT NAME | : BioSquare Phase II |
| PROJECT LOCATION | : Boston |
| PROJECT WATERSHED | : Boston Harbor |
| EOEA NUMBER | : 12021 |
| PROJECT PROPONENT | : Boston University and Boston Medical Center |
| DATE NOTICED IN MONITOR | : December 7, 2011 |

Pursuant to the Massachusetts Environmental Policy Act (G. L., c. 30, s. 61-62I) and Sections 11.11 of the MEPA regulations (301 CMR 11.00), I have reviewed the Notice of Project Change (NPC) and request for a Phase I Waiver. I hereby grant a waiver that will allow the proponent to conduct lower level research, known as Biocontainment Safety Level (BSL) 2 in the National Emerging Infectious Disease Laboratories (NEIDL) Building prior to the submission of the Supplemental Final Environmental Impact Report (SFEIR) for the above project.

NPC Project Change Description

According to the NPC, the proposed project change consists of the utilization of approximately 65,280 square feet (sf) of BSL-2 and BSL-3 laboratory space within the completed 192,000 sf NEIDL Building prior to the completion of the additional risk assessment/SFEIR. The proponent is currently utilizing approximately another 96,000 sf of support space for offices, clinical research and lab support. Nearly three years after the building has been completed, the NIH's risk assessment has not yet been completed. The proponent estimates that it may take as much as a year before the risk assessment is completed and the SFEIR is subject to my review. Before the NEIDL Building is approved for 30,720 sf of BSL-4 laboratory use, the highest BSL level for a research laboratory, the general public will be provided with an opportunity to review and comment on the risk assessment and the SFEIR, and state and federal agencies will take action approving, denying, or conditioning the BSL-4 laboratory use. Additionally, the proponent estimates that six to nine months will be needed for any applicable administrative

and/or judicial review. The proponent's best estimate is that BSL-4 research would begin no earlier than October 2013.

The proponent would like to access the building for lower level biological research prior to the completion of the administrative and judicial reviews of the BSL-4 activities. The proponent has also stated that it will not commence actual BSL-3 level research until the risk assessment has been completed and considered by NIH. The proponent is accordingly seeking a "conditional approval" under MEPA. The proponent initially requested approval to operate the laboratory at the BSL-2 level starting this winter and would seek additional City and State regulatory approvals necessary for BSL-3 level operations so that BSL-3 research can begin immediately following the completion of the risk assessment by NIH, without my further review of the assessment. However, on October 24, 2011, the proponent sent a clarifying letter stating that the Waiver request is not conditioned upon any other action being taken by any other agency and is not a request that I improperly delegate any of my responsibilities under MEPA to other agencies.

Project History

In 1999, an Environmental Notification Form was submitted for the proposed project. The project required a mandatory EIR. In 2003, the DEIR was determined to be adequate. In the FEIR, the proposed project consisted of the development of 428,700 sf of medical research space, a 1,400 space parking garage (approximately 496,000 sf), and associated infrastructure on a 14.5-acre site along Albany Street in Boston. The project included the 192,000 sf NEIDL Building. The BioSquare Phase II project functions as an expansion of the BioSquare Phase I project (a.k.a. the University Associates Project, EEA #7034), which completed its EIR review process in 1991 and the Moakley Services Center Project (EEA #11883). On August 11, 2004, the FEIR for the BioSquare Phase II was determined to be adequate.

Following the issuance of that FEIR Certificate, a group of ten citizens commenced litigation against the proponent and other parties, challenging, among other things, the adequacy of the FEIR. In a Memorandum and Order dated July 31, 2006, the Court vacated the certification of the FEIR and remanded the matter to the then Secretary of Environmental Affairs for further administrative action in light of the Court's decision. Soon thereafter, the proponents petitioned the Appeals Court, pursuant to G. L. c. 231, s. 118, for interlocutory relief from the Superior Court's decision, and the matter was subsequently transferred to the Supreme Judicial Court (SJC). On December 13, 2007, the SJC rendered its decision in Allen v. BRA, et al, 450 Mass. 242 (2007), affirming the Superior Court decision and holding that: "the decision on the adequacy of the final EIR was arbitrary and capricious (1) in failing to consider likely damage to the environment caused by the release of a contagious pathogen, and (2) due to the developer's failure to address alternative locations for the project. In its decision, the SJC noted that the decision on the adequacy of the final EIR was arbitrary and capricious in that the "worst case scenario put forth by the proponent inadequately addressed the consequences of a release of contagious pathogens from the BioLab, potentially denying State Agencies the opportunity to

meaningfully review the environmental impact of such a release and consideration of the measures that would be necessary to mitigate environmental damage." Id. at 257.

As a result of the remand order from the Superior Court, the then Secretary issued a Certificate Following Remand on the FEIR on September 5, 2006, that required a Supplemental Final Environmental Impact Report (SFEIR). That certificate was not modified after the December 13, 2007 SJC affirmation of the Superior Court's remand[1].

The project has also undergone review under the National Environmental Policy Act (NEPA), and the National Institutes of Health (NIH) completed a Final Environmental Impact Statement and issued a Record of Decision in February, 2006. In response to issues raised in a federal court proceeding regarding the NIH Final Environmental Impact Statement (FEIS), the NIH completed additional reviews of the potential impacts of the BSL-4 Biolab, including a report entitled the *Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University* (DSER)[2], which was developed, in part, to address the Superior and SJC directive that the SFEIR provide additional worst case scenario analysis and evaluate the comparative levels of risk associated with alternative locations for the BSL-4.

In 2007, former Secretary Ian Bowles requested that the National Research Council (NRC) convene an expert committee to provide technical input on the DSER. Secretary Bowles asked that the Committee evaluate only the DSER, and not mitigation. The Committee was asked to review the DSER and meet to discuss the methodologies and analyses therein and to address the following specific questions pertaining to the scientific adequacy of the NIH Study:

- Determine if the scientific analyses in the NIH Study are sound and credible;
- Determine whether the proponent has identified representative worst case scenarios; and
- Determine, based on the study's comparison of risk associated with alternative locations, whether there is a greater risk to public health and safety from the location of the facility in one or another proposed location.

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[1] The 2006 Certificate required the SFEIR to evaluate an additional "worst case" scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The 2006 Certificate further stated that, in light of the Superior Court suggestion that smallpox, SARS, and the Ebola virus as potentially representing "worst case" contagious pathogens, the SFEIR should incorporate the analysis of anthrax from the FEIR to facilitate comparison and review. The 2006 Certificate also noted that the SFEIR should identify a feasible alternative location for the biocontainment building in a less densely populated area.

[2] The DSER was intended to form the scientific basis of the SFEIR, which Boston University has not yet filed for MEPA review.

The parties agreed that the Committee 's report would be limited to a technical review of the DSER, and that the Contractor, the National Research Council (NRC), would not make any findings or recommendations regarding the adequacy of any determinations or decisions made by any agency or department of the U.S. Government or the Commonwealth under NEPA or MEPA. Furthermore, NRC would not be responsible in any way for any such decisions or determinations. Thus, the questions addressed by the Committee solely pertain to the scientific adequacy of the risk assessment and other analytical methodologies used in the DSER and whether the report responds to former Secretary Bowles' questions in a scientifically sound and credible manner.

The committee's assessment was critical of the DSER, finding that it was not sound and credible, did not adequately identify and thoroughly develop worst-case scenarios, and did not contain the appropriate level of information to compare the risks associated with alternative locations. The report also raised specific concerns about agent selection, scenario development, modeling methodology, environmental justice issues, and risk communication.

As a result of the concerns raised by the NRC, NIH established its Blue Ribbon Panel (BRP) in March, 2008, to provide scientific and technical advice to NIH. This process culminated in the NRC committee delivering its third report in April, 2010, which found the proposed approaches to conducting the risk assessment suitable and well planned. Additionally, the NRC committee determined that the 13 pathogen agents selected for analysis were appropriate and comprehensive, and the expertise available on and to the assessment team seemed strong. The committee encouraged NIH and its contractor (Tetra Tech) to develop qualitative analyses (an explanation of the safety and risk profile) of all 13 pathogens in a manner that is clear and accessible to the public. The committee also suggested that the qualitative analyses in the body of the assessment be supplemented with results of quantitative modeling planned for five pathogens, with details provided in appendices. Further, the committee encouraged NIH to rely on data available from existing case studies, public health surveillance of the surrounding communities, and release incidents, not only to support its models but also to provide a complete and understandable picture for the public. The NRC committee again emphasized that the final risk assessment serve as an effective risk communication tool.

On September 22, 2010, NIH submitted and presented supplemental materials to the NRC committee, and after reviewing the material, the NRC committee concluded that it could not endorse NIH's supplemental materials and illustrative analyses. In summary, the results presented on September 22 were insufficient for the committee to find that the analyses presented thus far will lead to a scientifically and technically sound risk assessment. The illustrative results presented to date were not sufficiently documented and supported to convince the committee that the contractors are on track to completing a comprehensive assessment of risk for the NEIDL facility. The committee also noted that based on the limited information provided by NIH's contractor, the information was not responsive to the committee's recommendation that qualitative analyses addressing the three questions raised in its 2008 letter report be prepared first and that these qualitative analyses then be supplemented by quantitative analysis through

modeling using available data on the agents in question. The NRC committee also found that any modeling be used in a context that reflects scientific knowledge and experience. The committee reiterated the need to include actual data based on published results in the models where possible, and that the models be transparent and couched in the context of the risk assessment and address appropriate uncertainties. As it currently stands, BU has yet to complete its risk assessment of the 13 pathogens that are under review by the NRC committee.

Against this backdrop it is important to note two important aspects of the pending Superior Court decision: (1) the inclusion of "contagious pathogens" in its requirement for an SFEIR and (2) strong litigation language in a footnote relative to the Secretary's inability to delegate his authority under MEPA to a federal agency. First, the Superior Court found that "no EIR regarding the BioLab project can rationally be found to comply with MEPA that failed to consider any 'worst case' scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen..." The NPC does not outline or examine the differentiation between the BSL-3 and BSL-4 risk assessment being undertaken by NIH. What is clear is that a risk assessment is being carried out on BSL-3 pathogens. Some comment letters have pointed out that certain BSL-3 agents may present more serious potential risks than BSL-4 agents and may be described as contagious pathogens[3].

Secondly, the Superior Court has required a risk assessment for the more serious contagious pathogens and has emphasized that the Secretary may not delegate his requirement to examine the issues before MEPA to a federal authority. Specifically, the Court states: "all parties acknowledge that the Secretary may not properly delegate her responsibility to ensure an adequate Final EIR to any federal agency. Nor may she certify an inadequate EIR based on her expectation that the issues inadequately analyzed will later be adequately analyzed in a federal EIR." Ten Residents vs. Boston Redevelopment Authority, 24 Mass. L. Rep. 324, fn10 (2006). This judicial edict continues to govern my ability to render MEPA decisions with respect to the BioLab. The ongoing risk assessment development brought about by both federal and state court decisions contains some BSL-3 pathogens, as well as BSL-4 pathogens. Therefore, in spite of the proponent's clarifying letter, I am legally barred from acting on the proponent's waiver

[3] In the November 7, 2007 report prepared by an expert committee that was convened by the National Research Council to review the *Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University* (DSER) that was prepared in connection with the National Environmental Policy Act, the NRC committee noted that: "Agents such as *Yersinia pestis* (pneumonic plague), influenza virus (including virulent strains), SARS virus, and highly pathogenic avian influenza virus are often studied in BSL-3 and other lower-level containment facilities." See NRC Report, page 8. The Committee also noted that "the selection of agents for the worst case scenario was appropriately not limited to BSL-4 agents as some agents handled in BSL-3 facilities may present more serious potential risks than BSL-4 agents. Agents are categorized for BSL-4 containment because they cause deadly disease for which there is no treatment, not because they are highly infectious and cause widespread disease." Id.

request for BSL-3 level research until I am able to independently review the risk assessment for the contagious pathogens proposed for study by BU at the BioLab. I have reached this conclusion only as it relates to BSL-3 and the intersection of the Court's requirements, after consultation with counsel, including the Office of the Attorney General. In addition, I have requested that the Office of the Attorney General submit the NPC Certificate to the Court as an informational filing.[4]

Jurisdiction and Permitting

The project as a whole is subject to a mandatory EIR pursuant to Section 11.03(6)(a)(6) and (7) of the MEPA regulations because it will (1) require State Agency Permits (2) generate 3,000 or more new vehicle trips per day and 3) provide greater than 1,000 new parking spaces at a single location. It required a Vehicular Access Permit from the Massachusetts Department of Transportation (MassDOT). After it has received all the necessary reviews and approvals for lower level research operations, the proponent must obtain a Sewer Use Discharge Permit from the Massachusetts Water Resources Authority (MWRA). The project required a minor modification to an existing Urban Renewal Plan from the Boston Redevelopment Authority (BRA). The proponent was required to comply with the National Pollutant Discharge Elimination System (NPDES) General Permit for stormwater discharges from a construction site.

Because the proponent has received a transfer of state land for a portion of the project[5], MEPA jurisdiction over this portion of the project subject to the land transfer is broad and extends to all aspects of the project that are likely, directly or indirectly, to cause Damage to the Environment, as defined in the MEPA regulations. In relation to this NPC and the NEIDL Building, the State Agency Action involved is a Sewer Use Discharge Permit from the MWRA.

Summary of Potential Environmental Impacts

There is no identified increase in traffic generation, parking demand and stormwater flow from the proposed project change. The project has been designed to meet or exceed the performance standards in the Massachusetts Stormwater Policy. The project has access from the Frontage Road-South and from existing streets that connect to Albany Street.

The BioSquare Phase II project added 1400 structured parking spaces. On a typical

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[4] To differentiate BSL-3 and BSL-4 from BSL-2, I note that none of the 13 pathogens being studied in the NIH risk assessment are BSL-2 agents. While the Superior Court decision did not specifically remove BSL-2 from its risk assessment requirements, it is clear that the Court was asking that highly dangerous pathogens be examined, not the more moderate BSL-2 pathogens.

[5] The plaintiffs have challenged the efficacy of the transfer of land in the litigation now pending before the Superior Court, and that matter remains before the Court as well.

weekday, the proponent has estimated that the total project will generate approximately 3,115 unadjusted weekday vehicle trips. The corresponding weekday morning and evening peak hour traffic volume increases are approximately 436 and 419 unadjusted weekday vehicle trips per hour respectively. The low level research portion of the NEIDL Building should have fewer trips than the total buildings utilization that was estimated at 491 adjusted weekday vehicle trips, 70 adjusted morning and 70 adjusted evening weekday vehicle trips. This amount of vehicle trips should have a minimal effect on area traffic.

Summary of Proposed Mitigation Measures

The NEIDL Building must meet applicable city, state and federal safety regulations. For the entire BioSquare Phase II, the proponent has committed to provide 4:1 Infiltration/Inflow (I/I) removal from the wastewater system. To date approximately 60,000 gallons per day (gpd) of the 183,000 gallons of I/I removal required for the full operation of the NEIDL Building has been accomplished. The remaining I/I removal will be accomplished through two projects that are awaiting engineering review by the Boston Water and Sewer Commission and will be implemented when the building becomes operational. The proponent created a pocket park along Albany Street. The proponent modified the East Newton/Albany Street intersection as a four-way intersection. It will provide traffic and parking management plan for Albany Street between East Newton and Union Park Streets to the Boston Transportation Department as part of the MassDOT Access Permit, which has not yet been issued. The proponent rebuilt Albany Street sidewalks and provided pavement markings along Albany Street, including lane striping and crosswalks and directional signing at the site. It installed fiber optic cables along a portion of Albany Street. The proponent will provide the City of Boston with up two variable message boards for real-time traffic information as part of the MassDOT Access Permit.

The proponent has instituted a Transportation Demand Management (TDM) program that includes membership in a Transportation Management Association, Transportation Solutions for Commuters. The TDM program included a 25 percent transit pass subsidy program to Boston Medical Center employees, a ridesharing program, preferential parking, a guaranteed ride home, direct deposit payrolls, shuttle bus service to the Orange and Red Lines, Zipcar, flex-time, and telecommuting. The proponent provided safe and secure bicycle storage/parking areas (up to 24 bicycle parking spaces in the garage 610 Albany Street) and approximately 170 bicycle parking spaces within a block of the site and shower facilities for employees.

Standards for All Waivers

The MEPA regulations at 301 CMR 11.11(1) state that I may waive any provision or requirement in 301 CMR 11.00 not specifically required by MEPA and may impose appropriate and relevant conditions or restrictions, provided that I find that strict compliance with the provision or requirement would:

(a) result in an undue hardship for the proponent, unless based on delay in compliance by the proponent; and
(b) not serve to avoid or minimize Damage to the Environment.

Determinations for a Phase I Waiver

The MEPA regulations at 301 CMR 11.11(4) state that, in the case of a partial waiver of a mandatory EIR review threshold that will allow the proponent to proceed with Phase I of the project prior to preparing an EIR, I shall base the finding required in accordance with 301 CMR 11.11(1)(b) on a determination that:

(a) the potential environmental impacts of Phase I, taken alone, are insignificant;
(b) ample and unconstrained infrastructure facilities and services exist to support Phase I;
(c) the project is severable, such that Phase I does not require the implementation of any other future phase of the project or restrict the means by which potential environmental impacts from any other phase of the project may be avoided, minimized or mitigated; and
(d) the agency action(s) on Phase I will contain terms such as a condition or restriction, so as to ensure due compliance with MEPA and 301 CMR 11.00 prior to commencement of any other phase of the project.

Findings

Based upon the information submitted by the proponent and after consultation with the state permitting agencies, I find that the Waiver Request for BSL-2 laboratory research has merit and that the proponent has demonstrated that the proposed project meets the standards for all waivers at 301 CMR 11.11(1). I find that strict compliance with the requirement to submit an SFEIR prior to the utilization of BSL-2 laboratory research space would result in an undue hardship for the proponent and would not serve to avoid or minimize Damage to the Environment. In accordance with 301 CMR 11.11(4), the latter finding is based on my determination that:

(a) the potential environmental impacts of Phase I (utilization of BSL-2 laboratory research), taken alone, are insignificant;

- Biological research at levels below BLS-3 is being safely conducted by the proponent at its other facilities and at many locations throughout the Commonwealth. Through the Boston Public Health Commission (BPHC) review and permitting, the proponent will be working closely with City officials in achieving a positive outcome for safety concerns and in improving health care research.

- The site on which the NEIDL Building has been constructed has no remaining areas of environmental impacts anticipated. Traffic impacts associated with

the utilization of the NEIDL Building were analyzed in the DEIR and FEIR and mitigation has been implemented. Considered by itself, the NEIDL Building, with estimates of approximately 930 unadjusted trips and wastewater generation of approximately 17,600 gallons per day (gpd), does not exceed mandatory EIR thresholds.

(b) ample and unconstrained infrastructure facilities and services exist to support BSL-2 laboratory research at the NEIDL Building;

- The building has been constructed and has the infrastructure necessary to support the operation of the building, including redundant water, sewer, electrical, and HVAC services, extensive security controls, and vehicle access and parking facilities. The existing driveways will continue to be used for ingress and egress. No additional infrastructure is necessary to make the building operational.

(c) the project is severable, such that BSL-2 laboratory research at the NEIDL Building does not require the implementation of any other future phase of the project or restrict the means by which potential environmental impacts from any other phase of the project may be avoided, minimized or mitigated; and

- The proposed interim use of the facility is completely separable from the potential future use of the project for BSL-3 and BSL-4 research use. While the building has been designed and constructed as an integral research facility, it has completely separate laboratories with independent infrastructure to support the different BSL levels of research. Thus, the decision on the future use of the building for BSL-3 and BSL-4 research is not constrained or affected by the use of the balance of the building's research laboratories.

(d) the agency action(s) for the utilization of the BSL-2 research laboratories in the NEIDL Building will contain terms such as a condition or restriction, so as to ensure due compliance with MEPA and 301 CMR 11.00 prior to commencement of any other phase of the project.

- The utilization of BSL-2 research laboratory space will require an MWRA Industrial Wastewater Discharge Permit. This proposed work will be done in strict accordance with existing MWRA protocol and requirements. The proponent is merely requesting that I allow this aspect of the project to move forward in advance of the completion of the SFEIR. I hereby direct the MWRA to incorporate clear and enforceable language into its Sewer Use Discharge Permit to ensure that only BSL-2 work be conducted at the NEIDL at this time.

Conclusion

Based on these findings, I determined that this waiver request has merit, and accordingly issued a Draft Record of Decision (DROD) that was published in the Environmental Monitor on December 7, 2011, in accordance with 301 CMR 11.15(2), which began the public comment period. The public comment period lasted for 14 days and ended on December 21, 2010. I hereby **grant** the waiver requested for this project change, which will allow the proponent to proceed with all applicable permitting necessary for the utilization of BSL-2 research space in the NEIDL Building prior to submitting the SFEIR for the entire project, subject to the above findings.

December 23, 2011
DATE

Richard K. Sullivan Jr.

Comments received:

Fort Point Associates, 12/14/11
Marc Pelletier, 12/20/11
Massachusetts Water Resources Authority, 12/21/11
Anderson & Krieger, 12/21/11
George Corey, 12/22/11
Fort Point Associates, 12/22/11

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Welcome to the *Environmental Monitor* page. In order to access previous issues of the *Environmental Monitor* published since the launch of the new MEPA website on September 23, 2009, please select the year and publication date from the following drop-down lists.

In order to access issues of the *Environmental Monitor* published from 2002 through September 9, 2009, please click on the Environmental Monitor Archives link.

Select Year: 2012

Select Publication Date: 08/08/2012

Back Environmental Monitor Archives

# MEPA Environmental Monitor

**Aug 08, 2012**
Volume 78, Issue 7

The Environmental Monitor
a publication of the
Massachusetts Executive Office of Energy and Environmental Affairs
Deval L. Patrick, Governor
Richard K. Sullivan, Jr., Secretary

**The Environmental Monitor** provides information on projects under review by the Massachusetts Environmental Policy Act (MEPA) office, recent MEPA decisions of the Secretary of Energy & Environmental Affairs, and public notices from environmental agencies. Please note that the links on this page require the use of Adobe Acrobat Reader®, which is available free of charge at http://www.adobe.com/products/acrobat/readstep.html.



## Projects Submitted 07/17/2012 to 07/31/2012

### Environmental Notification Forms

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|
| 14932 | Proposed Municipal Water Supply Wells | Dartmouth | 09/11/2012 | Douglas DeNatale (978) 905-2180 | Rick Bourré (617) 626-1130 |
| 14933 | Single Family Dwelling Addition | Falmouth | 08/28/2012 | Stanley Humphries (508) 746-9491 | Holly Johnson (617) 626-1023 |
| 14934 | Five Corners Intersection Improvement Project | Lancaster | 08/28/2012 | Mark Kolonoski (617) 973-8281 | Anne Canaday (617) 626-1035 |
| 14935 | Hewitts Point Sewall Revetment Repairs | Marshfield | 08/28/2012 | Russell Titmuss (508) 533-6666 | Holly Johnson (617) 626-1023 |

| | | | | | |
|---|---|---|---|---|---|
| 14936 | Reconstruction of Route 110 | Merrimac | 08/28/2012 | Mark Kolonoski (617) 973-8281 | Anne Canaday (617) 626-1035 |
| 14937 | Salem Harbor Station Redevelopment | Salem | 08/28/2012 | Joseph Freeman (508) 903-2000 | Deirdre Buckley (617) 626-1044 |
| 14938 | Westborough Woods | Westborough | 08/28/2012 | Michael Scott (508) 366-6552 | William Gage (617) 626-1025 |
| 14939 | Woburn Country Club Ninth Fairway Pond Restoration Project | Woburn | 08/28/2012 | Paul McLaughlin (781) 883-1935 | William Gage (617) 626-1025 |

### Environmental Notification Forms - Site Visits

| EEA No. | Date | Time | Location |
|---|---|---|---|
| 14935 | 08/15/2012 | 1:00 PM | Project Site – walkway near the center groin on Ocean Street opposite Puritan Street, Marshfield |
| 14937 | 08/21/2012 | 9:00 AM | City Hall Annex (3rd Floor)- 120 Washington Street, Salem |
| 14938 | 08/20/2012 | 10:30 AM | Waterman Design Associates - 31 East Main Street, Westborough |
| 14939 | 08/20/2012 | 2:00 PM | Woburn Country Club - 5 Country Club Road, Woburn |

### Environmental Impact Reports

| EEA No. | Project Name | Location | Document Type | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|---|
| 14822 | Interstate Reliability Project | Millbury, Sutton, Northbridge, Uxbridge and Millville | Single EIR | 09/07/2012 | Mary Ellen Radovanic (617) 896-4506 | Anne Canaday (617) 626-1035 |

### Notices of Project Change

No Data Found.

## Other Projects Under Review

### Environmental Notification Forms

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|
| 14923 | RiverMills at Chicopee Falls | Chicopee | 08/10/2012 | Lauren DeVoe (617) 924-1770 | Deirdre Buckley (617) 626-1044 |
| 14924 | Project First Light Destination Resort Casino | Taunton | 08/14/2012 | David Hewett (978) 897-7100 | Holly Johnson (617) 626-1023 |
| 14926 | Osterman Commerce Park | Northbridge | WITHDRAWN | Mark Anderson (508) 266-2066 | William Gage (617) 626-1025 |
| 14927 | Phase 2 Comprehensive Wastewater Management Plan | Groton | 08/14/2012 | Rosemary Blacquier (781) 251-0200 | Deirdre Buckley (617) 626-1044 |
| 14928 | Lee Sanitary Landfill Photovoltaic Array | Lee | 08/14/2012 | Richard Barthelmes (978) 777-7250 x12 | Nicholas Zavolas (617) 626-1030 |
| 14929 | 141 Eel Point Road | Nantucket | 08/14/2012 | Brian Madden (508) 746-9491 | Holly Johnson (617) 626-1023 |
| 14930 | Whitin Wellfield Water Treatment Facility | Northbridge | 08/14/2012 | Jack O'Connell (508) 303-9400 | William Gage (617) 626-1025 |
| 14931 | Little Quitticus Pond Solar Photovoltaic System | Rochester | 08/14/2012 | Samuel Moffett (978) 970-5600 | Rick Bourré (617) 626-1130 |

### Environmental Impact Reports

| EEA No. | Project Name | Location | Document Type | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|---|
| 13888 | North Bedford Street Business Park | East Bridgewater | FEIR | WITHDRAWN | David Kelly (781) 843-4333 | Anne Canaday (617) 626-1035 |
| 14594 | New Source of Groundwater Supply | Westfield | DEIR | 08/24/2012 | Raymond Talkington (603) 773-0075 | Holly Johnson (617) 626-1023 |
| 14634 | Proposed Retail Development | Wareham | FEIR | 08/10/2012 | Andrew Manning (508) 480-9900 | Nicholas Zavolas (617) 626-1030 |
| 14784 | South Sandwich Village | Sandwich | DEIR | 08/10/2012 | Scott Horsley (508) 833-6600 | William Gage (617) 626-1025 |

### Notices of Project Change

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|

| | | | Due | | |
|---|---|---|---|---|---|
| 14610 | Norton Commerce Center | Norton | 08/10/2012 | Mark Dibb (508) 510-6108 | William Gage (617) 626-1025 |
| 14755 | Martha's Vineyard Hybrid Cable Project (previously reviewed as Fiber Optic Cable Project) | Falmouth and Tisbury | 08/14/2012 | Lester Smith (978) 897-7100 | Anne Canaday (617) 626-1035 |

# Secretary's Certificates 07/17/2012 to 07/31/2012

## Environmental Notification Forms

| EEA No. | Project Name | Location | Action | Action Date |
|---|---|---|---|---|
| 14896 | Comprehensive Wastewater Management Plan | Barnstable | Requires an Environmental Impact Report | 07/20/2012 |
| 14909 | New Brighton Landing | Boston (Brighton) | Requires an Environmental Impact Report | 07/27/2012 |
| 14916 | Boston University School of Law | Boston | Does not require an Environmental Impact Report | 07/27/2012 |
| 14917 | Route 79/I-195 Interchange Reconstruction Project | Fall River | Does not require an Environmental Impact Report | 07/27/2012 |
| 14918 | Harwich Artificial Reef | Harwich | Does not require an Environmental Impact Report | 07/27/2012 |
| 14919 | Gateway Commons Commercial Development | Lakeville | Requires an Environmental Impact Report | 07/27/2012 |
| 14920 | Salem Intermodal Station Project | Salem | Does not require an Environmental Impact Report | 07/27/2012 |
| 14921 | T.H. Glennon Co., Inc. | Salisbury | Does not require an Environmental Impact Report | 07/20/2012 |

## Environmental Impact Reports

No Data Found.

## Notices of Project Change

No Data Found.

## Records of Decision

| EEA No. | Project Name | Location | Comments Due | Action | Action Date |
|---|---|---|---|---|---|
| 14920 | Salem Intermodal Station Project | Salem | 08/22/2012 | Secretary proposes to grant a Full EIR Waiver | 07/27/2012 |
| 6181 | Mixed Use Project | Littleton | N/A | Secretary has granted a Full EIR Waiver | 08/01/2012 |

## Special Review Procedures

No Data Found.

## Public Benefits Determinations

No Data Found.

## Advisory Opinions

No Data Found.

# Requests for Advisory Opinion

No Data Found.

# Public Notices

| Agency | Notice Type | Location |
|---|---|---|
| DEP | Notice of Application for a 401 Water Quality Certification | Weston |
| DEP | Notice of Application for a 401 Water Quality Certification | Auburn and Oxford |
| DEP | Notice of Application for a Water Management Act Permit | Blackston River Basin |
| DEP | Notice of Application for a 401 Water Quality Certification | Fall River |
| DEP | Notice of a Draft Operating Permit Renewal | GenOn Kendall LLC - Cambridge |

| | | |
|---|---|---|
| DEP | Notice of a Draft Operating Permit Renewal | Stony Brook Energy Center - Ludlow |
| DEP | Notice of Application for a 401 Water Quality Certification Variance | Methuen |
| DEP | Notice of Public Meeting, re: Response Action Outcome | DuBois Disposal Site - Watertown |
| DEP | Notice of Application for a Water Management Act Permit | Concord River Basin |
| DEP | Notice of Public Meetings, re: Annual Update and Status Report for Transit Projects | Boston |
| NIH | Notice of Availability of Final Supplementary Risk Assessment for the Boston University National Emerging and Infectious Diseases Laboratories (NIEDL) | Boston (South End) |
| WRC | Notice of Request for Determination of Insignificance under the Interbasin Transfer Act | Groton |

Welcome to the *Environmental Monitor* page. In order to access previous issues of the *Environmental Monitor* published since the launch of the new MEPA website on September 23, 2009, please select the year and publication date from the following drop-down lists.

In order to access issues of the *Environmental Monitor* published from 2002 through September 9, 2009, please click on the Environmental Monitor Archives link.

Select Year: 2012

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Back Environmental Monitor Archives

# MEPA Environmental Monitor

**Apr 11, 2012**
Volume 77, Issue 11

The Environmental Monitor
a publication of the
Massachusetts Executive Office of Energy and Environmental Affairs
Deval L. Patrick, Governor
Richard K. Sullivan, Jr., Secretary

**The Environmental Monitor** provides information on projects under review by the Massachusetts Environmental Policy Act (MEPA) office, recent MEPA decisions of the Secretary of Energy & Environmental Affairs, and public notices from environmental agencies. Please note that the links on this page require the use of Adobe Acrobat Reader®, which is available free of charge at http://www.adobe.com/products/acrobat/readstep.html.



## Projects Submitted 3/16/2012 to 4/2/2012

### Environmental Notification Forms

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|
| 14881 | UMass Lowell South Campus Parking Structure | Lowell | 05/01/2012 | Doug Vigneau (617) 924-1770 | Anne Canaday (617) 626-1035 |
| 14882 | Dock Refurbishment Project | Braintree | 05/01/2012 | Russell Titmuss (508) 533-6666 | William Gage (617) 626-1025 |
| 14883 | Lechmere Viaduct/Steam Pipeline Project | Cambridge and Boston | 05/01/2012 | Laura Rome (978) 897-7100 | Nicholas Zavolas (617) 626-1030 |
| 14884 | Herring Realty Trust Elevated Driveway | Harwich | 05/01/2012 | Timothy Brady (508) 255-7120 | Holly Johnson (617) 626-1023 |

| | | | | | |
|---|---|---|---|---|---|
| 14885 | North Pier Improvement Project | Marshfield | 05/01/2012 | Gregory Robbins (781) 278-4825 | Holly Johnson (617) 626-1023 |
| 14886 | Memorial Pond Dredging | Mount Washington | 05/01/2012 | Gail Garrett ((413) 578-9264 | Deirdre Buckley (617) 626-1044 |
| 14887 | Hammond Pond Walkway Project | Newton | 05/01/2012 | Kathy Bradford (978) 740-0096 | Anne Canaday (617) 626-1035 |
| 14888 | Commercial Redevelopment | Winthrop | 05/01/2012 | Richard Salvo (781) 231-1349 | William Gage (617) 626-1025 |

### Environmental Notification Forms - Site Visits

| EEA No. | Date | Time | Location |
|---|---|---|---|
| 14881 | 04/25/2012 | 12:00 PM | Campus Parking Lot on Broadway Street, Lowell |
| 14883 | 04/18/2012 | 12:30 PM | Museum of Science Atrium - 1 Science Park, Boston |
| 14884 | 04/25/2012 | 9:30 AM | Brax Landing Restaurant parking lot – 705 Route 28, Harwich |
| 14885 | 04/25/2012 | 12:30 PM | Harbormaster's Office, Town Pier - 100 Central Street, Marshfield |
| 14887 | 04/25/2012 | 9:30 AM | Boylston Street and Hammond Pond Parkway, Newton |
| 14888 | 04/26/2012 | 10:00 AM | Project Site - 49 Main Street, Winthrop |

### Environmental Impact Reports

No Data Found.

### Notices of Project Change

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|
| 14579 | Manchester Inner Harbor Dredging | Manchester-by-the-Sea | 05/01/2012 | Christine Player (508) 748-0937 | Aisling O'Shea (617) 626-1024 |

## Other Projects Under Review

### Environmental Notification Forms

| EEA No. | Project Name | Location | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|
| 14875 | Arborcrest Estates | Dighton | 05/01/2012 | Stuart Clark (401) 729-7241 | William Gage (617) 626-1025 |
| 14877 | Mill Pond Improvements | Barnstable (Marstons Mills) | 06/08/2012 | Neal Price (508) 833-6600 | Nicholas Zavolas (617) 626-1030 |
| 14878 | Bournes Pond Improvements | Falmouth | 06/08/2012 | Neal Price (508) 833-6600 | Nicholas Zavolas (617) 626-1030 |
| 14880 | Emerald Street Reconstruction Project | Winchendon | WITHDRAWN | David Loring (413) 562-1600 | Anne Canaday (617) 626-1035 |

### Environmental Impact Reports

| EEA No. | Project Name | Location | Document Type | Comments Due | For Copies | MEPA Analyst |
|---|---|---|---|---|---|---|
| 14089 | Palmer Motorsports Park | Palmer | FEIR | 04/20/2012 | Thomas Speight (413) 731-9898 | Holly Johnson (617) 626-1023 |
| 14643 | Hampden County Reliability Project | Palmer, Monson and Hampden | FEIR | 04/20/2012 | Colin Duncan (978) 656-3615 | Aisling O'Shea (617) 626-1024 |
| 14803 | EF Office Building | Cambridge | Single EIR | 04/20/2012 | Daniel Padien (617) 924-1770 | Holly Johnson (617) 626-1023 |
| 14838 | First Bristol Mixed Use Development | Westport | DEIR | 04/20/2012 | Richard Rheaume (508) 947-0050 | Aisling O'Shea (617) 626-1024 |
| 8696 | L.G. Hanscom Field | Bedford | Environmental Status & Planning Report Scope | 05/11/2012 | Tom Ennis (617) 568-3546 | William Gage (617) 626-1025 |

### Notices of Project Change

No Data Found.

## Secretary's Certificates 3/16/2012 to 3/31/2012

### Environmental Notification Forms

| EEA No. | Project Name | Location | Action | Action |
|---|---|---|---|---|

| | | | | Date |
|---|---|---|---|---|
| 14853 | Ink Block | Boston (South End) | Requires an Environmental Impact Report | 03/16/2012 |
| 14862 | Fairhaven Shipyard – North Yard Construction of Additional Service Bays | Fairhaven | Does not require an Environmental Impact Report | 03/23/2012 |
| 14864 | Town Landing on the Parker River | Newbury | Does not require an Environmental Impact Report | 03/23/2012 |
| 14865 | Home Market Foods Wastewater Treatment Plant Modifications | Norwood | Does not require an Environmental Impact Report | 03/23/2012 |
| 14866 | Knowles Crossing Water Treatment Plant | Truro | Does not require an Environmental Impact Report | 03/23/2012 |

### Environmental Impact Reports

| EEA No. | Project Name | Location | Document Type | Action | Action Date |
|---|---|---|---|---|---|
| 14266 | Queset Commons | Easton | FEIR | Adequately and properly complies with MEPA | 03/30/2012 |
| 14634 | Proposed Retail Development | Wareham | DEIR | Adequately and properly complies with MEPA | 03/16/2012 |
| 14815 | Proposed Medical Office Building | Norwell | Single EIR | Adequately and properly complies with MEPA | 03/16/2012 |
| 14817 | Proposed Retail Development | Seekonk | DEIR | Adequately and properly complies with MEPA | 03/30/2012 |

### Notices of Project Change

| EEA No. | Project Name | Location | Action | Action Date |
|---|---|---|---|---|
| 10908 | Wastewater Treatment Plant Expansion Project | Provincetown | Does not require an Environmental Impact Report | 03/23/2012 |
| 4895 | BFI Fall River Landfill – Area 3 Landfill | Fall River | Does not require an Environmental Impact Report | 03/23/2012 |

### Records of Decision

| EEA No. | Project Name | Location | Comments Due | Action | Action Date |
|---|---|---|---|---|---|
| 14572 | Ludlow Mills Preservastion and Redevelopment Project | Ludlow | N/A | Secretary has granted a Phase 1 Waiver | 03/27/2012 |

### Special Review Procedures

| EEA No. | Project Name | Location | Action | Action Date |
|---|---|---|---|---|
| 14881 | University of Massachusetts Lowell | Lowell | Secretary has established a Special Review Procedure | 03/23/2012 |

### Public Benefits Determinations

No Data Found.

### Advisory Opinions

No Data Found.

## Requests for Advisory Opinion

| Project Name | Location | Comments Due | MEPA Analyst |
|---|---|---|---|
| Pepperell Hydro Company Penstock Replacement Project | Pepperell | 05/01/2012 | Rick Bourré (617) 626-1130 |
| Proposed Pipeline Replacement Project | Westfield | 05/01/2012 | Rick Bourré (617) 626-1130 |

## Public Notices

| Agency | Notice Type | Location |
|---|---|---|
| City of Boston/EEA | Notice of Quarterly Meeting of City/State Groundwater Working Group | Boston |
| CZM | Notice of Federal Consistency Reviews | Gosnold (Cuttyhunk) and Marshfield |

| | | |
|---|---|---|
| DAR | Notice of Submission of a Yearly Operational Plan | Fore River Transportation Corporation |
| DAR | Notice of Submission of a Yearly Operational Plan | Massachusetts Coastal Railroad |
| DAR | Notice of Submission of a Yearly Operational Plan | Massachusetts Bay Commuter Railroad |
| DAR | Notice of Submission of a Yearly Operational Plan | Rovidence and Worcester Railroad Company |
| DAR | Notice of Submission of a Yearly Operational Plan | Town of Scituate |
| DAR | Notice of Submission of a Yearly Operational Plan | AMTRAK National Passenger Railroad Corporation |
| DAR | Notice of Submission of a Yearly Operational Plan | Bay Colony Railroad Corporation |
| DAR | Notice of Submission of a Yearly Operational Plan | City of Chelsea |
| DAR | Notice of Submission of a Yearly Operational Plan | CSX Transportation, Inc. |
| DAR | Notice of Submission of a Yearly Operational Plan | Town of Mansfield |
| DAR | Notice of Submission of a Yearly Operational Plan | Massachusetts Bay Transportation Authority (MBTA) Rapid Transit System |
| DAR | Notice of Submission of a Yearly Operational Plan | Massachusetts Department of Transportation Highway Division |
| DAR | Notice of Submission of a Yearly Operational Plan | Town of Wellesley |
| DAR | Notice of Submission of a Yearly Operational Plan | Pioneer Valley Railroad Company |
| DCR | Notice of Public Meeting, re: Resource Management Plan | Harold Parker and Boxford State Forests |
| DEP | Notice of Application for a Chapter 91 License | Plymouth |
| DEP | Notice of Application for Site Assignment | Fitchburg |
| DEP | Notice of Availability of Draft Addendum: Final Pathogen Total Maximum Daily Loads (TMDL) | Cape Cod Watershed |
| DEP | Notice of Application for a 401 Water Quality Variance and a Wetlands Protection Act Variance | Needham and Wellesley |
| DEP | Notice of Application for a Groundwater Discharge Permit | Westford |
| NIH | Notice of Availability of Draft Supplementary Risk Assessment | Boston University National Emerging and Infectious Diseases Laboratory - Boston (South End) |

# Appendix 2

## DISTRIBUTION LIST

# APPENDIX 2: DISTRIBUTION LIST

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205B Lowell Street
Wilmington , MA 01887

Brona Simon, Executive Director
Massachusetts Historical Commission
220 Morrissey Boulevard
Boston, MA 02125

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MA Department of Transportation
Public Private Development Unit
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Boston, MA 02201

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State House, Room 234
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Boston, MA 02116

Dudley Branch
65 Warren Street
Roxbury MA 02119

Grove Hall Branch
41 Geneva Avenue
Dorchester, MA 02121

South End Branch
685 Tremont Street
Boston, MA 02118

# Appendix 3

# PROPOSED SECTION 61 FINDINGS

# Draft Section 61 Findings

| | |
|---|---|
| **Project Name:** | **BioSquare Phase II - NEIDL** |
| **Project Location:** | **South Boston, Massachusetts** |
| **Project Proponent:** | **Biosquare Realty Trust** |
| **EOEA File No.:** | **#12021** |

# DRAFT FINDING BY THE MASSACHUSETTS DEPARTMENT OF TRANSPORTATION HIGHWAY DIVISION (EXCAVATIONS OR DRIVEWAY OPENINGS ON STATE HIGHWAYS) UNDER M.G.L. CHAPTER 81: SECTION 21

The Massachusetts Department of Transportation ("MassDOT") declares as follows:

## Introduction

Massachusetts General Laws, Chapter 30, section 61 ("Section 61") requires that "[a]ll agencies, departments, boards, commission and authorities of the Commonwealth shall review, evaluate, and determine the impact on the natural environment of all works, projects, or activities conducted by them and shall use all practical means and measures to minimize damage to the environment. Any determination made by an agency of the Commonwealth shall include a finding describing that all feasible measures have been taken to avoid or minimize said impact." The finding required by Section 61 "shall be limited to those matters which are within the scope of the environmental impact report, if any, required [on a project]." M.G.L. c. 30. S. 62A

Biosquare Realty Trust ("Proponent"), a trust whose beneficiaries are Boston Medical Center Corporation (BMC) and the Trustees of Boston University, is developing the National Emerging Infectious Diseases Laboratories ("NEIDL") as part of the second phase of the BioSquare Research Park in the South End of Boston. The first phase, BioSquare Phase I, was approved by the BRA and MEPA in 1991. The NEIDL will provide additional medical research space to serve the needs of the medical and educational institutions and hospitals in the area.

The NEIDL project will require a Highway Access permit from MassDOT for access to Frontage Road Southbound. Therefore, MassDOT must issue such a finding.

## MEPA Review

An Environmental Notification Form (ENF) for the BioSquare Phase II Project was prepared and filed in August of 1999 and on October 11, 1999 the Secretary of the Executive Office of Environmental Affairs (the Secretary) issued a Certificate on the ENF specifying the scope for a Draft Environmental Impact Report (EIR). The Draft EIR was filed with the Secretary on September 30, 2003. The Secretary issued the Certificate on the Draft EIR on December 1, 2003. The Final EIR was filed with the Secretary on July 30, 2004. The Secretary issued the Certificate on the Final EIR on November 15, 2004. Following the issuance of that certificate, litigation was commenced in Superior Court challenging the adequacy of the FEIR. In July 2006, the Superior Court vacated the Certificate and remanded the matter to the Secretary for further administrative action. The Secretary issued a Certificate in September 2006 requesting the filing of a Supplemental Final Environmental Impact Report (SFEIR). The Scope of the SFEIR includes only the NEIDL facility. The Supplemental Final Environmental Impact Report was filed on January 9, 2013.

## Project Description

Biosquare Realty Trust is developing the site into approximately 428,700 sf of biomedical research and office space with associated parking. The portion of BioSquare Phase II currently under MEPA review is Building F, the NEIDL building, which consists of 192,000 sf of biomedical research facilities.

The NEIDL facility will utilize Frontage Road Southbound as a major access point for the site. Therefore, a highway access permit is required from the Massachusetts Department of Transportation.

### Mitigation Measures

The proposed access points to Frontage Road Southbound will effectively shift vehicle trips from Massachusetts Avenue and Albany Street to the I-93 Frontage Road Southbound. The roadway mitigation associated with the NEIDL at BioSquare will include the following:

- The proponent will construct a right-in/right-out driveway to Frontage Road Southbound;
- The proponent will modify the signalized intersection of East Newton Street and Albany Street as a four-way intersection; and
- The proponent will develop a traffic and parking management plan for Albany Street between East Newton Street and Union Park Street. The plan would convert Albany Street to a three-lane cross-section that typically consists of a single travel lane in each direction and a center left-turn lane. No widening of the street would occur. The plan would also include recommendations for changes to the existing on-street parking regulations.
- The proponent will continue to participate in programs offered by the Transportation Solutions for Commuters (TranSComm) which is the Transportation Management Association (TMA) for the Boston University Medical Center and BioSquare.

## Conclusion

Now, therefore, MassDOT, having reviewed the MEPA filings for the BioSquare Phase II - NEIDL project and the mitigation measures proposed, finds pursuant to M.G.L. c. 30, section 61 that with the implementation of the aforesaid measures, all practical and feasible means and measures will have been taken to avoid or minimize potential damage to the environment from the project.

MASSACHUSETTS DEPARTMENT OF TRANSPORTATION

_____ _____

Date By

**MASSACHUSETTS WATER RESOURCES AUTHORITY**
**TOXIC REDUCTION AND CONTROL**
**M.G.L. c.30, § 61, FINDINGS MADE PURSUANT TO 301 C.M.R. § 11.12(5)**

| | |
|---|---|
| EOEA PROJECT NAME: | BioSquare Phase II<br>Boston University Medical Campus - National Emerging Infectious Disease Laboratory (NEIDL) |
| PROJECT PROPONENT: | Boston University Medical Campus |
| EOEA NUMBER: | 12021 |
| MWRA PERMIT NUMBER: | 45403758 |

BACKGROUND

Boston University has applied for a permit from Massachusetts Water Resources Authority to discharge from research laboratory operations, photoprocessing operations, glassware washers, autoclaves, cage washing operations, and reverse osmosis water purification system to the MWRA's sewer system from Boston University National Emerging Infectious Disease Laboratory, 620 Albany Street, Boston, MA 02118. The permit is required by MWRA regulations at 360 C.M.R. §§ 10.007(l)(a) and 10.051.

As required by the Massachusetts Environmental Policy Act (MEPA), the proponent filed an Environmental Impact Report (EIR) for the project with the Secretary of the Executive Office of Environmental Affairs. On _____, the Secretary issued the Certificate on the Final Supplemental Environmental Impact Report for the project, determining that no further review is required under MEPA and allowing the proponent to seek permits to conduct higher level research, known as Biocontainment Safety Level (BSL) 3 and BSL4 in the National Emerging Infectious Disease Laboratories (NEIDL) Building. The proponent previously received authorization from MEP A and a permit from MWRA for the discharge of laboratory wastes from BSL2 activities.

For any project for which an EIR was required, MEPA regulations require agencies that take an agency action on the project to make Section 61 findings, that is, to determine whether the project is likely, directly or indirectly, to cause any damage to the environment and make a finding describing the damage to the environment and confirming that all feasible measures have been taken to avoid or minimize the damage to the environment 301 C.M.R. § 11.12(5). In the case of a project that requires a permit, but does not involve financial assistance, the agency shall limit its findings and mitigation measures specified as conditions to or restrictions on the agency action, to those aspects of the project that are within the subject matter of the required permit 301 C.M.R. § 1 1. 12(5)(c).

For MEP A's purposes, MWRA is considered an agency and its issuance of a permit is considered agency action 301 C.M.R. 11.02(2). Thus, in this matter, MEPA regulations require MWRA to make Section 61 findings because the project required an EIR and now requires a permit from MWRA. MWRA's Section 61 findings are limited to those aspects of the project that are within the subject matter of the required permit: the impact on the environment of allowing the discharge of discharge from the research laboratories, photoprocessing operations, glassware washers, autoclaves, cage washing operations, and reverse osmosis water purification system to MWRA's sewer system.

# FINDINGS

MWRA finds that the discharge from the BSL3 and BSL4 research laboratories, photoprocessing operations, glassware washers, autoclaves, cage washing operations, and reverse osmosis water purification system to MWRA's sewer system from Boston University National Emerging Infectious Disease Laboratory Project to its sewer system will not cause damage to the environment, provided that the discharge meets MWRA's limits for sewer discharges, 360 C.M.R. §§ 10.021-10.025. Those limits were adopted to ensure that discharges to the sewer will not damage the environment. There have been many other similar discharges of laboratory wastewater and photoprocessing wastewater to MWRA's sewer system without damage to the environment. This particular building and these particular laboratories includes additional safeguards to ensure that damage to the environment will not be caused by the discharge wastes to the MWRA system.

Based on its review of the documentation submitted by the permit applicant, MWRA has determined that the discharge of laboratory wastewater and photoprocessing wastewater should not contain excessive levels of pollutants and the discharge should comply with MWRA discharge limits, provided that the discharger takes certain mitigation measures. To help ensure that the discharge meets the limits, MWRA intends to include specific provisions in the permit it will issue to the discharger, including that the discharger:

- Comply with MWRA discharge limits, which are set forth in MWRA's regulations and the MWRA Permit #_____, Category: 02, and a Significant Industrial User (SIU) due to the discharge's potential. to violate MWRA Regulations.
- Treat all of its discharge wastewater via the pH neutralization system at Sampling Location 0101, prior to mixing with any other streams.
- Maintain its continuously pH recording meter at Sampling Location 0101.
- Maintain its open-channel primary flow measuring device and continuously recording flow meter at Sampling Location 0101 prior to mixing with any other streams to allow the accurate measurement of wastewater flow.
- Measure its daily flow of its discharge at Sampling Location 0101 in gallons per day (GPD).
- Sample its discharge at Sampling Location 0101, from the spigot located on the discharge line of the pH neutralization system quarterly and have the discharge analyzed by a DEP certified laboratory for pollutants listed in the permit, and report the results to MWRA quarterly.
- Follow the sampling and reporting requirements at Sampling Location 0101 for Chromium (Total), Copper (Total), Formaldehyde, Lead (Total), Mercury (Total), Mercury (Total), Nickel (Total), Phenol, Silver (Total), TTO (Volatile Organic Fraction), Zinc (Total), pH, and Flow (GPD).
- Stop its discharge immediately if its discharge is not in compliance with MWRA regulations or upon notice to stop by MWRA.
- Submit a copy of its pH log to the MWRA quarterly for every quarterly sampling period.
- Submit a copy of its daily low flog in gallons per day (GPD) for Sample Location 0101 for every quarterly sampling period.
- Submit a Compliance Report for the Photo Processing and Printing Operation annually for its photoprocessing operation on site.

- Submit a Slug Control Plan to the MWRA within (10) weeks from the date of permit issuance.

For the reasons stated above, MWRA finds that there will be no damage to the environment, with the implementation of the provisions it will include in the permit it will issue for the discharge.

_____
Carolyn Fiore, Director
Toxic Reduction and Control Department

Date

# Appendix 4

# RESPONSES TO COMMENTS ON THE FEIR

# APPENDIX 4: RESPONSES TO COMMENTS ON THE FEIR

This Appendix provides a response to those comments submitted to the Secretary of the Executive Office of Environmental Affairs (the Secretary), currently known as the Executive Office of Energy and Environmental Affairs (EOEEA), in response to the filing of the FEIR which are relevant to the scope of the SFEIR. The Scope of the SFEIR as it pertains to the Comment letters received is described below.

## INTRODUCTION

The MEPA Certificate following Remand on the FEIR (the Remand Certificate), issued by the Secretary on September 5, 2006, requested that a Supplemental Final Environmental Impact Report include a response to comments on the FEIR. The Remand Certificate states:

"The SFEIR should respond to the comments received on the FEIR to the extent that they are within the Scope of the SFEIR. The SFEIR should include a copy of each comment letter received. The SFEIR need not reproduce every form letter received but should include one template and any form letters that included additional individual comments. The SFEIR should present any additional narrative or quantitative analysis necessary to respond to the comments received."

As defined by the Remand Certificate, as well as subsequent MEPA filings and Certificates, the Scope of the SFEIR is limited to two primary issues: risk assessment and alternative location analysis for operation of the NEIDL, specifically as they pertain to BSL-3 and BSL-4 research.

This SFEIR also includes any mitigation measures which may be directly related to those two remaining issues. Both transportation safety and emergency response mitigation measures fit this description, and are thoroughly analyzed and described in the Final Supplementary Risk Assessment, which is included as Appendix 11. In addition the FSRA includes an extensive Response to Comment section, as well as a transcript of the NIH Public Meeting on the Risk Assessment of the NEIDL, which was held at the Boston University Medical Campus on April 19, 2012.

## RESPONSES TO COMMENTS

Table A4-1 presents a list of the comments received on the FEIR. Tables A4-2 through A4-5 provide a response to each comment which meets the requirements of the Remand Certificate. Where appropriate, sections of the Supplemental Final Environmental Impact Report and its Appendices are cited for reference. Copies of comments received on the FEIR are included in this Appendix.

**Table A4-1 – MEPA Comments**

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Alternative Sites** | **Risk Assessment** | **Emergency Response** | **Transportation Safety** |
| 8/20/2004 | Oxxon Therapeutics | **S** | | | | |
| 8/31/2004 | MA Biologic Laboratories | **S** | | | | |
| 9/7/2004 | Coalition of Boston Teaching Hospitals | **S** | | | | |
| 9/8/2004 | Conservation Law Foundation | **O** | ☑ | | | |
| 9/9/2004 | BU School of Public Health | **S** | | | | |
| 9/20/2004 | Fort Point Associates | **S** | | | | |
| 9/20/2004 | Lawrence S. Blaszkowski | **S** | | | | |
| 9/21/2004 | Christopher Brayton | **S** | | | | |
| 9/24/2004 | Fort Point Associates | **S** | | | | |
| 9/27/2004 | University of Maryland School of Medicine | **S** | | | | |
| 9/29/2004 | Kenneth Olken | **S** | | | | |
| 9/29/2004 | President, Boston City Council (Michael Flaherty) | **S** | | | | |
| 9/29/2004 | Long Bay Management Company | **S** | | | | |
| 9/29/2004 | Kevin C. Peterson | **S** | | | | |
| 9/30/2004 | Novo Biotic Pharmaceuticals | **S** | | | | |
| 10/1/2004 | Taylor Smith Realty | **S** | | | | |
| 10/6/2004 | Michael E. Capuano, U.S. House of Representatives | **S** | | | | |
| 10/7/2004 | Conservation Law Foundation | **O** | ☑ | | | |
| 10/8/2004 | Fort Point Associates | **S** | | | | |
| 10/12/2004 | South Boston Community Health Center | **S** | | | | |
| 10/12/2004 | Sheil Grove | **S** | | | | |
| 10/13/2004 | DEP/NERO | **N** | | | | |
| 10/19/2004 | Inner Core Committee (MAPC) | **N** | | | | |
| 10/19/2004 | Virginia Pratt | **O** | | | | |
| 10/21/2004 | Paul Zigurds Rinkulis | **S** | | | | |
| 10/22/2004 | CUH2A | **S** | | | | |
| 10/22/2004 | The Ellis South End Neighborhood Association | **O** | | | | |
| 10/22/2004 | Boston Environmental Hazards Program | **O** | | ☑ | ☑ | |
| 10/25/2004 | Massachusetts Water Resources Authority | **N** | | | | |

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Alternative Sites** | **Risk Assessment** | **Emergency Response** | **Transportation Safety** |
| 10/25/2004 | Conservation Law Foundation | **O** | ☑ | | | |
| 10/25/2004 | Hemisphere (John Chomiak) | **S** | | | | |
| 10/25/2004 | David S. Mundel | **O** | ☑ | ☑ | ☑ | |
| 10/27/2004 | CUH2A (J. Crane) | **S** | | | | |
| 10/28/2004 | Pam Kennedy | **O** | | | | |
| 10/28/2004 | John E. Mann | **O** | | | | |
| 11/2/2004 | Patricia Glynn | **O** | | ☑ | | ☑ |
| 11/3/2004 | Jessie Partridge | **O** | ☑ | ☑ | | ☑ |
| 11/3/2004 | William J. Santoro | **O** | ☑ | ☑ | | ☑ |
| 11/3/2004 | Susan Gracey | **O** | | ☑ | | |
| 11/4/2004 | Neighborhood of Affordable Housing | **O** | ☑ | ☑ | | ☑ |
| 11/4/2004 | Cambridge Health Alliance | **O** | | ☑ | ☑ | |
| 11/4/2004 | Dorothy Woelfel | **O** | ☑ | ☑ | | ☑ |
| 11/4/2004 | Miriam Shenitzer | **O** | ☑ | ☑ | | ☑ |
| 11/5/2004 | Phoebe Knopf | **O** | | ☑ | | ☑ |
| 11/5/2004 | Vicky Stenitz (UMASS) | **O** | ☑ | ☑ | | |
| 11/5/2004 | Boston Water and Sewer Commission | **N** | | | | |
| 11/5/2004 | Watertown Citizens for Environmental Safety | **O** | ☑ | ☑ | ☑ | ☑ |
| 11/5/2004 | William S. Grenzebach | **S** | | | | |
| 11/5/2004 | Robina E. Folland | **S** | | | | |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | **O** | ☑ | ☑ | | ☑ |
| 11/5/2004 | Joan Ecklein | **O** | | | | |
| 11/5/2004 | Newton Department of Planning & Development | **O** | | ☑ | ☑ | ☑ |
| 11/7/2004 | Helaine Simmonds & Cinda Stoner | **O** | | ☑ | ☑ | |
| 11/8/2004 | Metropolitan Area Planning Council | **O** | | | ☑ | ☑ |
| 11/8/2004 | Shirley Kressel | **O** | ☑ | ☑ | | ☑ |
| 11/8/2004 | Old Dover Neighborhood Association | **O** | | | ☑ | |
| 11/9/2004 | Marc Pelletier | **O** | ☑ | ☑ | | ☑ |
| 11/9/2004 | Fort Point Associates | **S** | | | | |
| 11/9/2004 | Massachusetts Historical Commission | **N** | | | | |

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Alternative Sites** | **Risk Assessment** | **Emergency Response** | **Transportation Safety** |
| 11/9/2004 | Executive Office of Transportation (EOT) | **N** | | | | |
| Various | Form Letters Opposed to Project (12) | **O** | ☑ | ☑ | | ☑ |
| Various | Form Letters Supporting the Project (157) | **S** | | | | |
| Various | Form Cards Supporting the Project (476) | **S** | | | | |

**Table A4-2 - Alternative Site Comments**

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 9/8/2004 | Conservation Law Foundation | The proponent has failed to provide a study of feasible alternatives. A full analysis of all reasonable siting alternatives needs to be submitted. | A full alternative siting analysis was completed by the proponent, as described in Section 3.2 of the SFEIR. In addition, the NIH undertook an unprecedented effort to prepare, under the guidance of a Blue Ribbon Panel of experts and the National Research Council, a supplementary risk assessment. The Final Supplementary Risk Assessment (FSRA) evaluates the relative risks as well as the frequency and public health consequences associated with potential loss of pathogen biocontainment events in a range of population density areas that represent urban, suburban and rural environments. The FSRA evaluated the current NEIDL facility as well as two alternative sites. | A.1 |
| 9/8/2004 | Conservation Law Foundation | Should address how Proponent decided to site the lab here (criteria in selecting site, listing and description of alternative sites evaluated inc. pop density, reasons for rejection, description of how site criteria were developed and extent to which the various sites met the criteria). Include population density, environmental justice, demographics, public health/safety | A full alternative siting analysis was completed by the proponent. A summary of the analysis which discusses process, locations considered, and site screening criteria, is included in Chapter 3, Alternative Sites and Relative Risks. The selected NEIDL site and alternative locations in suburban Tyngsborough, MA, and rural Peterborough, NH, are examined in full detail. A supplemental review of these three sites was completed by the NIH and has been included as part of Appendix 11, SFRA. The SFRA includes detailed information about the communities, including environmental justice characterizations, demographics, available infrastructure, and environmental resources. This risk assessment also includes an evaluation of the relative risks to public health posed by identical losses of biocontainment at the alternative sites. | A.2 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 9/8/2004 | Conservation Law Foundation | Should address whether there are alternative locations for the lab, including an alternative location elsewhere in Massachusetts, or siting the main portion in Boston but siting the BSL-4 lab in a less densely populated area. | See Response A.2, Chapter 3, and Appendix 11. The selected NEIDL site and two alternative locations in suburban Tyngsborough, MA, and rural Peterborough, NH, are examined in full detail. | A.3 |
| 10/7/2004 | Conservation Law Foundation | It is our understanding that BU owns property along Commonwealth Avenue and in Tyngsboro, MA and Peterborough, NH. These sites should be analyzed as alternative locations for this project in addition to any other BU-owned or controlled properties. … We request that you release a list of all locations owned or controlled by BU. An analysis of these locations as alternative sites should be included in a supplemental MEPA filing. It is important that we understand how and why BU chose this location for the BSL-4 facility and how it compares to other property owned or controlled by BU. | See Response A.2, Chapter 3, and Appendix 11. All Boston University owned and controlled properties were considered in the initial alternative site analysis conducted by BUMC in 2003. | A.4 |
| 10/25/2004 | Conservation Law Foundation | MEPA requires analysis of all feasible locations. For private projects, any sites which are owned or controlled by the proponent must be analyzed. It is our understanding that BU owns property along Commonwealth Avenue, in Tyngsboro, MA and in Peterborough, NH. These sites should be analyzed as alternative locations for this project in addition to any other BU-owned or controlled properties. | See Response A.2, Chapter 3, and Appendix 11. All Boston University owned and controlled properties were considered in this alternative site analysis. | A.5 |
| 10/25/2004 | David S. Mundel | The FPIR/FEIR contains no analysis that suggest that the proponent has considered feasible alternatives that it might find somewhat more inconvenient, more expensive and/or less attractive but which would be safer and potentially less harmful to the surrounding neighborhoods. | See Response A.2, Chapter 3, and Appendix 11. | A.6 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 11/3/2004 | Jessie Partridge | The FEIR does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End. | See Response A.2, Chapter 3, and Appendix 11. | A.7 |
| 11/3/2004 | William J. Santoro | The FEIR does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End. | See Response A.2, Chapter 3, and Appendix 11. | A.8 |
| 11/4/2004 | Neighborhood of Affordable Housing | The FEIR does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End. | See Response A.2, Chapter 3, and Appendix 11. | A.9 |
| 11/4/2004 | Miriam Shenitzer | The FEIR does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End. | See Response A.2, Chapter 3, and Appendix 11. | A.10 |
| 11/5/2004 | Vicky Stenitz (UMASS) | I have serious questions about B.U.'s failure to comply with the requirement that there be an alternatives analysis of other potential locations for the laboratory. What criteria were used by University Associates in making the decision to locate the laboratory on Albany Street in Boston's South End? There are serious environmental justice issues that need to be addressed. | See Response A.2, Chapter 3, and Appendix 11. | A.11 |
| 11/5/2004 | Watertown Citizens for Environmental Safety | There should be an analysis of alternative locations for the laboratory. On what basis was the decision made to use the current location? | See Response A.2, Chapter 3, and Appendix 11. | A.12 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | Supplemental FEIR should include criteria used for locating lab in a densely populated EJ community, the other locations considered, including population density and characteristics of these locations, why those locations were rejected and how the current site meets those criteria. To the extent proximity to researchers at BU and at the NIAID RCE is a criterion, the SFEIR must explain why the project proponent did not consider or rejected other locations in less densely populated areas within a one hour drive of Boston. The SFEIR must also explain how the decision considered risks to public health and safety and the environment and how a decision could have been made on siting before the RWDI Summary Report was completed. | See Response A.2, Chapter 3, Appendix 5, and Appendix 11. The criteria used to evaluate the sites are outlined in the Alternative Site Analysis. The public health risks associated with the project have been addressed in the risk assessments as described in Chapter 4. The FSRA concludes that the risks to public health posed by the facility are very low to only remotely possible and that there are no significant differences in risks between alternative locations. | A.13 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | To the extent that the proponent did not consider other locations, the SFEIR should identify and consider other locations. We anticipate proponent will say location was chosen due to ownership of the land, but that reasoning is not sufficient. | See Response A.2, Chapter 3, and Appendix 11. Ownership or control of land was a prerequisite for receiving funding to construct the NEIDL. All Boston University owned and controlled properties were considered as potential siting locations for the NEIDL. | A.14 |
| 11/8/2004 | Shirley Kressel | The most basic evaluative element, a study of alternative sites for the lab, has not been attempted, despite repeated and widespread public demand. This is the only such lab in the United States to be located in a dense urban environment, which I suspect is not by accident; is this not an indication of an issue that at least bears examination? In addition to the extraordinary public health risk of this siting, there is a lost opportunity for community benefit. This site was previously to hold a mix of institutional and commercial uses, which could provide a more diverse economic development base, without risk to life and limb. Further, the prison-like urban design environment of this lab is likely to impede the City's contemplated development of the BU surroundings as "neighborhood | See Response A.2, Chapter 3, and Appendix 5. See Section 2.2 for a discussion of Community Benefits associated with the project. Four other Biosafety Level 4 (BSL-4) labs are located in urban areas: the Centers for Disease Control in Atlanta, Georgia; the Georgia State University BSL-4 in Atlanta, Georgia; the National Biocontainment Laboratory at the University of Texas Medical Branch in Galveston, Texas; and the Southwest Foundation for Biomedical Research in located in San Antonio, Texas. The demonstrated safety record of BSL-4 laboratories and the risk assessments discussed in Chapter 4 demonstrate that the risks to public health posed by the facility are very low to only remotely possible. There are no significant differences in risk between alternative locations. | A.15 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| | | fabric." It is absolutely unacceptable that such a decision be made without even an attempt to consider other site. | | |
| 11/9/2004 | Marc Pelletier | There is no assessment of alternative sites for the proposed lab. The fact that the $128 million dollar grant from NIAID to BU was contingent on the lab being placed in this site places huge monetary pressure on the outcome of this site comparison. Public safety concepts appear to be a secondary consideration. | See Response A.2, Chapter 3, and Appendix 11. | A.16 |
| | Opposition Form Letter | The FEIR does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End. | See Response A.2, Chapter 3, and Appendix 11. | A.17 |

**Table A4-3 - Risk Assessment Comments**

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 10/22/2004 | Boston Environmental Hazards Program | Why was the accidental dropping and breaking of a 15cc vial of purified anthrax (1 g) chosen for the Maximum Possible Risk scenario? How was it determined that only 400,000 respirable particles could become airborne from such an accident? Why cannot a release of anthrax spores and the subsequent public health impacts that occurred at Sverdlosk in April of 1979 also happen in Boston from the NEIDL? Is the maximum quantity of culture and spores permitted at the NEIDL too small to allow such a release during a worst case possible accident? | The quantity of agent being studied for release in the quantitative risk assessment is the result of a laboratory accident involving 10 billion spores. Preliminary range finding studies were performed simulating accidental laboratory releases to determine the number of particles that become airborne. Approximately 400,000 particles were produced in the range findings studies of simulated laboratory accidents and were available to become airborne (Wilson, 2004). Through the state and federal environmental review process, a number of risk assessments have been conducted for the NEIDL. It is important to note the "worst-case scenario" assumed an accident involving a quantity of spores estimated to be approximately 10 times larger than the actual amount expected to be used in experiments within the NEIDL. The FSRA examines 12 pathogens in addition to Anthrax. See Chapter 4 and Appendix 11 for a thorough discussion of the pathogens studied and the results of a potential accidental or malevolent release of these pathogens. | R.1 |
| 10/25/2004 | David S. Mundel | Although, the purported "worst case analysis" (Appendix 6 FEIR) addresses one environmental hazard (Anthrax spore release), the proponent has presented no analysis that either suggests or proves that the potential release of this hazardous agent which was chosen for analysis is, in fact, a 'worst case' release. | See Response R-1, Chapter 4 and Appendix 11. | R.2 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 10/25/2004 | David S. Mundel | The "worst case analysis" is woefully inadequate an unconvincing. It contains no sensitivity analysis indicating how the simulated findings of environmental impact would be different if different assumptions were used in examining the nature of the incident leading to the release. The analysis contains no assessment regarding whether the range of weather conditions considered is representative of the full range of weather conditions occurring in Boston. The statistical component of the analysis is naive and incorrect - the reported data do not portray the 'maximum number of inhaled spores', they portray the expected number of spores that would be inhaled by a single individual. The data included in the report actually suggest that some individuals may inhale zero spores, some may inhale one spore, and some may inhale more spores. | See Response R-1, Chapter 4 and Appendix 11. | R.3 |
| 10/25/2004 | David S. Mundel | In addition, the worst case analysis includes no assessment of the impact of a potential release on the vulnerable populations living, working hospitalized, and incarcerated in nearby neighborhoods and facilities. The proponent has noted that the "precise dose of Bacillus anthracis (anthrax) spores required to cause human pulmonary anthrax is not known" and that "this number would vary considerably from person to person depending upon age (and) overall medical history" (p 5-22.) But, these issues of population sensitivity are not addressed anywhere in the so-called 'worst-case analysis." | See Response A-1, R.1, Chapter 4 and Appendix 11. | R.4 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 10/25/2004 | David S. Mundel | The casual and incomplete assessment and analysis of the potential risks associated with an accidental release from the proposed Biocontainment Laboratory suggests an almost cavalier attitude on the part of the analysts engaged by the proponent. If these analysts and the proponent's personnel responsible for directing the preparation of the analysis actually believe that the risks of negative health effects from a potential release are so small as to be "practically considered as zero" (as suggested in the summary of the "Hazard and Risk Assessment"), perhaps they should accept an alternative design in which the exhaust from the proposed Biocontainment Laboratory is vented directly into their offices rather than into and over the surrounding residential neighborhoods. | See Response R.1, Chapter 4 and Appendix 11. | R.5 |
| 11/2/2004 | Patricia Glynn | The worst case scenarios are poorly thought out. What about infected mice escaping through air vents or other channels that rodents find easily, but humans do not even consider? | See Response R.1, Chapter 4 and Appendix 11. The FSRA includes scenarios involving transmission through infected animals. | R.6 |
| 11/3/2004 | Jessie Partridge | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat | See Response R.1, Chapter 4 and Appendix 11.<br>A Threat and Vulnerability Analysis has been prepared for the NEIDL which includes analysis and countermeasures, both overt and covert, to minimize and mitigate potential acts of bioterrorism.<br><br>The FSRA includes scenarios involving accidental releases resulting from transportation accidents. | R.7 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | | |
| 11/3/2004 | William J. Santoro | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | See Response A-1, R.1, R-7 Chapter 4 and Appendix 11. | R.8 |
| 11/3/2004 | Susan Gracey | The FEIR offers no adequate worst case scenario. Is it really even possible to imagine the worst case? | See Response R.1 and Appendix 11. | R.9 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 11/4/2004 | Neighborhood of Affordable Housing | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | See Responses R.1, R.7, Chapter 4, and Appendix 11. | R.10 |
| 11/4/2004 | Cambridge Health Alliance | The risk assessment analysis is faulty, claims that the accidental release of such pathogens would be harmless to the local population, and provides no plan for dealing with the environmental and community impacts of such a release if it were to take place. | See Response R.7 and Appendix 11. A full discussion of emergency response planning measures can be found in Appendix 7. | R.11 |
| 11/4/2004 | Dorothy Woelfel | FEIR is inadequate because it 1) fails to include an accurate 'worst case scenario'; i.e. the accidental or intentional release of toxins or viruses that are highly contagious within the lab. 2) fails to include a 'worst case scenario' for a chemical agent in transit to the lab. 3) fails to include a 'worst case scenario' in the event of a catastrophic terrorist attack, resulting in the release of toxins to the surrounding community. | See Response R.7 and Appendix 11. | R.12 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/4/2004 | Miriam Shenitzer | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | See Response R.7 and Appendix 11. | R.13 |
| 11/5/2004 | Phoebe Knopf | The worst case scenario described in the FEIR was clearly not taking seriously the health concerns of residents. The scenario said, in very sophisticated language, that essentially, if a few bugs got out we'd all be ok. I felt that the profound questions of those of us who oppose the lab were seriously disrespected when I read this part of the FEIR because the language was so arrogant and cool and so dismissive of the cry for truth and justice from residents who understandably don't want plague germs in their back yards, their city, or their world. We already know the lab is dangerous and that if smallpox or plague germs escape we would be in deep trouble, not only in and around Boston but also around the world, since all it would take for the plague to spread would be for one infected person to board a plan at Logan bound for anywhere. We are not stupid people. So please | See Responses R.7 and Appendix 11. | R.14 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | respect our honest and passionate request for an FEIR that contains a legitimate analysis of worst case scenario dangers. | | |
| 11/5/2004 | Phoebe Knopf | The FEIR was also gravely deficient in its lack of an analysis of a worst case scenario in the case of an accidental or terrorist release of germs in transit to or from the lab. This deficiency along should be grounds enough to require a supplemental FEIR. Another blatant problem with the FEIR was that there was no analysis of a worst case scenario in the case of a terrorist attack on the lab. I feel deeply concerned that the planners of a lab that is supposed to protect us from terrorism haven't provided us with evidence that they've carefully considered such a basic problem. I want to see an FEIR the proves to me that the planners of the lab have thought through the real dangers. Denial of our human fallibility and vulnerability, while humanly understandable, won't make our problems go away, and in the case of the lab, such denial could pave the way to an immense public health catastrophe. | See Response R.7 and Appendix 11. | R.15 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | Vicky Stenitz (UMASS) | As I understand it, BU was asked to provide a detailed account of a "worst case scenario" and then, outline their plans for dealing with this emergency. I have read Jean Guillemin's critique of the FEIR "worst case scenario" and find myself appalled at her detailing of its inaccuracies and omissions. Given the numerous reports in recent weeks of accidents at BSL4 labs, it is unconscionable to place this facility in such a densely populated, urban area without a full consideration of the real risks. | See Responses R.7, Chapter 4, and Appendix 11. A full discussion of emergency response planning measures can be found in Appendix 7. In addition, BU has a transparent reporting mechanism in place with the Institutional Biosafety Committee (IBC), which reports on incidents occurring in the laboratories. Information about the IBC can be found in Appendix 8 and on the NEIDL website. | R.16 |
| 11/5/2004 | Watertown Citizens for Environmental Safety | 1) The "worst case scenario" described significantly underestimates the disastrous impacts on the surrounding community of a release of anthrax or other deadly and incurable viruses and toxins from the proposed laboratory. This facility would be the first to be built in a densely populated area; a NIAID memo in 2000 stated that a BSL4 lab should be well removed from major population's centers in order to reduce the possibility of an accidental release of an organism leading to a major public health disaster. The report should contain a site-specific release analysis and should fully consider the environmental impact of any release. | The SFRA (Appendix 11) includes site-specific release analyses. The NAIAD memo referred to in the comment was never officially signed or sent, and its author is unknown. NIH does not support the content of the memo as rationale for the location of any laboratory. Four other Biosafety Level 4 (BSL-4) labs are located in urban areas: the Centers for Disease Control in Atlanta, Georgia; the Georgia State University BSL-4 in Atlanta, Georgia; the National Biocontainment Laboratory at the University of Texas Medical Branch in Galveston, Texas; and the Southwest Foundation for Biomedical Research in located in San Antonio, Texas. The demonstrated safety record of BSL-4 laboratories and the risk assessments discussed in Chapter 4 show that the risk of the facility to the surrounding community is negligible. The risk would be negligible whether the facility was in an urban environment or a rural environment. | R.17 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | Watertown Citizens for Environmental Safety | 2) There have been documented cases of accidental releases of pathogens during transport to laboratories. The report fails to provide information about transport of hazardous agents to the laboratory and does not describe such a "worst case scenario." 3) The laboratory could be subject to intentional acts of sabotage, resulting in releases of pathogens into the surrounding community. There should be an analysis of vulnerability to an attack. | See Response R.7. The SFRA (Appendix 11) includes a detailed analysis of a number of potential transportation accident scenarios, including truck and air transport. A full discussion of transportation security measures can be found in Appendix 7. | R.18 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | See Response R.1, R.7, and Appendix 11. | R.19 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | The Summary Report (RWDI) is faulty because it suggest zero risk to the public, fails to consider contagious disease outbreaks, does not address workplace contamination, ignores environmental contamination (such as soil contamination). Supplemental risk assessment should be completed by an independent committee. | See Response R.7 and Appendix 11. The FSRA was completed by the NIH in association with outside, independent panels of experts. | R.20 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | FEIR fails to contain assessment of release of select agent when in transit to the laboratory. Stating that the risk (during transport) is negligible, without any support whatsoever for that statement, does not satisfy safety considerations. | See Response R.7 and Appendix 11. | R.21 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | Shipping accidents do happen. The FEIR provides no information on designated transport routes. | A full discussion of select agent transportation and related security measures can be found in the FSRA, Appendix 11. | R.22 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | An attack on, or infiltration of, the laboratory could result in the release of pathogens or the escape of infected insects or animals, with deadly results. An attack on the lab that did not release pathogens might nonetheless cause damage to nearby communities.... The proponent has claimed that any attack would destroy the stored pathogens, but that analysis must be provided in a SFEIR for review and comment. The FEIR contains no analysis of the risks... from an infected animal. | See Response R.7. The SFRA (Appendix 11) includes scenarios involving the release of infected animals. | R.23 |
| 11/5/2004 | Newton Department of Planning & Development | The proponent should revise the FEIR to further elaborate on the amounts of agents including Anthrax, Plague, Ebola, and Smallpox, to be stored on-site and limits should be set and monitored. Releases could occur through many means and consequences could be deadly. The lab could be a potential target for terrorists, and transportation of pathogens and/or waste to and from the site pose a risk for the entire metropolitan region. | See Response R.7. The SFRA includes a detailed analysis of the pathogens suggested for study as well as a thorough analysis of potential malevolent acts. | R.24 |
| 11/5/2004 | Newton Department of Planning & Development | Further discussion of the regional impact or a release and "worst case scenarios" should be included in the FPIR/FEIR. The safety of the region should not be compromised to construct a BSL-4 laboratory. Policies and procedures on a regional level to respond to a potential release of a deadly agent have not been addressed in the FEIR. The proponent should be expected to present further analysis regarding the potential release of any hazardous agent in a "worse-case" scenario. Water contamination, hijacking or transportation or waste disposal vehicles, animal carcass disposition, or losses of the laboratory's containment systems also represent potential scenarios that should be further analyzed, as they represent a concern to the City of Newton. | See Response R.7. A full discussion of emergency response plans and transportation security measures can be found in Appendix 7. | R.25 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/7/2004 | Helaine Simmonds & Cinda Stoner | Not having access to independent consultants, we are unable to assess the accuracy of their scenarios or whether in fact they are the proper ones to use. As a result of this we do not feel any comfort in their use of the word negligible in describing the risks associated with any mishap that might occur at the facility or any potential release of infectious agents. We also question why the worst case risk scenario only refers to the release of anthrax spores. There must be other risk scenarios with other pathogens that have not been studied. The proponents should be required to do this. | See Responses R.1, R.7, Chapter 4 and Appendix 11. | R.26 |
| 11/8/2004 | Shirley Kressel | The FEIR is seriously deficient because a) To my understanding it does not represent the way that anthrax has usually been accidentally disseminated. A literature review of anthrax infection episodes should be provided to document the nature of the likeliest anthrax escape. b) It does not consider any of the other microorganisms that the Lab is expected to study, which may be dispersed in different ways, and which most likely are not as treatable as anthrax. c) It does not even attempt to consider the microorganisms that the Lab may later undertake to study, including those that may results from experiments in rDNA.... No risk assessment in 2004 is predictive without specific inviolable limits on the lab's scope, limits which are not forthcoming. | See Response R.1 and R.7. The SFEIS Risk Assessment (Appendix 11) modeled the release of specific infectious disease agents of concern to the community, including Ebola virus, monkeypox, Sabia virus, and Rift Valley Fever virus. All prospective research projects are reviewed through the IBC. See Section 5.3 for a discussion about the selection of research projects at the NEIDL. | R.27 |
| 11/8/2004 | Shirley Kressel | d) it does not consider environmental contamination, only individual human infection. In addition to the usual air, soil, and vegetation issues, we are a peninsula, surrounded by river, bay, and ocean waters the contamination of which could transfer serious harm very widely. e) It does not examine transportation-related risks, either in product delivery/disposal, nor in emergency escape. f) It does | See Response R.7. The SFRA (Appendix 11) includes multiple release scenarios, including a transportation accident. | R.28 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | not consider the risks of terrorist attack, which such a facility invites, and the possible collateral damage to surrounding neighborhoods. | | |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/9/2004 | Marc Pelletier | 1) The assessment of a worst-case scenario release is extremely superficial at beast. RWDI West Partners have chosen anthrax as their release organism. In assessing the plume of contamination that would be released from the lab, they measure the exposure of individuals at a single point at ground level. A true assessment of the exposure must include a 3-D model of dispersal in the area, taking into account buildings and the presence of people at many elevations throughout the plume. Localized wind patterns may lead to concentrations of anthrax spores in discreet spots within the neighborhood. | See Response R.1 and Appendix 11. | R.29 |
| 11/9/2004 | Marc Pelletier | 2) The danger posed to community depends not only on the nature of the released organism, but also on the health and available healthcare of the resident population. It is known that the population around the proposed site suffers abnormally high incidences of asthma and other respiratory diseases. The population is also under-insured and may not have access to medical care. These factors must be taken into account to get a realistic picture of the risk posed by this lab to the neighborhood. | See Response R.7 and Appendix 11. | R.30 |
| 11/9/2004 | Marc Pelletier | 3) The choice of anthrax as the studied organism does not take into account the much greater danger posed by a true contagion. Accidental or intentional release of an organism that is spread from person to person poses a very different set of very serious health risks. This must also be included in a true assessment of a worst-case release. | See Response R.7. The SFRA (Appendix 11) models multiple scenarios of infectious disease release. | R.31 |
| 11/9/2004 | Marc Pelletier | 4) The FEIR does not look at the dangers posed by transport of infectious agents through the neighborhood going to and from the lab. | See Response R.7. The SFRA (Appendix 11) includes multiple release scenarios, including a transportation accident. | R.32 |

| Date Received | Sender | Comment | Response | Response Number |
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| Various | Opposition Form Letter | The FEIR does not include a true or accurate worst case scenario. Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious. FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transportation of hazardous biological and toxic agents to the laboratory. FEIR fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community. | See Response R.7 and Appendix 11. | R.33 |

**Table A4-4 - Emergency Response Comments**

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 10/22/2004 | Boston Environmental Hazards Program | How will public health and safety emergency responders be trained equipped and kept informed of the locations of Select Agents, Risk Group 3 agents and Risk Group 4 agents to protect them from harm and to protect the public from the risk of unknowing unsafe disturbances of these organism during emergency responses? | BUMC has an excellent working relationship with external emergency response agencies. Appendix 7 describes the planning, training, and response procedures that are in place to provide coordination between BUMC and public health and safety responders. | E.1 |
| 10/22/2004 | Boston Environmental Hazards Program | How will the public and its regulatory agencies be kept informed in detail of the work that will be ongoing at the NEIDL, the biohazards present, and the biohazard controls and emergency response plans in use by the facility for the various projects being undertaken? | See Response E.1. | E.2 |
| 10/22/2004 | Boston Environmental Hazards Program | How would the public be protected from biohazard risk resulting from a significant laboratory fire or explosion at the NEIDL? | See Response E.1. | E.3 |
| 11/5/2004 | Newton Department of Planning & Development | Policies and procedures on a regional level to respond to a potential release of a deadly agent have not been addressed in the FEIR. The FEIR should be revised to describe evacuation strategies and the chain of command on a regional level, and to explain how regional roads, hospitals, and airports would be affected in the event of an emergency. Emergency Evacuation of the building should be discussed in the FEIR. In the event of an emergency, there may not be adequate time for the evacuation and/or proper decontamination of employees. The FEIR should be revised to analyze how an emergency evacuation could take place expediently to ensure employee | See Response E.1. | E.4 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | safety, and how such an evacuation would affect surrounding communities. | | |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/7/2004 | Helaine Simmonds & Cinda Stoner | In case of an accident at the facility, how will the community be notified and in fact will we be notified? Will we be quarantined? Will we be given treatment and what is the priority of treatment for the hospital and the community? The FEIR sets out none of this... Although in Section 5-5 the proponent talks about a disaster plan, we have lived in this community for over 20 years and never have we been informed of any disaster drill or plan. When will we find out? When the disaster happens? The proponents should be required to lay this out and have practice drills. | See Response E.1. | E.5 |
| 10/25/2004 | David S. Mundel | The efficacy of the emergency response procedures is questionable. It is disturbing to note that the proponent states that its emergency procedures "**may** involve the City of Boston" (emphasis added, see page 5-8). | See Response E.1. The appropriate emergency response is determined by the type of incident encountered. Coordination of response efforts is discussed in Appendix 7. | E.6 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/4/2004 | Cambridge Health Alliance (Elliot Mishler) | The FEIR... provides no plan for dealing with the environmental and community impacts of such a release if it were to take place. | See Response E.1. | E.7 |
| 11/8/2004 | Metropolitan Area Planning Council | During an emergency or heightened security, would air space, nearby roads and the interstates be affected? Have areas around other facilities been restricted or shut down for any amount of time? If the answer to either of these questions is "yes" - or even "maybe" - a plan must be introduced to cope with such circumstances. | See Response E.1. | E.8 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/8/2004 | Metropolitan Area Planning Council | Additional concerns expressed about security fence, evacuation procedures, size of secure area, mitigation through emergency preparedness training | See Response E.1. | E.9 |
| 11/8/2004 | Old Dover Neighborhood Association | [Makes the following request of the project/city:] A known response plan, for both the occupants and the surrounding neighborhood, in the event of a problem, accidental or otherwise. | See Response E.1. | E.10 |

**Table A4-5 - Transportation Safety Comments**

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| 11/2/2004 | Patricia Glynn | I would like to see…real worst case release scenarios from the lab and while the hazardous materials are in transport to the lab. | The SFRA (Appendix 11) models multiple release scenarios, including a transportation releases scenario. Appendix 7 includes a detailed public safety plan as well as Emergency Response and Public Safety Measures. | T.1 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/3/2004 | Jessie Partridge | The FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory. | See Response T.1 | T.2 |
| 11/3/2004 | William J. Santoro | The FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory. | See Response T.1. | T.3 |
| 11/4/2004 | Neighborhood of Affordable Housing | The FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory. | See Response T.1. | T.4 |
| 11/4/2004 | Dorothy Woelfel | The FEIR fails to include a 'worst case scenario' for a chemical agent in transit to the lab. | See Response T.1. No chemical agents will be studied at the laboratory. | T.5 |
| 11/4/2004 | Miriam Shenitzer | The FEIR fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory. | See Response T.2. | T.6 |
| 11/5/2004 | Phoebe Knopf | The FEIR was also gravely deficient in its lack of an analysis of a worst case scenario in the case of an accidental or terrorist release of germs in transit to or from the lab. This deficiency alone | See Response T.1. | T.7 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | should be grounds enough to require a supplemental FEIR. | | |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | Watertown Citizens for Environmental Safety | There have been documented cases of accidental releases of pathogens during transport to laboratories. The report fails to provide information about transport of hazardous agents to the laboratory and does not describe such a "worst case scenario." | See Response T.1. | T.8 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | The FEIR must be required to include an analysis of a release when select agents are in transit to the laboratory and other essential information about the transport of hazardous biologic and toxic agents to the laboratory. | See Response T.1. | T.9 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | The FEIR fails to contain any assessment of a release of a select agent when in transit to the laboratory. Instead, the FEIR discusses the protocols it will use for shipment of biological materials and claims, without any support, that "the risk to the community from transport of infectious agents or other biological derived material is negligible." (FEIR 5-26).) That is inconsistent with 301 CMR 11.07(6)(h) and the Certificate, which require the FEIR to "address safety considerations related to any transport of potentially hazardous biological agents to and from the biocontainment facility." Simply stating that the risk is negligible, without any support whatsoever for that statement, does not address the safety considerations of what would occur if there were a release during transport or allow agencies and the public to determine whether the level of risk | See Response T.1. | T.10 |

| Date Received | Sender | Comment | Response | Response Number |
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| | | asserted in the FEIR is accurate. | | |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | Two recent accidents when shipping infectious agents show that there is indeed a risk to the public from shipping and consequently the proponent must be required to analyze that risk. First, earlier this year a laboratory accidentally shipped live, rather than dead, anthrax from Maryland to California. The mistake was discovered only when laboratory animals in California died from anthrax and the researchers using the anthrax found that the dead anthrax that they had ordered was alive and virulent. The laboratory shipping the anthrax has admitted the error. Second, last year a package containing West Nile virus exploded at the Federal Express facility in the Port Columbus International Airport, Ohio, forcing the evacuation from the facility of about fifty workers. Fortunately, no persons died from these accidents, but they show that there is a real and substantial risk of errors in shipping that may put the public at risk. | See Response T.1. | T.11 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | In addition to the two recent shipping accidents, the federal government itself has acknowledged the vulnerability of shipping biological agents, writing that infectious agents such as anthrax may pose a security risk in transport and that it needs to determine if additional federal rules are necessary to assure the safety of hazardous materials in transit. 67 Fed.Reg.157, p.53131 (August 14, 2002). | See Response T.1. Transportation of infectious substances will be conducted in accordance with all existing and future local, state, federal and international regulations, guidance and standards. These regulations are discussed in Appendix 7. | T.12 |

| Date Received | Sender | Comment | Response | Response Number |
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| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | Further, the FEIR provides no information on designated transport routes. The only references is that "the receiving and shipping location(s) for select agents will have a designated route to and from BUMC and will be accessed and egressed to the site only by the local highway system (presumably Frontage Road)." Yet, the Massachusetts Turnpike Authority prohibits the transport of hazardous materials in all its tunnels, including the tunnel under the Prudential Center, and the Central Artery, Callahan, Sumner, and Ted Williams tunnels. 730 CMR 7.10. Hazardous materials are those defined and listed in 49 CFR Chapter 1, Subchapter C, which include infectious materials. Because designated routes are not mentioned in the FEIR, other than noting access and egress by the local highway system, it is unknown whether the project proponent is aware of or has considered the prohibition and how the routes will be adjusted accordingly. Because vehicular traffic to the project site may be primarily from Frontage Road, it is essential that the public and regulatory agencies are fully aware and have the opportunity to comment during MEPA review on the routes of transport of select agents to the site. | See Response T.1. Appendix 11 includes an analysis of a transportation release scenario. | T.13 |
| 11/5/2004 | SafetyNet / Alternatives for Community & Environment (ACE) | We request that the recommended oversight committee include an analysis of risk during transport of biological agents to the laboratory and that you require a report on transit risks as part of | See Response T.1. | T.14 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| | | a Supplemental FEIR. | | |
| 11/5/2004 | Newton Department of Planning & Development | The lab could be a potential target for terrorists, and transportation of pathogens and/or waste to and from the site pose a risk for the entire metropolitan region. | See Response T.1. | T.15 |
| 11/8/2004 | Metropolitan Area Planning Council | No issues on the transportation of hazardous materials to and from the site have been addressed. The Transportation section of Chapter 5, Operational, Safety, and Security Issues, merely notes that federal regulations and protocols are in place and will be followed. Regardless of how safe the laboratories themselves are, the hazardous materials must be shipped to, and eventually away from, the facility using the local and regional street network. Since crashes en route and even assault on the vehicles are a possibility, some discussion of containment practices during these trips, and hazardous transport issues in general, should be included in the FEIR. | See Response T.1. | T.16 |
| 11/8/2004 | Metropolitan Area Planning Council | While shipment will be according to "strict federal guidelines" there is no information on how these guidelines apply to this specific Boston location. For example, in the section on packaging, the outer package must comply with a "drop test of 1.2 m", and "a temperature tolerance range of 40 - 131 degrees F." A crash on one of our numerous overpasses/bridges could result in a fall well over 1.2 meters, and the temperature does occasionally fall | See Response T.1. | T.17 |

| Date Received | Sender | Comment | Response | Response Number |
|---|---|---|---|---|
| | | below 40 degrees Fahrenheit here. Again, the FEIR should demonstrated that the anticipated hazardous materials can be safely transported in Boston. | | |
| 11/8/2004 | Shirley Kressel | The FEIR does not examine transportation-related risks, neither in product delivery/disposal, nor in emergency escape. | See Response T.1. | T.18 |
| 11/9/2004 | Marc Pelletier | The FEIR does not look at the dangers posed by transport of infectious agents through the neighborhood going to and from the lab. | See Response T.1. | T.19 |

BG

OXXON THERAPEUTICS™

RECEIVED
AUG 20 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

II

Dear Secretary Herzfelder: — / 2021

I am writing to provide my full support to Boston University Medical Center's proposed Biosafety Lab, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July, 2004.

I am a physician with over 18 years of research and development experience in infectious diseases and vaccine and drug development, including 6 years at the US Army Medical Research Institute of Infectious Diseases (USAMRIID) in the Maryland suburbs of Washington, DC. During my career I have worked in BL-3 and BL-4 suites and trained in BL-4 medical care. I was also a member of various inspection teams that have evaluated BL-3 and BL-4 laboratories in Russia and Iraq. I also have a number of colleagues who have safely worked in the USAMRIID and the Centers for Disease Control (CDC), Atlanta BL-4 facility. With my experience and my understanding of the design and plans around the BU proposed Biosafety Lab, I can, without reservation, tell you that I strongly support the proposed laboratory. My reasons for this support are as follows:

1. The additional Level 4 laboratory space built into the BU facility will be critical to the future needs for understanding existing and emerging pathogens and for accommodating the development of treatments and vaccines to deal with these pathogens.

2. The Boston University Medical Center staff has prepared a scientifically and environmentally sound plan for the construction and operation of the laboratory to the highest safety standards to protect the workers, the community, and the environment. These standards exceed those that I have witnessed in established BL-4 institutions in Atlanta and Maryland; institutions that have maintained excellent safety operations records.

3. This laboratory and the research conducted on the BU campus will be a critical resource for the medical community globally and the Greater Boston area locally. The existing talent in Boston is why companies such as ours, Oxxon, have located here. The laboratory and the research conducted in the BU facility will help expand the depth and breadth of infectious disease research activity in Boston. Those efforts have the real and invaluable potential to be translated to new drug and/or vaccine products by the surrounding biotechnology industry.

4. The proximity of the BU facility to Logan Airport offers a key and unique advantage for this laboratory in the race to identify and characterize new pathogens. Specifically, in this era of terrorism and increased world travel it is possible that a new pathogen might make landfall in the US in Boston. With the BL-4 facility in Boston then locally identified pathogens can be rapidly and safely managed.

5. The alternative, to have no BL-4 capability, is an even greater threat to the safety of the Boston community because, without this facility, new and emerging pathogens may go undetected for unacceptable periods of time, causing significant and potentially avoidable morbidity and mortality before we're able to cope with them. Having this facility in this city will ensure the rapid identification and characterization of these pathogens by highly competent and well respected experts who are attracted to the intellectual environment of Boston and its surrounding academic, biotechnology, and pharmaceutical communities.

While existing BL-4 level facilities in the US have had excellent safety records handling BL-4 pathogens, I can tell you that the thought and care that has gone into the design and planning of the BU laboratory exceeds measures in place in those facilities. Thus the BU facility will likely be the safest facility in the country, if not the world, when it is complete and operational. Establishing this facility in Boston is not only safe but will bring with it an expansion of biomedical expertise in Boston that will continue to attract the best and the brightest to this center and city of excellence.

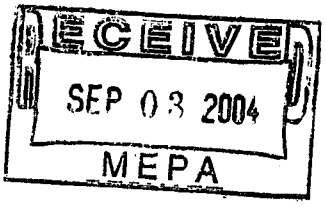
Sincerely,

Frank J. Malinoski, M.D., Ph.D.
Executive Vice President Development Chief Medical Officer
Oxxon Therapeutics Inc.
Old City Hall
45 School Street
Boston, MA 02108
617.383.2100
fmalinoski@oxti.com

**Massachusetts Biologic Laboratories**
University of Massachusetts Medical School
305 South Street, Jamaica Plain, MA 02130

UMASS. Telephone: 617-983-6400 Facsmile: 617-983-9081

BG
12644




August 31, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Herzfelder:

I am writing about Boston University Medical Center's proposed Biosafety Lab, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July 2004.

As Director of the Massachusetts Biologic Laboratories, I oversee the development and manufacture of vaccines and monoclonal antibodies designed to combat illness. Throughout my career I have been involved in researching infectious diseases to develop innovative vaccines and treatments. Therefore, I strongly support the proposed laboratory. There is critical need for more Level 4 laboratory space if this country's scientists are to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

Diseases such as HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza threaten populations in every country and challenge the public health system worldwide. Research into these and other illnesses is essential.

I support Boston University Medical Center's solid proposal to construct and operate, to the highest safety standards, a biosafety laboratory that will save lives.

Sincerely,

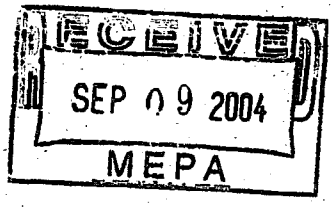
Donna M. Ambrosino, M.D.
Director and Professor
Massachusetts Biologic Laboratories
University of Massachusetts Medical School

BG #12644

COBTH
CONFERENCE OF BOSTON TEACHING HOSPITALS

c/o Boston University Medical Center
715 Albany Street
Boston, MA 02118-2531
phone: 617/414-1888
fax: 617/414-1887
e-mail: estengel@bu.edu

Elizabeth Bell Stengel
Executive Director




September 7, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA #1021

Dear Secretary Herzfelder:

On behalf of the Conference of Boston Teaching Hospitals (COBTH), I am writing in support of Boston University Medical Center's proposed Biosafety Lab, as detailed in the report filed with the Boston Redevelopment Authority in July, 2004.

As the organization representing fourteen Boston-area teaching hospitals, we strongly support the proposed laboratory. In addition to patient care, teaching, and community service, research is one the four core missions of our organization and its member institutions. As organizations concerned about public health in today's ever-changing environment, we are concerned that there is currently a critical need for Level 4 laboratory space to accommodate the work that needs to be pursued if we are to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

COBTH is proud of its part in making Boston a leader not only in the field of biomedical research, but also in disaster preparedness. Certainly, renewed emphasis on the field of public health must continue to be part of this preparedness, as new challenges emerge. Examples of public health threats include HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza, but we also know that terrorists are interested in using biological agents against us. Thus it is critically important that researchers study and understand the biology of these disease-causing agents. This type of work can only be done in specially designed, safe laboratory facilities like the one proposed for BUMC. Researchers at several of COBTH's institutions will be working collaboratively with BUMC researchers to develop life-saving preventions and treatments for the future. We are confident that

both the proposed facility and the research that will take place there will be vital in a world that every day faces new public health and biological threats.

The Conference of Boston Teaching Hospitals supports Boston University Medical Center's proposal for a biosafety laboratory as an important addition to our community that will protect public health and save lives.

Sincerely,

James Mandell MD

James Mandell, M.D., President and CEO
Children's Hospital Boston
Chairman, Conference of Boston Teaching Hospitals

BG

CONSERVATION LAW FOUNDATION

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SEP 13 2004
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September 8, 2004

Secretary Ellen Roy Herzfelder
EOEA, MEPA Office
251 Causeway Street, Suite 900
Boston, MA 02114

Mr. John O'Brien, Project Manager
Boston Redevelopment Authority
One City Hall Plaza, 9th Floor
Boston, MA 02201

*Re:* **Matter:** Comments on the Final Environmental Impact Report (EOEA #12021) and Final Project Impact Report for the BioSquare Phase II Project in Boston

Dear Secretary Herzfelder and Mr. O'Brien,

By this letter, the Conservation Law Foundation (CLF) submits comments on the Final Environmental Impact Report and Final Project Impact Report (FEIR/FPIR) for the proposed BioSquare Phase II Project in Boston. Since the FEIR/FPIR is a joint document, the comments are provided to give guidance under the MEPA Statute and Article 80 of the Boston Zoning Code to EOEA and the BRA. CLF is submitting these comments prior to the official deadline date of 13 October 2004 and therefore reserves the right to submit additional comments later.

CLF is the oldest and largest regional environmental advocacy organization in the United States. Founded in 1966 as a nonprofit, member-supported organization, CLF maintains advocacy centers in five of the six New England states. CLF works to solve the environmental problems that threaten the people, natural resources, and communities in the region. CLF's Smart Growth Program works for open and inclusionary planning and approval processes for proposed development projects in order to ensure that urban neighborhoods are shaped by and for those who live and work there.

Community residents and others have raised a variety of legitimate concerns with respect to this Project, whose overall built area of 194,000 square feet includes an 84,100 square foot national biocontainment laboratory facility (the National Emerging Infectious Diseases Laboratory or Boston-NBL), which in turn houses a 13,100 square foot BioSafety Level-4 (BSL-4) laboratory. The purpose of the BSL-4 laboratory will be to conduct research employing the most deadly bacterial and viral agents known to humanity. The public health hazards associated with these agents, through accidental or intentional release, have caused CLF to question the appropriateness of siting the biocontainment laboratory in the heart of New England's most densely populated neighborhoods.

CLF's comments address one particular concern: the lack of an alternative analysis in the FEIR/FPIR. In response to comments section of the FEIR/FPIR, the Proponent claims that an alternative analysis is being developed for the Environmental Impact Statement under NEPA. However, 301 CMR 11.07(6)(f)

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NEW HAMPSHIRE: 27 North Main Street, Concord, New Hampshire 03301-4930 • Phone 603-225-3060 • Fax 603-225-3059
RHODE ISLAND: 55 Dorrance Street, Providence, Rhode Island 02903-2221 • Phone 401-351-1102 • Fax 401-351-1130
VERMONT: 15 East State Street, Suite 4, Montpelier, Vermont 05602-3010 • Phone 802-223-5992 • Fax 802-223-0060

clearly states that, unless the Secretary has indicated otherwise, a proponent's EIR shall include an analysis of alternatives to the project that includes a "no build" alternative for the purpose of creating a baseline to assess differences in impacts of the Project and its alternatives. In addition, the Secretary's Certificate on the DEIR, which was incorporated by reference and made a part of the Preliminary Adequacy Determination issued by the BRA on the Draft PIR, states that "[t]he purpose of MEPA review is to ensure that a project proponent studies feasible alternatives to a proposed project." In this case, the Proponent has failed to provide a study of feasible alternatives, and CLF has not been able to identify any documentation where EOEA relieved the Proponent of its obligation to provide an alternatives analysis for this Project.

CLF believes that, for EOEA and the BRA to find that the FEIR/FPIR complies with the MEPA statute and Article 80 of the Boston Zoning Code and adequately addresses the impacts of the proposed project, a full analysis of all reasonable siting alternatives needs to be submitted as part of the MEPA/Article 80 process. The Proponent therefore needs to file a Supplemental FEIR/FPIR in order to make the case that the BioSquare Medical Research campus of the Boston Medical Center, or another site, is the most appropriate location for this research facility based on a consideration of all the reasonable alternatives available for this proposed activity. This alternatives analysis is particularly critical given the urban setting of the facility and the fact that a BSL-4 lab handles contagious and lethal diseases, disease-causing bacteria and viruses for which there are no known cures.

The first issue to be addressed in the alternatives analysis is how the Proponent made the decision to site the proposed Boston-NBL Facility and the BSL-4 lab in such a densely-populated neighborhood. This section of the Supplemental FEIR/FPIR should present the criteria used by the Proponent in seeking the grant from the National Institute of Health to construct and operate a Boston-NBL facility and the BSL-4 lab at the proposed site. The Supplemental FEIR/FPIR should include:

- a detailed description of the Proponent's criteria and analysis which resulted in selecting BioSquare as the preferred location of the Boston-NBL/BSL-4 Project;
- a listing and description of the alternative sites that were evaluated, including population density in the areas surrounding those sites, and reasons why they were rejected;
- an explanation of how the site selection criteria were developed and the extent to which BioSquare and the alternative sites met those criteria.

This portion of the alternatives analysis should address the extent to which population density and environmental justice were considered as factors in site selection i.e. the extent to which the Proponent considered the demographics of the population immediately adjacent to the proposed facility and environmental justice implications. It should also include a discussion of the extent to which the siting process incorporated an assessment of risks to public health and safety for the proposed and alternative sites.

The second issue to be addressed in the alternatives analysis is whether there are alternative locations for the Boston-NBL and BSL-4. CLF maintains that it is critical to consider two types of alternatives:

- alternatives for siting the facility elsewhere in Massachusetts, particularly in locations with lower population density yet relatively convenient to Boston-based scientific talent (for example Fort Devens in Ayer or the Naval Air Base in South Weymouth); and
- alternatives in which the main portion of the Boston NBL would remain at BioSquare but the BSL-4 laboratory would be separated out and located in a secure and less-densely populated location convenient to Boston.

**Conclusion**

An integral feature of the MEPA statute and regulations is consideration of alternatives. By assessing alternatives pursuant to MEPA, as suggested above, a responsible and legally mandated approach to minimizing risk to the public and the environment will be taken. CLF therefore urges the MEPA Unit and the BRA to implement the foregoing recommendations regarding the need for a Supplemental FEIR/FPIR for the proposed Boston-NBL/BSL-4 project.

Thank you for considering our comments. We look forward to the issuance of the final certificates requiring the Proponent to prepare and file a Supplemental FEIR/FPIR for this Project.

Sincerely,

Philip Warburg, Esq.
President

cc: Mayor Thomas Menino
Secretary Doug Foy, OCD
Director Mark Maloney, BRA
Jim Hunt, MEPA
Peter Shelley, CLF
Jamie Fay, FPA

BG

Boston University
School of
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September 9, 2004



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

#12021

Dear Secretary Herzfelder:

I am writing in strong and, I believe, informed support of Boston University Medical Center's proposed Biosafety Lab as described in detail in the Final Project Impact Report/Environmental Impact Report that was filed with the Boston Redevelopment Authority in July, 2004.

I am writing in four capacities. As a former Commissioner of Public Health for the Commonwealth, I am acutely aware of the State's responsibility to protect its citizens. And, having grappled with a number of complex environmental issues myself, I know how difficult it is to sort out competing claims. My second capacity is in my role as an expert on bioterrorism, particularly smallpox. Over the past three years I have been very active in promoting sound, feasible and safe methods for protecting the country against smallpox and have published, testified and spoken widely on this subject. I was struck and continue to be amazed at the persistence of widely believed misinformation about smallpox in particular and bioterrorism in general. With my work on bioterorism, I have become very familiar with risk assessment for the bioterrorism big three – smallpox, anthrax and botulinum toxin. My third capacity is as a faculty member of the Schools of Public Health and Medicine concerned with bringing to our University and the State the very best that science has to offer. My last capacity is as a citizen who lives a bit south of Boston but will be working on a daily basis in close proximity to the proposed Level 4 facility.

As I mention smallpox, let me put to rest any fears about smallpox. That is not available to civilian researchers and is kept in a secured facility at CDC. And, there are no plans for any laboratory activities involving smallpox at the proposed facility. Thus, perhaps the riskiest and scariest pathogen does not even get to the table.

The bottom line is one of safety and risk. Is the risk, however small, worth the benefit? How small is the risk? Based on discussions I have had with Dr. Klempner and others,

my review of materials and my participation in forums about the Level 4 facility, I am convinced the measures taken to reduce risk are well conceived, will work and the actual future adverse likely impact on the public is close to nil. I encourage careful and regular federal and state oversight of operations, but I believe the safety issue has been and will continue to be well and fully addressed.

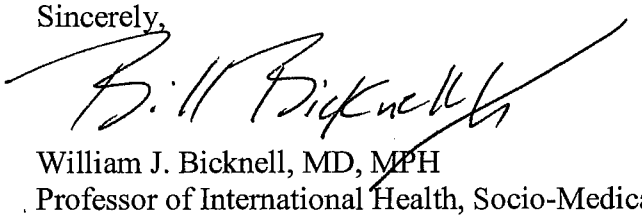
The benefits of the new facility are many. Assuring that Boston and Massachusetts remain at the forefront of biomedical science, medical education and health care is of paramount interest. This facility assures that our State will be at the cutting edge of new work on vaccines, new treatment methods and the basic science research needed to illuminate new opportunities for improvements in prevention and treatment of ALL infectious diseases. Pre-eminence in medicine is not only good for individual patients, it is very good for the long-term growth of the Massachusetts economy.

Not moving forward with the Level 4 facility is a bit like cutting off your nose to spite your face. It just doesn't make sense. Safety is assured and the benefits are many. I urge and strongly support your approval of the Boston University Medical Center proposal for the Level 4 facility.

To sum it up: After the facility is built and operational, would I buy a condominium in the South End and have my grandson visit. The answer is yes.

If you or your staff have any questions, I would be pleased to meet or otherwise do my best to be helpful.

Sincerely,



William J. Bicknell, MD, MPH
Professor of International Health, Socio-Medical Sciences, and Community Medicine, Department of International Health
Professor of Family Medicine and Director of International Programs, Department of Family Medicine
Boston University Schools of Public Health and Medicine

FORT POINT ASSOCIATES, INC.
286 Congress Street
6th Floor
Boston, Massachusetts 02210
617 / 357-7044
FAX 617 / 357-9135

September 20, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
100 Cambridge Causeway Street, Suite 900
Boston, MA 02114
Attn. Janet Hutchins, MEPA Office

RE: University Associates Limited Partnership
BioSquare Phase II Project, EOEA # 12021
Final Project Impact Report/Environmental Impact Report (FPIR/EIR)

Dear Secretary Herzfelder:

As requested, University Associates would like to withdraw and resubmit the Final Project Impact Report/Environmental Impact Report for the BioSquare Phase II Project to allow for the public comment period to extend until October 25, 2004 with the Secretary's decision issued on November 1, 2004.

We look forward to working with you and your staff in the review and evaluation of this exciting project. If you have any questions please feel free to contact me at 617-357-7044.

Sincerely,

Susan St. Pierre
Senior Associate

cc: W. Gage, MEPA
J. O'Brien, BRA
D. Camiolo, RF Walsh
R. Towle, Boston University
J. Greene, Rubin and Rudman
J. Fay, FPA

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER℠

MASSACHUSETTS
GENERAL HOSPITAL

HARVARD
MEDICAL SCHOOL

20 September 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Herzfelder;

I am writing this letter in support of the proposed Biosafety Laboratory at Boston University Medical Center, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July 2004.

I strongly support the proposed laboratory which will aid in developing treatments and vaccines to deal with both emerging and re-emerging infectious diseases. Such work must be performed in a Level 4 laboratory and there is currently insufficient space in which to do it.

We are all too familiar with the infectious disease that have impacted our society over the past decade, but with the current concern of biological warfare/terror, it is essential that we be prepared. Laboratories such as that proposed by Boston University Medical Center, are essential to provide for the safety of our city, state, and our nation.

I hope your office will also support the proposed Laboratory.

Sincerely,

Lawrence S. Blaszkowsky, MD

BG

Christopher Brayton
3 Haven Street
Boston, MA 02118

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SEP 24 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

September 21, 2004

**RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

I am writing regarding the above-referenced biosafety laboratory that Boston University Medical Center is proposing to build on its campus in the South End.

I am a resident of Boston's South End and I support the construction of this biocontainment facility. We live in a time when we are no more than 36 hours away from infectious diseases that can threaten us. Facilities like the BUMC Biosafety Laboratory have the potential to develop cures to save lives and to protect us and our children from the ravages of these diseases, whether these agents occur naturally or are introduced by terrorists.

I have seen Boston University Medical Center demonstrate respect for its neighbors by its enhanced outreach activities and by its efforts to inform the South End community as well as communities throughout Boston about the project and to answer questions about its development.

I have been particularly reassured by the safety presentations by project officials that the laboratory will be safely built and operated.

I strongly support Boston University Medical Center's proposal to build a biosafety laboratory here in my neighborhood/this community/the South End.

Sincerely,

Christopher Brayton

FORT POINT ASSOCIATES, INC.
286 Congress Street
6th Floor
Boston, Massachusetts 02210
617 / 357-7044
FAX 617 / 357-9135

September 24, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
100 Cambridge Causeway Street, Suite 900
Boston, MA 02114
Attn. Bill Gage

RE: BioSquare Phase II (EOEA #12021)
FPIR/EIR Comments of Clarification

Dear Ms. Herzfelder:

Attached please find the enclosed comment document submitted by University Associates Limited Partnership ("University Associates") entitled "Comments of Clarification on the FPIR/EIR".

The enclosed comments of clarification are submitted by the project proponent, University Associates Limited Partnership, to assist the agency reviewers and the public in an examination of the filings submitted to the BRA and MEPA in connection with the BioSquare Phase II project and the NBL project as a part thereof, and include an elucidation of components and materials contained in the filings, including the DPIR/DEIR and the FPIR/EIR.

We are distributing this document to those listed on the distribution list included in the FPIR/EIR and to those persons who have requested copies of the document. Please do not hesitate to call me if you have any questions concerning these comments.

Sincerely,

Susan St. Pierre
Senior Associate

dd. D. Camiolo, RF Walsh
R. Galvin, RF Walsh
R. Towle, BU
J. Fay, FPA
J. Greene, RR

BG

MYRON M. LEVINE, M.D., D.T.P.H.
Professor and Director

CENTER FOR VACCINE DEVELOPMENT

# UNIVERSITY OF MARYLAND
# SCHOOL OF MEDICINE

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OCT. 1 2004
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September 27, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Herzfelder: — # 12021

I am writing concerning Boston University Medical Center's proposed Biosafety Lab, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July, 2004.

As the Director of the Center for Vaccine Development which conducts research in the areas of bacterial diseases, parasitic diseases, viral diseases, novel delivery systems, combination vaccines and public health and policy, I strongly support the proposed laboratory. In addition, as Principal Investigator at the lead institution of the NIH NIAID Middle Atlantic Region Center of Excellence (MARCE) for Biodefense and Emerging Infectious Diseases Research I am fully aware and supportive of the need for such facilities to support continued research in this area. The MARCE investigators within this consortium of 16 biomedical research institutions conduct research aimed at carrying out the NIAID's strategic plan for biodefense research. The MARCE researchers aim at developing new and improved vaccines, diagnostic tools and treatments to help protect the country and world from the threat of bioterrorism and naturally occurring infectious diseases.

There is critical need for additional Biosafety Laboratory facilities to provide support for ongoing and new biomedical research to protect this country from threat of bioterrorism. There is not enough Level 4 laboratory space to accommodate the work that needs to be pursued if we are to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

Challenges to public health continue to emerge. Some examples include HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza. We know too that terrorists are interested in using biological agents against us, therefore scientists must be able to understand the biology of these disease-causing agents. This type of work can only be done in specially designed, safe laboratory facilities like the one proposed for BUMC.

I support Boston University Medical Center's solid proposal for a biosafety laboratory that will save lives and be constructed and operated at the highest safety standards.

Sincerely,

Myron M. Levine, M.D., D.T.P.H.
Professor and Director
University of Maryland School of Medicine
Principal Investigator, MARCE

Department of Medicine • Division of Geographic Medicine
Department of Pediatrics • Division of Infectious Diseases and Tropical Pediatrics
Department of Pediatrics • Division of Pediatric Gastroenterology

685 West Baltimore Street • Baltimore, Maryland 21201-1509 • 410 706 5328 • 410 706 6205 *fax*

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SEP 29 2004

MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

**RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

I am writing regarding the above-referenced biosafety laboratory that Boston University Medical Center is proposing to build on its campus in the South End.

I am a resident of the South End and I support the construction of this biocontainment facility. It is critical that our country construct such laboratories in this age of terrorism. We live in a time when we are no more than 36 hours away from infectious diseases that can threaten us. Facilities like the BUMC Biosafety Laboratory have the potential to develop cures to save lives and to protect us and our children from the ravages of these diseases, whether these agents occur naturally or are introduced by terrorists. I am considerably more fearful that a new decease will crop up somewhere in the world and be spread by travelers throughout the world (SARS)

I have seen Boston University Medical Center demonstrate respect for its neighbors by its enhanced outreach activities and by its efforts to inform the South End community as well as communities throughout Boston about the project and to answer questions about its development.

I have been particularly reassured by the safety presentations by project officials that the laboratory will be safely built and operated. I consider such a facility to be a far greater risk to its staff and their families, then to its neighbors, making self-preservation the strongest assurance that the lab will meet or exceed all of the relevant safety standards.

I strongly support Boston University Medical Center's proposal to build a biosafety laboratory here in my neighborhood/this community/the South End.

Kenneth Olken
1313 Washington Street #609
Boston, MA 02118

BG

MICHAEL F. FLAHERTY
PRESIDENT OF THE
BOSTON CITY COUNCIL



September 29, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
100 Cambridge Street
Boston, MA 022114



Re: EOEA # 12021

Dear Secretary Herzfelder:

This letter is to express my unqualified support for the proposal of Boston Medical Center and Boston University to help establish a bio-safety Research Facility at Boston Medical Center.

My colleagues and I have been fully briefed in the proposed facility that would be located adjacent to the Boston Medical Center campus in Boston's South End neighborhood. Bio-terrorism represents a serious and substantial threat to those who live, work and visit in the City of Boston. It is my strong hope that the impact of bio-terrorism be prevented through scientific research and it's harmful effects limited by medical vaccinations.

A bio-safety research facility such as the one you propose is key to making such safeguards possible. It is my hope that this necessary project can move forward to benefit and protect the City of Boston. Please feel free to contact me if I can offer any additional assistance or support.

Very truly yours,

**MICHAEL F. FLAHERTY**
President
Boston City Council

BOSTON CITY HALL, ONE CITY HALL SQUARE, BOSTON, MASSACHUSETTS, 02201
617-635-4205 FAX: 617-635-4203 Michael.F.Flaherty@cityofboston.gov

# long bay management company

351 massachusetts avenue • boston • massachusetts 02115 • tel (617) 266-8604 • fax (617) 266-0185


BG

September 29, 2004

RECEIVED

OCT 1 2004

MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

**RE: Final Project Impact Report/ Environmental Impact Report BioSquare Phase II Project, EOEA # 12021**

Dear Mr. Maloney,

I am writing in regards to the above-referenced bio-safety laboratory that Boston University Medical Center is proposing to build on its campus in the South End.

On behalf of the Burroughs Group, a forty-five-member organization comprising of business owners and operators in the City of Boston, I write to you in my capacity as a member. I strongly support the construction of the bio-containment facility.

It is critical to our community that such a facility be built in this age of increasing diseases affecting our communities such as HIV, Sickle Cell Disease and Asthma to name a few. We live in a time when we are no more than 36 hours away from infectious diseases that can threaten our existence. Facilities like the BUMC Bio-safety Laboratory have the potential to develop cures to save lives and to protect us and our children from the ravages of theses diseases.

I also believe that the Bio-safety Laboratory will be, on many levels, an important economic catalyst for the community that will provide employment opportunities on all levels. Special emphasis should be placed on making training programs available to the members of the community. I trust that BUMC will provide the accessibility for the following initiative:

- Community Education Programs
- Lab Technician Jobs
- Scholarships for high level Research positions
- Construction Jobs
- Small Business support

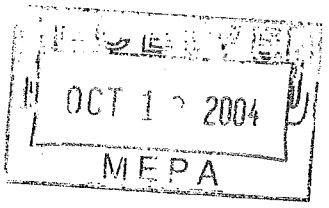
I strongly support Boston University Medical Center's proposal to build a bio-safety laboratory in the South End and feel confident they will build and operate it safely.

Sincerely,

Kenneth I. Guscott
General Manager

BG

September 29, 2004




Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021

Dear Secretary Herzfelder:

I live in the city of Boston and, given the information presented to me, believe that the biosafety lab will provide many benefits to our community.

Indeed, it already is providing these benefits. In August 2004, Boston University announced that it would give $1 million in scholarships so that over 100 Boston residents can be trained for positions in biotechnology and biomedicine as a direct result of the siting of this laboratory here in Boston. Such a commitment represents the first of many different resources Boston University can bring to this neighborhood and residents across the city of Boston.

I believe this project has the potential to act as an economic stimulus, attracting other biotech companies to the area. It is also hoped that other "spin-off" industries and/or businesses will be attracted to this potential project. I ask that you use your offices to identify these additional benefits to the community and its residents.

Boston, as one of the leading cities in biotechnology and biomedical research, needs projects like these. Project officials have addressed a number of my concerns about transportation and safety. I trust BU officials will continue to work with those in the community who feel that this project is a threat. Clearly more dialogue is needed in this regard.

With this said, I endorse the proposed biosafety laboratory, as I believe it is one of the keys to building Boston future as a city committed to providing jobs and ensuring the public's safety.

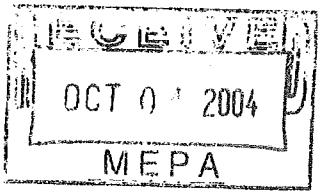
Sincerely,

Kevin C. Peterson

NOVOBIOTIC
PHARMACEUTICALS

BG

September 30, 2004




Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Herzfelder:

I am writing to support Boston University Medical Center's plans to build the Biosafety laboratory as part of the BioSquare development on Albany Street.

This laboratory will save lives, and the development of the lab will enable Boston to maintain its lead in biotechnology. The laboratory is an important economic development that will create many jobs.

After reviewing the plans I am convinced that B.U. will construct and operate the most secure biosafety lab in the world.

I am also confident that B.U. has addressed every relevant community and environmental issue and urge your agency to approve this worthwhile project.

Sincerely,

Aram Salzman
President and CEO

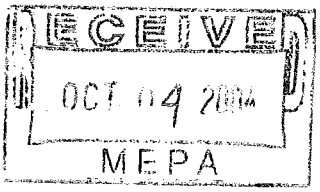
767C Concord Avenue • Cambridge, MA 02138
ph: (617) 864-2880 • fax: (508) 685-5083 • web: www.novobiotic.com

# TAYLOR SMITH

REALTY, INC.

B6

October 1, 2004




Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021

Dear Secretary Herzfelder:

I have worked as a real estate developer and entrepreneur in the Roxbury South End community for more than 20 years. During that period the community has always struggled with the concept of job creation that is both meaningful to community residents and in close proximity to the neighborhoods.

The Bio Safety Lab currently proposed by Boston University and the Boston Medical Center offers tremendous promise for this job creation struggle. The lab will offer hundreds of non-scientist jobs that will allow local residents to work and earn a good salary. Moreover, Boston University has established a very generous scholarship training program that will assist people in accessing the first rung on the employment ladder.

In addition there is the connection to the Longwood Medical area that could also offer future work once people are trained and available to work. There is also the high probability of spin off companies growing in the area all along the Southwest Corridor as the experiments and research at the lab leads to commercial transfer technology applications. The Bio Safety Lab and its construction represent a high opportunity to give jobs and growth in the Southwest Corridor and surrounding communities.

I believe this project will act as an economic stimulus, attracting other biotech companies to the area. Boston, as one of the leading cities in biotechnology and biomedical research, needs projects like this. Project officials have addressed my concerns about transportation and safety, which are outweighed substantially by the benefits.

I strongly endorse the proposed biosafety laboratory, as I believe it is the key to tying Roxbury to the 21st century economy in Greater Boston.

Very Truly Yours,

Richard L. Taylor

100 Huntington Avenue ● Copley Place ● Boston, MA 02116 ● 617 424.8200 ● Fax 617 424.8201

Committee on Financial Services

Committee on Transportation & Infrastructure

Democratic Regional Whip

Democratic Steering & Policy Committee

www.house.gov/capuano/

# Congress of the United States
## House of Representatives
Michael E. Capuano
8th District, Massachusetts

**Washington Office:**
1232 Longworth Building
Washington, D.C. 20515-2108
202-225-5111
Fax:; 202-225-9322

**District Offices:**
110 First Street
Cambridge, MA 02141
617-621-6208
FAX: 617-621-8628

Roxbury Community College
Room 110



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

October 6, 2004

RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA #12021

Dear Secretary Herzfelder:

I am writing to you regarding the Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA #12021, the proposed Boston University Medical Center's National Center for Infectious Diseases and Biodefense (the biolab).

My staff and I have made a serious effort to better understand the issues involved with the biolab. To that end, I have sought out the opinions of scientists around the country about this proposal. In particular, I have asked for the perspective of researchers with advanced degrees in microbiology and molecular biology. Thus far, the response I have received has been "these labs can and are built and operated so that they are safe."

Respected scientists nationwide tell me that biocontainment measures are well understood and applied elsewhere – such as the Center for Disease Control in Atlanta, where a comparable lab has been in operation since 1989. No one – working there or living near it – has been infected by materials studied in the lab. When I contacted my colleagues in Congress who have this lab in or near their districts for their insight, they had no concerns about the lab's safety. Moreover, the Boston biolab will be supervised by the National Institute of Allergy and Infectious Diseases, part of the National Institute of Health. On the basis of what I have learned so far, I support building the biolab at this time.

I do not take this stance lightly, nor do I make it with absolute finality. Although there are significant benefits to the regional economy in maintaining our preeminence in biomedical sciences, my constituents' safety is my paramount concern. To that end, I continue to search out perspectives and information on this project. If I should come to believe the biolab posed a danger, I would oppose it. That said, I am currently satisfied that security and safety concerns have been and will continue to be addressed appropriately.

In addition to the issue of safety, which I will continue to monitor, I am also concerned about the impact that construction of the biolab may have on the quality of life for the neighborhoods closest to the site. As with all other projects occurring in the city of Boston, the city is responsible for overseeing actual construction. Just the same, I have communicated my concerns to Boston University, and I expect that BU will do all it can to maintain the quality of life of the surrounding neighborhoods during construction and that it will take care to minimize any inconveniences that may occur.

Sincerely,

Michael E. Capuano
Member of Congress

BG FYI MEPA

# CONSERVATION LAW FOUNDATION

RECEIVED
OCT 13 2004
MEPA

RECEIVED
OCT 12 2004
EXECUTIVE OFFICE OF
ENVIRONMENTAL AFFAIRS

October 7, 2004

Richard Towle
Senior Vice President
Boston University – Office of the Senior Vice President
One Sherborn Street
Boston, MA 02215

**RE: Biosquare II Alternative Sites Analysis**

Dear Mr. Towle:

Thank you and the project team for meeting with us to discuss the MEPA/Article 80 process for the Biosquare II Project (Project). It was helpful to learn more about the progress Boston University (BU) has made since our last meeting and that BU will release the Draft Environmental Impact Report (DEIR) in the next few weeks. The DEIR is another important stage in reviewing the environmental impacts of this project.

However, we are very concerned that BU failed to provide an alternative analysis for this Project as part of the MEPA/Article 80 process. An alternative analysis, especially discussing the siting issues, is of paramount concern to us. We need to have the necessary information to understand why a project proponent selected one location over another it owned or controlled. It is our understanding that BU owns property along Commonwealth Avenue and in Tyngsboro, MA, and Peterborough, NH. These sites should be analyzed as alternative locations for this project in addition to any other Boston University-owned or controlled properties.

We believe that the "generic" analysis of alternatives which you stated the forthcoming EIS would contain simply will not address the physical siting issues. NEPA, MEPA, and Article 80 review processes were established to facilitate informed decision-making. As we pointed out in our comment letter of September 8, 2004 and as the Secretary's Certificate on the DEIR explains, "the purpose of MEPA review is to ensure that a project proponent studies feasible alternatives to a proposed project." We have not yet seen any study of feasible alternatives, especially addressing the siting of this facility, and we are very concerned that the level of forthcoming analysis of alternatives you described will not sufficiently facilitate informed decision-making on this issue.

We request that you release a list of all locations owned or controlled by Boston University. An analysis of these locations as alternative sites should be completed as part of any supplemental MEPA/Article 80 and NEPA filings.

62 Summer Street, Boston, Massachusetts 02110-1016 • Phone: 617-350-0990 • Fax: 617-350-4030 • www.clf.org

MAINE: 14 Maine Street, Brunswick, Maine 04011-2026 • 207-779-7733 • Fax: 207-779-7373
NEW HAMPSHIRE: 27 North Main Street, Concord, New Hampshire 03301-4930 • 603-225-3060 • Fax: 603-225-3059
RHODE ISLAND: 55 Dorrance Street, Providence, Rhode Island 02903 • 401-351-1102 • Fax: 401-351-1130
VERMONT: 15 East State Street, Suite 4, Montpelier, Vermont 05602-3010 • 802-223-5992 • Fax: 802-223-0060

Again, we very much appreciated your explanations of the process and the reasoning behind selection of the current Biosquare II site. However, it is important that we understand how and why BU chose this location for the BSL4 facility and how it compares to other property owned or controlled by BU. We look forward to reviewing this analysis when it is released.

Sincerely,

Philip Warburg, Esq.
President

CC: Mark Klempner, M.D. (BU)
Steve Williams, Esq. (BU)
Jamie Fay (FPA)
Peter Shelley (CLF)
Carrie Schneider (CLF)
Mayor Thomas Menino (COB)
Secretary Doug Foy (OCD)
Secretary Ellen Roy Herzfelder (EOEA)
Director Mark Maloney (BRA)
Jim Hunt, Esq. (MEPA)

## Hutchins, Janet (ENV)

**From:** Jamie Fay [jfay@fpa-inc.com]
**Sent:** Friday, October 08, 2004 1:17 PM
**To:** Jim Hunt
**Cc:** James H. Greene; Richard Towle; Jay Russo; John O'Brien; Dick Galvin; camiolod@rfwalsh.com; Janet Hutchins
**Subject:** BioSquare EIR EOEA #12021

Pursuant to our prior conversation, this email shall confirm our consent/request to administratively withdraw and resubmit the Final EIR on the above referenced project. The comment period will now extend through November 8th and the Secretary's decision will be issued on November 15.

Jamie Fay
President
Fort Point Associates, Inc.
286 Congress Street, 6th Floor
Boston, MA 02210
(617) 357-7044 ph
(617) 357-9135 fax

BG

SOUTH BOSTON COMMUNITY HEALTH CENTER

William J. Halpin, Jr.
*Chief Executive Officer*

Nisha Thakrar, M.D.
*Medical Director*

October 12, 2004

RECEIVED
OCT 14 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

**RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

We are writing regarding the above-referenced biosafety laboratory that Boston University Medical Center is proposing to build on its campus in the South End.

We are the primary health care provider in South Boston and we support the construction of this biocontainment facility. It is critical that our country construct such laboratories in this age of terrorism. We live in a time when we are no more than 36 hours away from infectious diseases that can threaten us. Facilities like the BUMC Biosafety Laboratory have the potential to develop cures to save lives and to protect us and our children from the ravages of these diseases, whether these agents occur naturally or are introduced by terrorists.

We have seen Boston University Medical Center demonstrate respect for its neighbors by its enhanced outreach activities and by its efforts to inform the South End community as well as communities throughout Boston about the project and to answer questions about its development.

We have been particularly reassured by the safety presentations by project officials that the laboratory will be safely built and operated.

We strongly support Boston University Medical Center's proposal to build a biosafety laboratory here in my neighborhood/this community/the South End.

Sincerely,

William J. Halpin, Jr.
Chief Executive Officer

BG

Sheila Grove
51 Union Park
Boston MA 02118

617-482-4888

Fax 617-292-4666

October 12, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA # 12021

Dear Secretary Herzfelder:

Biosafety labs are certainly necessary facilities to continue efforts to combat diseases that can plague our planet. I live in the South End and believe that the biosafety lab can be operated safely in our neighborhood.

The biosafety lab can also provide economic benefits to Boston. These benefits are off to a good start with Boston University's recent announcement that it would give $1 million in scholarships so that over 100 Boston residents can be trained for positions in biotechnology and biomedicine. I trust that this sort of training will be provided as an ongoing benefit to the community.

To ensure that the biosafety lab is constructed and operates in a safe manner, I urge that an independent community oversight group have real power over the types of research conducted at the facility and the safety of that research. With this type of committee in place, I feel comfortable with having the biosafety lab in my neighborhood.

Very truly yours,

Sheila Grove

COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENVIRONMENTAL AFFAIRS
DEPARTMENT OF ENVIRONMENTAL PROTECTION
METROPOLITAN BOSTON – NORTHEAST REGIONAL OFFICE

MITT ROMNEY
Governor

KERRY HEALEY
Lieutenant Governor

ELLEN ROY HERZFELDER
Secretary

ROBERT W. GOLLEDGE, Jr.
Commissioner



October 13, 2004

Ellen Roy Herzfelder, Secretary
Executive Office of
Environmental Affairs
251 Causeway Street, Suite 900
Boston MA, 02114

RE: Boston
Biosquare II
EOEA # 12021

Attn: MEPA Unit

Dear Secretary Herzfelder:

The Department of Environmental Protection Northeast Regional Office has reviewed the Final Environmental Impact Report (FEIR) submitted by University Associates Limited Project for the development of a 9.3 acre site in South Boston with two medical research buildings totaling about 428,700 square feet, and a 1,400 space parking garage (EOEA# 12021). The project in the FEIR differs from the project described in the DEIR; the Boston-NBL building has been reduced by about 29,000 square feet, and the security building and maintenance facility have been eliminated. The Department requests that mitigation measures be included in the Section 61 Findings for DEP permits to address the following comments on wastewater and construction-related issues.

**Wastewater**

The FEIR estimates that 63,452 gpd of sanitary sewage will be discharged from the Biosquare II development. The Department appreciates the proponent's commitment to remove extraneous clean water (e.g., infiltration/inflow (I/I)) from the system, and will include this commitment in the Section 61 Finding for the DEP sewer connection permit. Working with the Boston Water and Sewer Commission (BWSC), the DEP, and the MWRA, the proponent is proposing to remove, or cause to be removed, 253,808 gpd of I/I, in accordance with the BWSC I/I removal formula, which is based on elimination of 4 gallons of I/I for every gallon of new wastewater flow added to the wastewater system.

The proponent also has acknowledged that pretreatment of industrial wastewater will be required prior to discharge into the MWRA system. This work will be coordinated with the DEP-NERO Bureau of Waste Prevention.

**Construction Impacts**

The project proponent is advised that removing contaminated soil, pumping contaminated groundwater, or working in contaminated media must be done under the provisions of MGL c.21E/21C and OSHA. Site work usually cannot be redirected to alternate locations and construction cannot proceed through contaminated areas without health and safety precautions, proper contaminated soil handling and disposal practices, and contaminated groundwater management practices. According to the DEIR, it appears that appropriate soil and groundwater tests are being conducted. However, to avoid delay of the project, obtain the necessary permits under these provisions well in advance of construction.

**Construction Period Air Quality Impacts**

The Response to Comments section of the FEIR indicates that the proponent will *consider* implementing a construction equipment retrofit program and the use of low sulfur diesel fuel. The Department believes the proponent should make a firm commitment to these construction period mitigation measures based on the following. First, diesel equipment emits exhaust containing fine particles and other toxic air pollutants, which have been linked to cancer, asthma, bronchitis and other respiratory illnesses. Second, the proposed project is in close proximity to sensitive receptors including residential, commercial, and institutional buildings. Finally, a recent study by the Northeast States for Coordinated Air Use Management has shown that operators are exposed to elevated levels of diesel emissions from off-road construction equipment, in some cases up to sixteen times more than recommended federal levels. The level of diesel emissions during the construction period and the associated health risks can be greatly reduced with the use of retrofits and low sulfur diesel fuel.

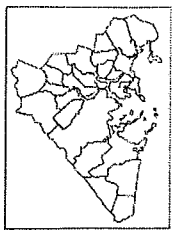
The DEP Northeast Regional Office appreciates the opportunity to comment on this proposed project. Please contact John Zajac at (617) 654-6600 for further information on the sewer issues. If you have any general questions regarding these comments, please contact Nancy Baker, MEPA Review Coordinator at (617) 654-6524.

Sincerely,

John D. Viola
Assistant Regional Director

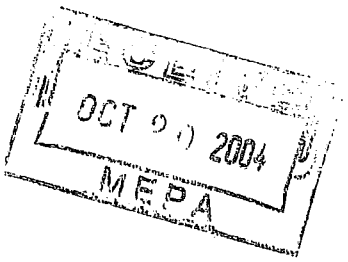
cc: Brona Simon, Massachusetts Historical Commission
Christine Kirby, DEP-Boston
Jack Zajac, DEP-NERO
Muhammed Ashan, DEP-NERO, BWP

BG



# INNER CORE COMMITTEE

Metropolitan Area Planning Council
60 Temple Place, 6th Floor
Boston, MA 02111
Tel: 617-451-2770 • Fax: 617-482-7185




October 19, 2004

Ellen Roy Herzfelder, Secretary
Executive Office of Environmental Affairs
Attention: MEPA Office
William Gage, MEPA # 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: BioSquare Phase II, EOEA # 12021 FEIR

Dear Secretary Herzfelder:

The Inner Core Committee is a subregional organization set up by the Metropolitan Area Planning Council, comprised of the 24 municipalities in the heart of the Boston region. It is the intent of the Committee to encourage proponents of large-scale developments to incorporate sound regional planning principles into their projects and respond to the unique needs of the Inner Core Subregion. The Committee reviewed the FEIR for the BioSquare Phase II and offers the following comments.

The Inner Core Committee has been an strong supporter of the Urban Ring project. This project is critical to meeting to the mobility needs of residents and workers in Boston and the surrounding communities. The FEIR notes that the proposed project would affect the Urban Ring Bus Rapid Transit route in this area, and that the new route would no longer include an exclusive bus right-of-way. As of the writing of the FEIR, it does not appear that the MBTA has concluded that these changes are acceptable. In addition, the proponent has not determined how these changes would affect the remainder of the route in terms of delays and impact on ridership. It is critical that the proponent, the MBTA, and the City of Boston agree on a plan that will not decrease the level of service planned for the route.

The site is near important regional transportation facilities – I-90, I-93, MBTA subway lines and several bus routes – and is also close to Logan International Airport. The FEIR is not clear on how these facilities could be affected if there is an actual toxic release or a threat of one. The proponent must disclose the possible effects of any such event, and, as mitigation for the project, work with the appropriate state, regional, and local agencies to create a contingency plan.

Finally, while reviewing the proposed project and comment letters by others, we wonder if, in the future, MEPA Review Thresholds need to be updated to allow more careful analysis of a project such as this one. Technology, science, and the nature of security threats have all changed since MEPA was created. It may be time to modernize the MEPA thresholds to ensure that appropriate analyses and mitigation result from the MEPA process.

Sincerely,

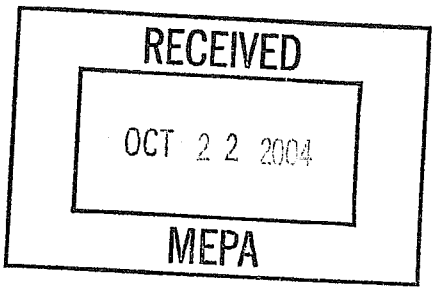
Jeff Levine (JL)

Jeff Levine
Chair, Inner Core Committee

Cc: Inner Core Committee

BG

Virginia Pratt
7 Segel Street, Unit 3
Jamaica Plain, MA 02130




October 19, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office, attn: EOEA # 12021
100 Cambridge St., Suite 900
Boston, MA 02114

RE: Opposition to the proposed Level 4 Bio-Terror Lab for Boston

Dear Secretary Roy Herzfelder:

I am writing to you to inform of my continued opposition to the proposed Bio-Terror Level 4 Lab for Boston. I write to you as a long-term resident of Boston, who exercises her voting rights, and is active with a variety of civic organizations including the Women's International League for Peace and Freedom (WILPF). WILPF has gone on record as opposing the Lab. Members of WILPF tend to be highly educated, politically active, and concerned world citizens. We are active on local, national and international issues.

Many of us have attended the community meetings intended to wear down the opposition to the lab. I was not able to attend the last meeting on October 4, 2004, but was told that it was much like other meeting with experts with power point presentations dominating the meeting and not taking comments from citizens seriously.

We are not opposed to research for medical purposes. We are opposed to the secrecy that would shroud this lab and its possible links with defense. We oppose the proliferation of bio-weapons research. And, we are genuinely concerned about possible outbreaks, leaks and terrorist attacks. We feel this lab makes us and people around the world less safe. If the purposes were strictly medical the research could be conducted in a Level 2 lab. Level 4 is top secret and highly sensitive.

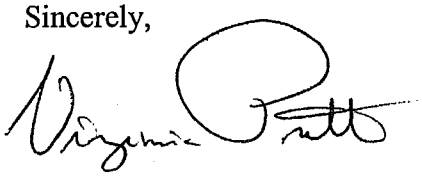
How could you possible expect us to believe that this lab poses no threat when everyday we uncover report after report of safety violations from bio-laboratories, including labs operated by BU? I am enclosing a copy of a recent article from the New York Times about the Plum Island Animal Disease Center. According to the article, Plum Island was charged with more than 260 violations of workplace safety law violations. They are still in operation. They haven't been shut down even though they pose a clear threat the community.

I agree with Boston's esteemed city councilor Felix Arroyo. The community would benefit more from a supermarket. I would create about the same number of jobs,

pay about the same level of wages, and be safer for the workers and the community. The potential for BoPaul(sp) scale accident such as the one in India with the Dow chemical plant can not be dismissed. Residents are still suffering as result of that chemical accident more than 2 decades ago. With the proposed lab we also run the risk of terrorist attack.

In response to my letter dated August 5, 2004 to Dr. Faucci I was sent me a letter along with documents. These official documents have not persuaded me. Instead, they make me angrier that so much money is being wasted on this effort to build this lab. I would prefer that the money go to expanding services for the uninsured or flu shots for the elderly. I look forward to the day when we along with the residents of Davis, California can celebrate the Peoples' victory of having been successful in preventing the lab from being built here in Boston. For ethical and safety reasons, this lab should never be built.

Sincerely,



Virginia Pratt

P.S. I salute my local city councilors: Arroyo, Hennigan, and Turner for their concern for their constituents and public opposition to the lab.

Enclosure

cc: Senator Edward Kennedy
Mr. John O'Brien, Boston Redevelopment Authority
John Tobin, City Councilor
Sue Gracey, WILPF

http://www.nytimes.com/2004/10/17/opinion/opinionspecial/17LIcarroll.html
Island Fever
By MICHAEL CHRISTOPHER CARROLL

Bellmore - This summer, the Plum Island Animal Disease Center off the east end of Long Island suffered two outbreaks of the foot-and-mouth virus, one of many microbes researched and stored there. Despite letters from federal, county and town officials, researchers from the Department of Homeland Security and the Department of Agriculture failed to disclose the outbreaks, which took place in June and July, until nearly a month after the second occurrence. The public learned of them only after an anonymous tip reached the ears of a reporter.

While the virus can cause illness in humans, it is not fatal. But these latest accidents raise the specter of a future outbreak of other germs with lethal consequences. They also represent another instance in a long history of failed and belated disclosures at Plum Island. Unless changes are made, the government should close the lab.

Plum Island has a long and checkered history. It began as the brainchild of a German biological warfare scientist, Erich Traub, who was secretly smuggled into the United States in 1949 to perform biological weapons research for the Central Intelligence Agency, the Army and the Navy. The laboratory was established in 1954 by the Army to research exotic germs for use against enemy food supplies.

In the mid-1950's, the Army turned over control of Plum Island to the Department of Agriculture, which in turn relinquished much of it to the Department of Homeland Security last year. A number of the germs researched on Plum Island are dangerous to humans and animals and some are lethal, including the mosquito-borne Rift Valley fever virus, which causes hemorrhagic fever akin to the Ebola virus and killed 600 people in Egypt in 1977 and 1978.

During the 1980's and early 1990's, Plum Island was charged with more than 260 violations of workplace safety law violations by the Occupational Safety and Health Administration, including improper disposal of virus syringes and radioactive cobalt-60, unlabeled and
mislabeled hazardous chemical containers and workers bitten and trampled by test animals. In addition, according to the Environmental
Protection Agency, from the mid-1990's to 2002 there were violations of state and federal environmental laws, including illegal animal
sewage discharges into local waters under the Clean Water Act. The New York State Department of Environmental Conservation described the
environmental pollution as troubling, and in December 2002, the island made the National Resources Defense Council's "Dirty Dozen" list of the 12 worst polluters in New York and New Jersey.

After the Sept. 11 attacks, a file with information on Plum Island was found by American forces in Afghanistan in the Kabul residence of
Sultan Bashiruddin Mahmood, a former nuclear scientist from Pakistan whom American officials have identified as an associate of Osama bin
Laden. Last year, the Government Accountability Office, the investigative arm of Congress, found that laboratory officials "have not adequately controlled access to the pathogens."

Ostensibly in response to this and concerns raised by elected officials, in July Plum Island bolstered the small 24-hour detail
provided by a private security firm with part-time federally trained armed guards. Plum Island administrators claim that the laboratories
are as safe "as a federal courthouse." They stress that the scientists work only on animal pathogens, particularly diseases that
affect farm animals. They say that Plum Island is well protected, and that they meticulously detail biological safety and security
practices to reporters with whom they've pledged to be forthright about problems that arise. They boast on their Web site that they are

"proud" of their safety record.

But the foot-and-mouth outbreaks that occurred this summer raise important questions: How did it happen? Were proper safety measures followed? What is being done to prevent it from happening again?

To address some of these problems, several security measures should be taken. First, armed couriers should be employed to transport the foreign germs that arrive at nearby international airports and are carried along Connecticut and New York roads. Moreover, emergency first responders like county fire and police officials should be notified of each trip and be properly equipped and prepared to respond to a biological accident or terrorist attack. Second, the Department of Homeland Security must enforce a no-flight zone over Plum Island. And third, the department must re-establish full federal control of the island. Plum Island's biological containment, security, sewage and water systems are now run by a private contractor, but the work being done there is too dangerous to be in private hands.

By contrast, Plum Island's sister laboratory in Ames, Iowa, holds less dangerous germs and it is not privatized. In fact, in 2003, Senator Tom Harkin of Iowa blocked an effort to install private contractors there. The Ames laboratory, he said, is "a vital function of the federal government, and it should remain the responsibility of federal employees." New York's elected officials should follow Mr. Harkin's lead.

Until these steps are taken, Plum Island [like each and every other biocontainment laboratory possessing listed agents] will remain a threat to its neighbors and a soft target for terrorism. The scientists at Plum Island need to recognize that their laboratory needs an overhaul, and our elected leaders need to force real change there, before we all have to pay the price.

Arms Control Today October 2004

Printer Friendly

# Biological Threat Assessment: Is the Cure Worse Than the Disease?

Jonathan B. Tucker

In the three years since the September 11 terrorist attacks and the subsequent mailings of anthrax bacterial spores, federal spending to protect the U.S. civilian population against biological terrorism has soared more than 18-fold. For the 2005 fiscal year, the Bush administration has requested about $7.6 billion for civilian biodefense, up from $414 million at the time of the 2001 attacks.[1] Several federal agencies are involved in biodefense research and development (R&D),[2] and the huge increase in funding from the National Institutes of Health for work on "select agents," or pathogens and toxins of bioterrorism concern, has attracted thousands of academic scientists.[3]

Of growing concern to U.S. biodefense officials is the possibility that rapid advances in genetic engineering and the study of pathogenesis (the molecular mechanisms by which microbes cause disease) could enable hostile states or terrorists to create "improved" biowarfare agents with greater lethality, environmental stability, difficulty of detection, and resistance to existing drugs and vaccines.[4] (See ***ACT*, July/August 2004.**) It is known, for example, that the Soviet biological weapons program did extensive exploratory work on genetically engineered pathogens.[5] The Bush administration's response to this concern has been to place a greater emphasis on "science-based threat assessment," which involves the laboratory development and study of offensive biological weapons agents in order to guide the development of countermeasures. This approach is highly problematic, however, because it could undermine the ban on offensive development enshrined in the Biological Weapons Convention (BWC) and end up worsening the very dangers that the U.S. government seeks to reduce.

**Biological Threat Assessment—Weighing the Risks**

The Bush administration contends that science-based threat assessment is needed to shorten the time between the discovery of new bioterrorist threats, such as pathogens engineered to be resistant to multiple antibiotics, and the development of medical countermeasures, such as vaccines and therapeutic drugs. This rationale is flawed, however, for three reasons.

First, the administration's biodefense research agenda credits terrorists with having cutting-edge technological capabilities that they do not currently possess nor are likely to acquire anytime soon. Information in the public domain suggests that although some al Qaeda terrorists are pursuing biological weapons, these efforts are technically rudimentary and limited to standard agents such as the anthrax bacterium and ricin, a widely available plant toxin. Assistance from a country with an advanced biological weapons program may be theoretically possible, but no state has ever transferred weaponized agents to terrorists, and the risks of retaliation and loss of control make this scenario unlikely. Although more sophisticated bioterrorist threats may emerge someday from the application of modern biotechnology, they are unlikely to materialize for several years.

Second, prospective threat-assessment studies involving the creation of hypothetical pathogens are of limited value because of the difficulty of correctly predicting technological innovations by states or terrorist organizations. Distortions such as "mirror-imaging"—the belief that an adversary would approach a technical problem in the same way as the person doing the analysis—make such efforts a deeply flawed

BG

Paul Zigurds Rinkulis
130 Chandler Street, Unit Four
Boston, Massachusetts 02116



October 21, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: Final Project Impact Report/Environmental Impact Report BioSquare Phase II Project, EOEA #12021

Dear Secretary Herzfelder:

I am writing regarding the above-referenced biosafety laboratory that Boston University Medical Center is proposing to build on its campus in the South End.

I am a resident of 130 Chandler St. #4 and I support the construction of this biocontainment facility. It is critical that our country construct such laboratories in this age of terrorism. We live in a time when we are no more than 36 hours away from infectious diseases that can threaten us. Facilities like the BUMC Biosafety Laboratory have the potential to develop cures to save lives and to protect our children and us from the ravages of these diseases, whether these agents occur naturally or are introduced by terrorists.

I have seen Boston University Medical Center demonstrate respect for its neighbors by its enhanced outreach activities and by its efforts to inform the South End community as well as communities throughout Boston about the project and to answer questions about its development. I have been particularly reassured by the safety presentations given by project officials that the laboratory will be safely built and operated.

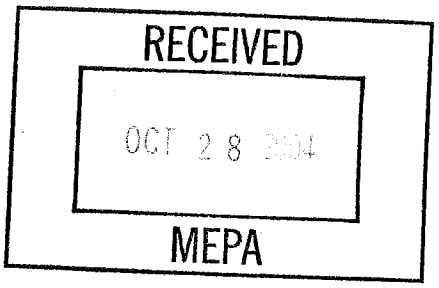
I strongly support Boston University Medical Center's proposal to build a biosafety laboratory here in my community.

Sincerely,

Paul Z. Rinkulis

CUH2A architecture. engineering. planning.

BG




October 22, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Subject: **Final Project Impact Report/Environmental Impact Report**
**BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

I am writing about Boston University Medical Center's proposed biosafety laboratory, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July 2004.

As a design professional working on biomedical research facilities for the NIH and universities across the country, I strongly support the proposed laboratory.

I recognize that there is public concern about safety issues associated with such critical facilities. As a professional responsible for design and engineering on such facilities, I know that these facilities are built fail safe with multiple redundant systems and intense security measures to protect the public realm. My confidence is supported by the fact that similar facilities across the country have been operating for decades without any safety incidents.

In addition, as a result of my involvement with multiple federal agencies involved in BSL-4 research across the country, I recognize that there is critical need for such facilities. There is not enough Level 4 laboratory space to accommodate the work that needs to be pursued if our scientific community is to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

Challenges to public health continue to emerge including HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza. We know too that terrorists are interested in using biological agents against us and so scientists must be able to understand the biology of these disease-causing agents. This type of work can only be done in specially and safely designed laboratory facilities like the one proposed for BUMC.

I support Boston University Medical Center's solid proposal for a biosafety laboratory that will save lives and be constructed and operated to the highest safety standards.

Sincerely,

Scott Butler, PE
Vice President, CUH2A

cc: File

CUH2A.com Tel 609.844.1212 CN-5380, Princeton, NJ 08543-5380
Fax 609.791.7700 1000 Lenox Drive, Lawrenceville, NJ 08648-2312

BG
#12021

OCT 29 2004

The Ellis South End Neighborhood Association, Inc.
Post Office Box 961
Boston, MA 02117
www.ellisneighborhood.org

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MEPA

October 22, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Commonwealth of Massachuesetts
251 Causeway Street, Suite 900
Boston MA 02114-2119

(attention: William Gage)

Director Mark Maloney
Boston Redevelopment Authority
One City Hall Square
Boston MA 02201-1007

(attention: Jay Russo)

Dear Secretary Herzfelder and Director Maloney,

This letter is written in response to your requests for comments regarding the University Associates Limited Partnership's proposal for "BioSquare Phase II". Our response is particularly addressed to Boston Medical Center's proposal to locate and operate a Level 4 Biocontainment Research Laboratory within Boston's South End.

First, we wish to compliment University Associates and the Boston Medical Center for their efforts to communicate with the various communities and neighborhoods surrounding and potentially impacted by the proposed project and research laboratory.

But, we must also be clear that we believe that the information that has been provided to date is not sufficient to make a thorough and complete assessment of the proposed Biocontainment Laboratory. There are several factors that limit our ability to assess the project. The analyses provided by the proponent -- e.g., the "Final Project Impact Report – Final Environmental Impact Report" -- do not allow us to evaluate the full range of potential environmental impacts of the proposed use. In addition, the analyses do not allow us to evaluate whether the potential benefits generated by the proposed project and laboratory outweigh the potential burdens imposed on the City, as a whole, and the surrounding South End neighborhood, in particular.

**Given these limitations, we cannot adequately assess the proposed project. Thus, we cannot endorse the project at this time.**

The Ellis South End Neighborhood Association requests that MEPA and the BRA extend the public comment period and require the project proponent to provide additional analyses which would allow us and other impacted neighborhoods and communities to carefully and thoroughly assess the proposed project. We would be happy to meet with you (or your representatives) and the proponent in order to outline the additional analyses that need to be provided.

Sincerely,

Norine Shults

Norine Shults
President
Ellis South End Neighborhood Association

BG

**Environmental Hazards Program**

October 22, 2004



Secretary Ellen Roy Herzfelder
EOEA, Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: BioSquare Phase II, Draft Environmental Impact Report, EOEA # 12021

Dear Secretary Herzfelder:

The Environmental Health Office of the Boston Public Health Commission would like to see full development of the following environmental health concerns before any certificate is issued by EOEA on this project:

1. What monitoring and controls will be used to protect abutters from the possible release of hydrogen sulfide gas from disturbed peat deposits during building foundation excavation?
2. How will the public and its regulatory agencies be kept informed in detail of the work that will be ongoing at the NEIDL, the biohazards present, and the biohazard controls and emergency response plans in use by the facility for the various projects being undertaken?
3. How will public health and safety emergency responders (EMS, BFD, BPD, etc.) be trained, equipped, and kept informed of the locations of Select Agents, Risk Group 3 agents, and Risk Group 4 agents to protect them from harm, and to protect the public from the risk of unknowing unsafe disturbance of these organisms during emergency responses?
4. Why was the accidental dropping and breaking of a 15 cc vial of purified anthrax (1 g) chosen for the Maximum Possible Risk scenario? How was it determined that only 400,000 respirable particles could become airborne from such an accident?
5. Why cannot a release of anthrax spores and the subsequent public health impacts that occurred at Sverdlosk in April of 1979 also happen in Boston from the NEIDL? Is the maximum quantity of culture and spores permitted at the NEIDL too small to allow such a release during a worst case possible accident?
6. How would the public be protected from biohazard risk resulting from a significant laboratory fire or explosion at the NEIDL?

Thank you for this opportunity to share these concerns.

Sincerely,

John Shea

John Shea, Director

MASSACHUSETTS WATER RESOURCES AUTHORITY
Charlestown Navy Yard
100 First Avenue
Boston, Massachusetts 02129

Telephone: (617) 242-6000
Facsimile: (617) 788-4899

Frederick A. Laskey
Executive Director

86

October 25, 2004

Ms. Ellen Roy-Herzfelder, Secretary
Executive Office of Environmental Affairs
Attn: MEPA Office, William Gage, EOEA #12021
100 Cambridge Street, 9th fl.
Boston, MA 02114

RECEIVED
OCT 25 2004
MEPA

Subject: Final Environmental Impact Report - EOEA #12021
BioSquare Phase II, Boston,

Dear Secretary Roy-Herzfelder:

The Massachusetts Water Resources Authority (MWRA) appreciates the opportunity to comment on the above-mentioned Final Environmental Impact Report for the proposed BioSquare Phase II project in Boston. The proponent, University Associates, proposes to develop the second phase of the BioSquare Research Park, a biomedical research development planned for a 14.5-acre parcel on Albany Street in the South End. The development for the Project includes two medical research buildings and an eight-level parking garage. The parking garage will accommodate 1,400 vehicles servicing the BioSquare Research Park as well as the adjacent Boston University Medical Center (BUMC) campus.

The facility will be owned, operated, and managed by the BUMC and it will contain state-of-the-art highly contained laboratories designed to conduct research in a safe and secure environment. Research will focus on finding treatments and vaccines for a variety of significant infectious diseases, some of which have potential as bioterrorism agents. The medical research buildings include Building F, a seven-story, 194,000 sf national biocontainment laboratory facility, called the National Emerging Infectious Disease Laboratory (Boston-NBL) and Building G, a 234,700 sf medical research facility that ranges in height from eight to eleven stories along Albany Street.

Pursuant to 360 C.M.R. 10.023(1), the MWRA prohibits the discharge of groundwater to the sanitary sewer system because the proponent has access to discharge via a storm drain. Therefore, if the proponent will need to discharge groundwater, a NPDES Construction Stormwater General Permit will be needed from the U.S. Environmental Protection Agency for this discharge.

BioSquare Phase II must comply with 360 C.M.R. 10.016, for the installation of gas/oil separators in the proposed parking garage. In addition to complying with 360 C.M.R. 10.000, the Owner shall conform to the regulations of the Board of State Examiners of Plumbers and Gas Fitters, 248 C.M.R. 2.00 (State Plumbing Code) and all other applicable laws. The installation of the proposed gas/oil separators will require MWRA approval and may not be back filled until inspected and approved by the MWRA and the Local Plumbing Inspector. To obtain an inspection the Owner should contact Paul Pisano, MWRA, Source Coordinator at (617) 305-5661.

Once the construction of BioSquare Phase II is completed, BUMC should contact Walter Schultz, MWRA, Industrial Coordinator in MWRA's Toxic Reduction and Control Department at (617) 305-5665 to obtain a MWRA Sewer Use Discharge Permit Application. MWRA will review the application and issue a Sewer Use Discharge Permit for waste streams that MWRA and the Boston Water and Sewer Commission determine will be acceptable for sewer discharge. BUMC must apply for and be issued a MWRA Sewer Use Discharge Permit for the BioSquare Phase II facility prior to discharging wastewater from the planned facilities into the MWRA sanitary sewer system.

Please contact me at (617) 788-1165 if you have further questions or need additional information.

Sincerely,

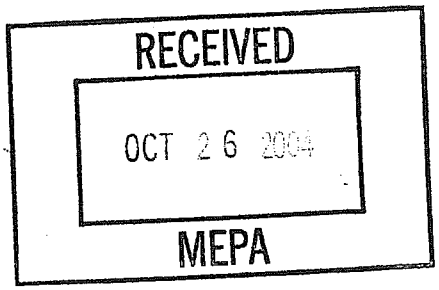
Marianne Connolly

Marianne Connolly
Program Manager, Regulatory Compliance

cc: Kattia Thomas, TRAC Unit, MWRA

BG

CONSERVATION LAW FOUNDATION




BY HAND DELIVERY

October 25, 2004

Secretary Ellen Roy Herzfelder
EOEA, MEPA Office
100 Cambridge St.
Boston, MA 02114

Mr. John O'Brien, Project Manager
Boston Redevelopment Authority
One City Hall Plaza, 9th Floor
Boston, MA 02201

*Re:* **Matter:** Comments on the Final Environmental Impact Report (EOEA #12021) and Final Project Impact Report for the BioSquare Phase II Project in Boston

Dear Secretary Herzfelder and Mr. O'Brien,

By this letter, the Conservation Law Foundation (CLF) submits additional comments on the Final Environmental Impact Report and Final Project Impact Report (FEIR/FPIR) for the proposed BioSquare Phase II Project in Boston. Since the FEIR/FPIR is a joint document, the comments are provided to give guidance under the MEPA Statute and Article 80 of the Boston Zoning Code to EOEA and the BRA. CLF reserved the right to submit additional comments in our previous comment letter of September 8, 2004.

We wish to elaborate on the need for analysis of alternative locations for the proposed Boston-NBL/BSL-4 project. The MEPA/Article 80 process requires analysis of alternatives, including analysis of alternative locations. MEPA requires analysis of all feasible locations. For private projects, any sites which are owned or controlled by the project proponent must be analyzed. It is our understanding that Boston University owns property along Commonwealth Avenue, in Tyngsboro, MA and in Peterborough, NH. These sites should be analyzed as alternative locations for this project in addition to any other Boston University-owned or controlled properties. Any other feasible sites should also be analyzed.

MEPA and Article 80 review processes were established to facilitate informed decision-making. Absent disclosure of the alternate sites for the proposed Boston-NBL/BSL-4 project and analysis of those sites, informed decision-making will not be possible. Currently, the FEIR/FPIR does not include any analysis of alternative locations for this project. We therefore urge the MEPA unit and the Boston Redevelopment Authority should require a supplemental FEIR/FPIR to address siting alternatives.

62 Summer Street, Boston, Massachusetts 02110-1016 • Phone: 617-350-0990 • Fax: 617-350-4030 • www.clf.org

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NEW HAMPSHIRE: 27 North Main Street, Concord, New Hampshire 03301-4930 • 603-225-3060 • Fax: 603-225-3059
RHODE ISLAND: 55 Dorrance Street, Providence, Rhode Island 02903 • 401-351-1102 • Fax: 401-351-1130
VERMONT: 15 East State Street, Suite 4, Montpelier, Vermont 05602-3010 • 802-223-5992 • Fax: 802-223-0060

Thank you for considering our comments. We look forward to reviewing full analysis of alternatives including alternative locations in order to evaluate this project more thoroughly.

Sincerely,

Philip Warburg, Esq.
President

cc: Mayor Thomas Menino
Secretary Doug Foy, OCD
Director Mark Maloney, BRA
Jim Hunt, MEPA
Peter Shelley, CLF
Jamie Fay, FPA

BG

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OCT 28 2004

MEPA

October 25, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: **Final Project Impact Report/Environmental Impact Report**
**BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

I am writing about Boston University Medical Center's proposed biosafety laboratory, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July 2004.

As a design professional working on biomedical research facilities for the NIH and universities across the country, I strongly support the proposed laboratory.

I recognize that there is public concern about safety issues associated with such critical facilities. As a professional responsible for design and engineering on such facilities, I know that these facilities are built fail safe with multiple redundant systems and intense security measures to protect the public realm. My confidence is supported by the fact that similar facilities across the country have been operating for decades without any safety incidents.

In addition, as a result of my involvement with multiple federal agencies involved in BSL-4 research across the country, I recognize that there is critical need for such facilities. There is not enough Level 4 laboratory space to accommodate the work that needs to be pursued if our scientific community is to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

ENGINEERING U.S. INC.
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Challenges to public health continue to emerge including HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza. We know too that terrorists are interested in using biological agents against us and so scientists must be able to understand the biology of these disease-causing agents. This type of work can only be done in specially and safely designed laboratory facilities like the one proposed for BUMC.

I support Boston University Medical Center's solid proposal for a biosafety laboratory that will save lives and be constructed and operated to the highest safety standards.

Sincerely,

John W. Chomiak
President and CEO

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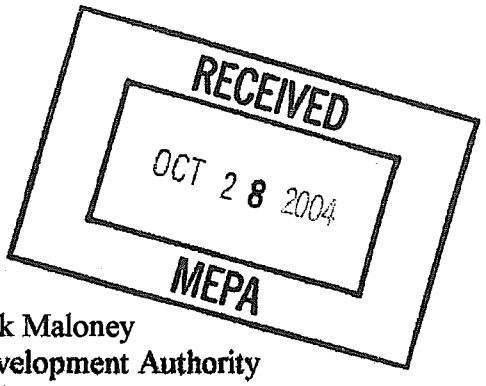
BE

**David S. Mundel**
36 Gray Street
Boston MA 02116




October 25, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Commonwealth of Massachuesetts
251 Causeway Street, Suite 900
Boston MA 02114-2119

(attention: William Gage)

Director Mark Maloney
Boston Redevelopment Authority
One City Hall Square
Boston MA 02201-1007

(attention: Jay Russo)

Dear Secretary Herzfelder and Director Maloney,

This letter responds to your requests for comments regarding the University Associates Limited Partnership's proposal for "BioSquare Phase II". This letter is particularly directed toward Boston Medical Center's proposal to locate and operate a Level 4 Biocontainment Research Laboratory within the proposed project, close to the residential communities of Boston's South End and other neighborhoods.

In assessing this proposed project, I urge you to carefully consider the potential environmental and health effects on the residents of Boston's neighborhoods, the inmates incarcerated in the nearby South Bay correctional facilities, and the patients served by the Boston Medical Center. In its Annual Report, the Boston Medical Center state that its mission is to "meet the health needs of the people of Boston and its surrounding communities by providing ...care to all, particularly mindful of the **needs of the vulnerable populations**" (emphasis added).

In addition, I urge you the carefully consider the criteria stated by your agencies -- the Executive Office of Environmental Affairs and the Boston Redevelopment Authority – in responding to the Draft Project Impact Report – Draft Environmental Impact Report submitted by the proponent.

In its December 1, 2003 response to the Draft Project Impact Report - Draft Environmental Impact Report (DPIR/DEIR), the Executive Office of Environmental Affairs stated:

> The Purpose of the MEPA review is to ensure that a project proponent studies feasible alternatives to the proposed project (and) fully discloses environmental impacts of the proposed project.
>
> The Final EIR should include more detail on the proposed use of the (Biocontainment) building and any potential environmental impacts from the proposed use.
>
> The Final EIR should evaluate a "worst case" safety event involving the loss of the physical integrity of the (laboratory's) containment systems.

In its January 8, 2004 response to the DPIR/DEIR, the BRA stated:

> Comments received to date indicate more needs to be studied about the environmental impacts that may be associated with the National Bio-Safety Laboratory.
>
> The FPIR/FEIR should respond to the questions and concerns raised by MEPA and a series of questions raised by the BRA, including 'What will be studied in the laboratory?'
>
> The basis for approval of a Development Plan for a PDA is a test to ensure that the benefits generated by the Project outweigh the burdens imposed on the City.

**The final project impact and environmental reports are not adequate responses to these concerns and requests** -- A careful analysis of the "Final Project Impact Report – Final Environmental Impact Report" (dated July 30, 2004) and the "Comments of Clarification on the FPIR/EIR" (dated September 24, 2004 and apparently, never publicly advertised) indicates that **the proponent's submissions fail, in many ways, to adequately fulfill the EOEA and BRA requirements and to fully address many important issues that must be considered prior to approving the proposed project.**

- The FPIR/FEIR does not fully assess the potential environmental impacts of the proposed Biocontainment Laboratory. Appendix 3 of the report lists 57 diseases "which may be studied" at the laboratory but the environmental risk/hazard analysis only addresses one of these diseases.

- The FPIR/FEIR does not provide full details on the proposed use of the Biocontainment Laboratory. Although the report lists 57 diseases "which may be studied", the proponent has stated that the nature of the agents studied and used within the containment facility are "variable and possibly unknown" (see page 5-6 of the report). This statement clearly indicates that the list of diseases that "may be studied" is incomplete.

- Although, the purported "worst case analysis" (Appendix 6 of the FPIR/FEIR) addresses one environmental hazard (the release of Anthrax spores), the proponent has presented no analysis that either suggests or proves that the potential release of this hazardous agent which was chosen for analysis is, in fact, a 'worst case' release.

- The purported "worst case analysis" is woefully inadequate and unconvincing. The analysis contains no sensitivity analysis indicating how the simulated findings of environmental impact would be different if different assumptions were used in examining the nature of the incident leading to the release. The analysis contains no assessment regarding whether the range of weather conditions considered is representative of the full range of weather conditions occurring in Boston. The statistical component of the analysis is naïve and incorrect – the reported data do not portray the 'maximum number of inhaled spores', they portray the expected number of spores that would be inhaled by a single individual. The data included in the report actually suggest that some individuals may inhale zero spores, some may inhale one spore, and some may inhale more spores.

  In addition, the purported 'worst case analysis' includes no assessment of the impact of a potential release on the vulnerable populations living, working, hospitalized, and

incarcerated in nearby neighborhoods and facilities. The proponent has noted that the "precise dose of Bacillus anthracis (anthrax) spores required to cause human pulmonary anthrax is not known" and that "this number would vary considerably from person to person depending upon age (and) overall medical history" (see page 5-22). But, these issues of population sensitivity are not addressed anywhere in the so-called 'worst case analysis.'

The casual and incomplete assessment and analysis of the potential risks associated with an accidental release from the proposed Biocontainment Laboratory suggest an almost cavalier attitude on the part of the analysts engaged by the proponent. If these analysts and the proponent's personnel responsible for directing the preparation of the analysis actually believe that the risks of negative health effects from a potential release are so small as to be "practically considered as zero" (as suggested in the summary of the "Hazard and Risk Assessment"), perhaps they should accept an alternative design in which the exhaust from the proposed Biocontainment Laboratory is vented directly into their offices rather than into and over the surrounding residential neighborhoods.

- The FPIR/FEIR contain no analysis that suggests that the proponent has considered feasible alternatives that it might find somewhat more inconvenient, more expensive, and/or less attractive but which would be safer and potentially less harmful to the surrounding neighborhoods.

- The efficacy of the proposed emergency response procedures is questionable. It is disturbing to note that the proponent states that its emergency procedures "**may** involve the City of Boston" (emphasis added, see page 5-8).

- In addition, the report includes no analysis suggesting that the benefits generated by the Project outweigh the burdens imposed on the City and on the surrounding neighborhoods.

**These failures and omissions are significant.**

As a result, I recommend that the Executive Office of Environmental Affairs and the Boston Redevelopment Authority reject the FPIR/FEIR and require the proponent to prepare a revised final report (including additional analyses) that is fully responsive to the requirements that have been articulated.

I thank you, in advance, for your consideration this recommendation.

Sincerely yours,

David S. Mundel

CUH2A architecture. engineering. planning.

BG



October 27, 2004

Via: Federal Express

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Massachusetts Environmental Policy Act Office – MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114
Phone: 617-626-1020

Subject: **Final Project Impact Report/Environmental Impact Report**
**BioSquare Phase II Project, EOEA # 12021**

Dear Secretary Herzfelder:

I am writing about Boston University Medical Center's proposed biosafety laboratory, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July 2004.

I am an architect that has been involved with the design of biocontainment laboratories in university and governmental settings since 1982. As a design professional working on these important facilities, I strongly support the proposed laboratory.

I have worked in Atlanta, a community that has had BSL4 laboratories, for over 25 years. For much of my career I have worked within a one-half mile radius of the CDC's BSL4 laboratories. Currently CUH2A maintains an office within one mile of CDC.

I recognize that there is a legitimate public concern about safety issues associated with BSL4 laboratories. I have personally observed over the years the care and diligence used by the scientists and safety professionals that work in and oversee these facilities. From my experience in designing biocontainment laboratories, I know that these facilities are built with the systems and security measures to protect the public.

I attended the October 4th BRA public hearing and wanted to comment on several issues raised by speakers at the meeting:

1) **Are the BSL4 labs in Atlanta near a populated area?**

   a) There are two locations with BSL4 labs in Atlanta. CDC has laboratories in a densely populated residential area of middle to upper class homes adjacent to Emory University. This includes Lullwater Road, one of the most prestigious residential streets in Atlanta. This neighborhood was featured in the movie "Driving Miss Daisy". Many of the scientists, physicians and administrators at both Emory and CDC live in the adjacent neighborhoods. This is a very stable area and home prices have not been impacted by the adjacency of the CDC BSL4 laboratories.

CUH2A.com Tel 404.815.1212 1201 Peachtree Street, NE, Suite 600
Fax 404.815.3107 400 Colony Square, Atlanta, GA 30361-6316

b) The second BSL4 laboratory in Atlanta is located downtown at Georgia State University with four blocks of the Georgia State Capital and the Atlanta City Hall. It has been in operation since 1996. Coincidentally, my son attended Georgia State from 1997 to 2001 and I never had a second thought about his going to school next to a BSL4 laboratory. Again, I have seen first hand how seriously the issues of safety are taken at these laboratories and understand how well they are designed and constructed.

2) **Is it a problem that a day care center is in the neighborhood of the proposed BU BSL4 lab?** CDC and Emory built a joint day care center within 200 feet of their existing BSL4 laboratory. It is important to note that they located the daycare center next to the BSL4 lab after the lab was constructed. They could have easily chosen another site for the daycare center if they had any concerns over it's proximity to CDC. Many CDC and Emory University personnel leave their children there every workday. When CDC relocated the day care center last year to make room for an expansion of their BSL4 laboratories, they place the relocated daycare center about the same distance from the new BSL4 laboratory.

Most importantly, in my evaluation of the infrastructure required to develop the drugs and vaccines required to protect the public from the extraordinary health and economic impact of a pandemic natural outbreak such as an avian flu or a major bioterrorist event, it is clear that the significant biomedical research that exists in Boston must be leveraged to help solve the problem. There is no community in the world better poised to become a leader in the solution to these potential threats. These threats from an outbreak pose a far greater risk to the citizens of Boston than the laboratory ever could.

Again, I support Boston University Medical Center's plans to build this important project. Please feel free to contact me if you need additional information or documentation to back up the above information.

Sincerely,

Jon Crane, AIA
Principal

BG

Pam Kennedy
164 Hudson St.
Somerville MA 02144
617 666-2274

October 28, 2004



Secretary Ellen Roy Herzfelder
EOEA, MEPA Office
Re: EOEA # 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Ms. Herzfelder:

Like thousands of other residents of the Boston area, I am vehemently opposed to the so-called Biosafety Lab. Several months ago, SARS escaped from secure laboratories in China and Taiwan when workers, unknowingly contracting SARS in the lab, left the lab and infected others. Now, China admits that the latest SARS outbreak was from laboratory workers who were infected in its version of our CDC, and left the lab and infected others. The lab that released SARS is considered one of the most-secure in the world. With a bioterror and infectious disease lab in the middle of a dense neighborhood, we risk similar outbreaks in Boston.

Moreover, if BU built its lab in Boston, we citizens would have no way of knowing what was going on inside its walls. The Sunshine Project, a biodefense watchdog group, has run into numerous difficulties in achieving disclosure from several universities labs - naming Princeton University, the University of Delaware, the University of Vermont and the University of Texas-Southwestern IBCs as the worst. According to Edward Hammond, Sunshine Project director, "these universities' biosafety committees have nothing but contempt for public disclosure. They black out their meeting minutes or write down virtually nothing, so as to frustrate public access."

Already BU shows signs that it's just as arrogant as these other universities. The advertisements it bought on the T, with happy shiny families pushing the "Biosafety" Lab, illustrate BU's patronizing attitude. Rather than involving the community and encouraging open debate, BU has sought to advertise its way out of a full and honest discussion.

I have donated as much money as I possibly can to ACE, the community group that has done such a heroic job of raising awareness about the lab. And I will continue to fight it in every way I can. This country does not need Level 4 labs, period; we'd be far better spending the money on public health programs. And if we do have a Level 4 lab, put out in some deserted area. Don't plunk it down in the middle of the busy neighborhood, where the residents vehemently object to the project.

-Pam Kennedy

P Kennedy

BG

John E. Mann
64 Hudson St.
Somerville MA 02144
617 628-7660
October 28, 2004



Secretary Ellen Roy Herzfelder
EOEA, MEPA Office
Re: EOEA # 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Ms. Herzfelder:

I am a retiree, a graduate of Harvard, a Navy veteran, and an active citizen. Below are my thoughts about BU's fantasy about a "biosafety" lab in the Boston area.

I think the idea of building a "Biosafety Lab" anywhere near Boston is about the most insane idea I have ever heard. It is comparable to talking on a cell phone while driving at 90 mph on Route I-93. There's of course no guarantee of an accident will occur, but if one must talk on a cell phone while driving at 90 mph it is much more sensible to do it on some salt flat in Nevada, not in the middle of urban traffic. Similarly, if the US needs a bioterror lab, it ought to be put out in the sticks, where it can't do any harm, like maybe Crawford, Texas.

The Boston area isn't just any-old location. It houses world-class universities which attract valuable human intellectual resources from around the world. Many global pharmaceutical firms are locating research facilities in Cambridge. Boston's medical resources are among the best in the world. Boston is a priceless resource; why expose all of this to an accident? However slim the probability of an accident may be, the potential cost of an accident is huge.

Right now we have an election to worry about, and most of my energy is directed toward preventing a disaster there. Starting November 3, I and thousands of others in the Boston area will be freed to direct our attention to this matter. I am quite sure that any effort to place this lab in the Boston area will turn out to be just a pointless waste of time and money.

Sincerely,

John E. Mann

BG

John E. Mann
64 Hudson St.
Somerville MA 02144
617 628-7660
October 28, 2004



Secretary Ellen Roy Herzfelder
EOEA, MEPA Office
Re: EOEA # 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Ms. Herzfelder:

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The Boston area isn't just any-old location. It houses world-class universities which attract valuable human intellectual resources from around the world. Many global pharmaceutical firms are locating research facilities in Cambridge. Boston's medical resources are among the best in the world. Boston is a priceless resource; why expose all of this to an accident? However slim the probability of an accident may be, the potential cost of an accident is huge.

Right now we have an election to worry about, and most of my energy is directed toward preventing a disaster there. Starting November 3, I and thousands of others in the Boston area will be freed to direct our attention to this matter. I am quite sure that any effort to place this lab in the Boston area will turn out to be just a pointless waste of time and money.

Sincerely,

John E. Mann

November 2, 2004



BG

Secretary Ellen R. Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St. Suite 900
Boston MA 02114

Re: Final Environmental Impact Report for BioSquare Phase II EOEA #12021

Dear Secretary Herzfelder,

I have read the EIS for the proposed lab in Boston with much alarm. It is surprisingly generalized. The worst case scenarios are poorly thought out.

One particular concern begins on p. 4-12 in the "Environmental Consequences" chapter, Section c) "Escape of an Infected Animal".

> "Infected animals would always be separated from exterior spaces by an at least an air lock with a series of two interlocked swinging doors.....The doors would be equipped with sweeps, eliminating the opportunity of even small animals such as mice from escaping through a closed door. "

What about infected mice escaping through air vents or other channels that rodents find easily, but humans do not ever consider?

I am not at all convinced by this EIS that the proposed lab will be safe for the surrounding neighborhood. I would like to see the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous materials are in transport to the lab.

Sincerely,
P. Glynn

Patricia Glynn
6 Fort Ave. Terr.
Roxbury MA 02119
617 442-6895
fthill6@hotmail.com

BG

7 Greenleaf Avenue, Apt. 1
Medford, MA 02155
November 3, 2004



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:

I am a chemical engineering student at Tufts University, and I have serious concerns about the proposed bioterrorism laboratory for many reasons. Though I understand that you are in no position to stop it completely, as I believe should be done, I do know that there are ways for you to improve the FEIR such that the safety of the lab is maximized and the environmental policies are enforced to the utmost extent, including policies of environmental justice.

These are my comments on the FEIR and the proposed bioterrorism laboratory. I believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR because the FEIR:

A. Does not include a true or accurate "worst case scenario."
Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that:

1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory;
2) fails to perform a site-specific release analysis,
3) fails to consider the environmental impact of the release; and
4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious.

B. Fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory.
C. Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.
D. Is inconsistent with the Massachusetts Environmental Justice Policy.
E. Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End.
F. Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.
G. Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.
H. Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.

I also request that you require the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous biological materials are in transport to the lab.

The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR.

Thank you very much for the opportunity to comment.

Sincerely,
Jessie Partridge

**William J. Santoro**
67 Forest St.
Winchester, MA 01890
(781) 721-9868

BG

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114



Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

November 3, 2004

Dear Secretary Herzfelder:

These are my comments on the FEIR and the proposed bioterrorism laboratory. I believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR because the FEIR:

Does not include a true or accurate, worst-case scenario. Instead, the FEIR contains an inaccurate and incomplete, worst case scenario that: 1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious.

Fails to include a worst-case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory.
Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.

Is inconsistent with the Massachusetts Environmental Justice Policy.
Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston,s South End.

Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.

Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.

Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.

I also request that you require the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous biological materials are in transport to the lab.

The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR.

Thank you very much for the opportunity to comment.

Sincerely,

William J. Santoro

BG

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NOV 5 – 2004

MEPA

18 Monmouth Court
Brookline, MA 02446
November 3, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II EOEA #12021

Dear Secretary Herzfelder:

In re the FEIR and the proposed bioterrorism lab in Boston:

Living as I do within three miles of this proposed lab, I object to the FEIR on more grounds than I can enumerate – BUT, for example, it…

…offers no adequate worst-case scenario. Is it really even possible to imagine the worst case?

…is a gross example of environmental injustice. On more than one occasion, Dr. Patricia Hynes of BU has publicly outlined why this is so. I believe the Commonwealth has a policy on such issues.

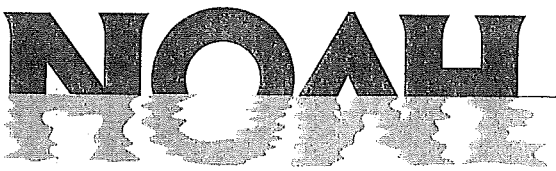
…optimistically relies on the infallibility of scientists, ignoring the lessons provided by (among others) Robert McNamara in The Fog of War, TMI, Chernobyl, while positing that (current) "state of the art" technology will guarantee safety to families living near to (and far from) the lab. The word "guarantee" is no longer reassuring to the general public, and previous threats pale in the face of the dangers inherent in these deadly, invisible, mutating and self-reproducing microorganisms.

I close with one of my favorite quotes from a non scientist but brilliant humanist and thinker, William Sloane Coffin: "Hell is the truth seen too late."

I don't envy you your responsibility, and believe me my prayers are with you as you consider these questions.

Yours truly,

Susan Gracey (member Women's International League for Peace and Freedom)



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November 4, 2004

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NOV 9 - 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:

I am writing on behalf of the Neighborhood of Affordable Housing to express our opposition to the construction of Boston University's proposed bioterrorism laboratory near Boston Medical Center, and to offer the following comments regarding this proposal.

- We believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR because the FEIR.
- The proposal does not include a true or accurate "worst case scenario." Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious.
- Fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory.
- Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.
- Is inconsistent with the Massachusetts Environmental Justice Policy.
- Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End.
- Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.
- Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.
- Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.

This year, the NOAH board voted to oppose this project as we believe that it not only poses a threat to the close by residents in the South End and Roxbury – but all Boston residents. We know what it is like to live with a project that impacts the environmental health of our community, and believe that the State should be practicing the precautionary principal when evaluating projects. We can not think of too many worse projects to be sited in a dense urban community.

Thank you for your attention to this matter, and for considering our comments. If you have any questions, you may reach me at (617) 567-5882 ext. 241.

Sincerely,

Stacey Chacker
Director, Community Building and Environment

36

Cambridge Health Alliance

1493 Cambridge Street • Cambridge, MA 02139 • 617.665.2300

Elliot G. Mishler, Ph.D.
Professor of Social Psychology
Department of Psychiatry
Tel: 617/503-8442
emishler@comcast.net

November 4, 2004



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: Comments on the Final Environmental Impact Report (FEIR) for BioSquare Phase II, EOEA #12021

Dear Secretary Herzfelder:

I have closely followed presentations in public forums and written documents of Boston University's proposal to construct and operate a BioSafetyLevel4 laboratory in the South End/Roxbury neighborhood of Boston. Many questions have been raised by residents of these and other Metropolitan Boston Area communities as well by independent bioscientists, academic scholars, and public health specialists about the health and safety risks of locating such a facility in a densely-populated area. The seriousness of these risks has either been ignored or denied by Boston University officials despite an increasing number of reports over the past year and a half of the accidental release of deadly pathogens or viruses from other similar laboratories both in the U.S. and other countries. The FEIR document continues this policy of evasion and deception. Its risk assessment analysis is faulty, claims that the accidental release of such pathogens would be harmless to the local population, and provides no plan for dealing with the environmental and community impacts of such a release if it were to take place.

Questions have also been raised repeatedly about the lack of an independent committee that would have the authority to review research undertaken in the laboratory and to determine whether particular studies, for example, those proposing to use recombinant DNA procedures, were allowed under local and state laws and ordinances or posed high levels of risk to the health and safety of the local population. The FEIR ignores the recommendations of independent scientists for such an oversight committee.

On these grounds alone, that is, the refusal to acknowledge and develop a response to the release of life-threatening pathogens or viruses and the failure to take seriously the importance of an independent oversight committee to represent the larger community, the FEIR should not be approved in its current form. Boston University should be required to submit a revision that takes these problems into account

Sincerely yours,

Elliot G. Mishler, PhD
Professor of Social Psychology

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November 4, 2004

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MEPA

Secretary Ellen Roy Hertzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St. Ste.900
Boston, MA 02114

Re: Comments on the Final Environmental Impact Report
BioSquare Phase II EOEA # 1201

Dear Secretary Herzfelder:

I believe that the FEIR is inadequate and incomplete and that you should require the project proponent to file a supplemental FEIR because the FEIR;

1) fails to include an accurate 'worst case scenario'; i.e the accidental or intentional release of toxins or virurses that are highly contagious within the lab.
2)fails to include a 'worst case scenario' for a chemical agent in transit to the lab.
3)fails to include a 'worst case scenario' in the event of a catastrophic terrorist attack, resulting in the release of toxins to the surrounding community.
4)fails to comply with the City of Boston regulation prohibiting recombinant DNA research requiring BSL4 containment.
5)fails to comply with the requirements of the Dec.1, 2003 Certificate of Environmental Affaires on the DEIR.

The DEIR is flawed. An independent advisory committeee with residents and scientists not associated with BU or NIH is required. This is a reasonable request. I live in this city which I love and which is my home.

Sincerely,

Dorothy Woelfel

Dorothy Woelfel
29 Concord Sq. #3
Boston, MA 02118

Copy to Mr. John O'Brien
Project Manager
BRA

BG

131 Carolina Ave
Jamaica Plain, MA 02130
November 4, 2004



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs

Attn: MEPA Office

William Gage, EOEA No. 12021
100 Cambridge St., Suite 900

Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II

EOEA # 12021

Dear Secretary Herzfelder:

These are my comments on the FEIR and the proposed bioterrorism laboratory. I believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR because the FEIR:

*

Does not include a true or accurate "worst case scenario." Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious.

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Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.
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Is inconsistent with the Massachusetts Environmental Justice Policy.
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Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End.
*
Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.
*
Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.
*
Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.
I also request that you require the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous biological materials are in transport to the lab.

The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR.

Thank you very much for the opportunity to comment.

Sincerely,

Miriam Shenitzer

BG



20 Charlesgate West
Boston, MA
02215

November 5, 2004

Secretary Ellen Roy Herzfelder
Executive Officeof Environmental Affairs
Attn: MEPA Office
William Gage, EOEA no. 12021
100 Cambridge St., Suite 900
Boston, MA 02114

Re: Comments on the Final Environmental Impact Report for Biosquare Phase 11
EOEA #12021

Dear Secretary Herzfelder:

The FEIR does not address my deepest concerns about the proposed bioterror lab and I strongly urge that you require a supplemental FEIR that honestly addresses not only my concerns but the concerns of many who oppose the lab. There has been a remarkable lack of any just and honest process to deal with the legitimate concerns of the many good citizens who oppose the lab and I can only hope that you will take our concerns seriously enough to really listen to what we are saying and require an FEIR that at least begins to answer our concerns in some substantial way.

My deepest concern about the lab is that while it is advertised as a public health project, it is funded by Homeland Security and, as stated in the NIH Request for Proposals, it is really intended for the purposes of military work around issues of biological warfare. While I'm sure there are good people at Homeland Security, NIH and B.U., who are trying to provide a real service to the nation in the best way they know how, the level of deception really bothers me. The lab is not essentially a public health project, as the public is led to believe through an expensive ad campaign.. It is a military project which includes concern for peoples' health, but which is most concerned with questions about germ warfare and terrorism..Because of the inevitable secrecy of national security projects we don't know exactly what will go on in the lab or who will be using it.. One of NIH's partners is the army, so presumbly, since this is a national security project, the army will be using the lab as well as other partners and groups in need of a

BSL4 facility. The public has not been assured in any substanitive way that germ warfare will not be created at the lab, a question whose gravity deepens in the light of the fact that the U.S. is the only nation out of more than 150 nations that refused to sign the inspections clause of the Global Convention Against Biolgical Warfare. If we won't allow inspections, and there is no way of knowing who will be using the lab, and the national security purpose of the lab requires secrecy, how can we know what is going on in the lab and what health and safety and environmental measures thus need to be taken? Please require a supplemental FEIR to adequately address these critical issues.

Whether or not the government plans to use the lab to create or help create germ warfare, many of us feel that Roxbury/the South End is no place for a military installation. If this is a democracy, then citizens should have the right to decide what gets built in their neighborhoods. Our culture is becoming increasingly militarized, but many do not agree with the current administration that military might is the chief way to solve our human problems. I feel quite disturbed because the country I love is insisting with increasing vehemence in a very undemocratic way that its leaders' military vision and agenda be adopted globally and locally, no matter what the consequences to good citizens, many of whom believe global and local problems can only be resolved through dialogue and the rule of truly democratic law. I think, with many others who oppose the lab, that the root of the problem of this nation's security lies in this nation's local and global oppression of poor people and people of color. The lab, which is intended to make us more secure, can only make us more insecure because once again poor people, people of color and other humble citizens are being required to bear the brunt of a military project which, though well-funded and thus well advertised, is not a project in which everybody wishes to engage, or from which everyone will profit in any worthwhile sense. To deny the community which is being asked to host the project any real democratic say in the matter is to use coercion. Coercion can't result in any lasting security but only bitterness and many serious kinds of individual and societal malaise.. Coercion isn't good for public health, cultural life, or the economy. Please require a supplemental FEIR that will analyze and address adequately the social,economic,psychological, and physical health consequences for the people who will suffer and who are already suffering from a coercive process toward militarization of their neighborhoods and institutions.

It is essential that a supplemental FEIR be required to honestly address deep, long-term community concern about environmental racism and classism that many of us lab opponents feel is fueling the wish to place the bioterror lab in Roxbury/the South End. This lab could not be built in Wellesley because the rich white people who live there would not allow it, and they have the social and economic power to prevent such an incursion. There is enough environmental racism already at work in the area proposed for the lab. The people of Roxbury already suffer eight times the normal asthma rate due to environmental racism and classism. The supplemental FEIR should include an analyis of the social/economic/psychological/health consequences of environmental racism and classism for the people nearest the lab along with the above mentioned analysis of the consequences of militarization on citizens' lives.

The germs that would be in the proposed level 4 lab are among the most dangerous disease germs in the world, The worst case scenario described in the FEIR was clearly not taking seriously the health concerns of residents. The scenario said, in very sophisticated scientific language, that essentially, if a few bugs got out we'd all be ok. I

fclt that the profound questions of those of us who oppose the lab were seriously disrespected when I read this part of the FEIR because the language was so arrogant and cool and so dismissive of the cry for truth and justice from residents who understandably don't want plague germs in their back yards, their city, or their world. We already know the lab is dangerous and that if smallpox or plague germs escape we would be in deep trouble, not only in and around Boston but also around the world, since all it would take for the plague to spread would be for one infected person to board a plane at Logan bound for anywhere.. We are not stupid people. So please respect our honest and passionate request for an FEIR that contains a legitimate analysis of worst case scenario dangers.

The FEIR was also gravely deficient in its lack of an analysis of a worst case scenario in the case of an accidental or terrorist release of germs in transit to or from the lab. This deficiency alone should be grounds enough to require a supplemental FEIR. Another blatant problem with the FEIR was that there was no analysis of a worst case scenario in the case of a terrorist attack on the lab. I feel deeply concerned that the planners of a lab that is supposed to protect us from terrorism haven't provided us with evidence that they've carefully considered such a basic problem. I want to see an FEIR that proves to me that the planners of the lab have thought through the real dangers. Denial of our human fallibility and vulnerablitiy, while humanly understandable, won't make our problems go away,and in the case of the lab, such denial could pave the way to an immense public health catastrophe.

Another major problem with the FEIR is that it doesn't deal with the issue of how the lab operator(s) intend(s) to follow the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in Boston. Surely such a serious omission requires amendment in the form of a supplemental FEIR. The rule of law must still have some authority in this country, no matter how powerful and prestigious the involved parties.

Finally, I ask you with utmost gravity to help formulate an independent advisory committee not affiliated with B.U. or NIH, to advise on the the safety issues that continue to surround the lab, including providing thorough-going analysis of worst case scenarios that could arise at the lab or in the process of transporting the hazardous biological materials to and from the lab. Basic justice compels me to request that such a committee be composed of residents and scientists whose judgements could not be swayed by any vested interests. Anything less would be an affront to the people of Roxbury/the South End, the rest of Boston and beyond. The process of negotiating with the community is now in sore need of justice and respect..

Thank you very much for this opportunity to share why I think it is critically important to require a supplemental FEIR.

Sincerely,

Phoebe Knopf

Phoebe Knopf
Boston

BG

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November 5, 2004



Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Dear Secretary Herzfelder:

I have been very concerned about Boston University's plans to build a bioterrorism lab next to the Boston Medical Center. I have attended numerous presentations and read a good deal of material about the proposed lab with growing alarm. I read the Final Environmental Impact Report for BioSquare Phase II EOEA # 1202 in hopes that it would at least address some of my concerns. Unhappily, this was not the case. I believe that the FEIR is grossly inadequate and that you should require the project's supporters to file a supplemental report in which they respond to its many inadequacies.

As I understand it, Boston University was asked to provide a detailed account of a "worst case scenario" and then, outline their plans for dealing with this emergency. I have read Jean Guillemin's critique of the FEIR "worst case scenario" and find myself appalled at her detailing of its inaccuracies and omissions. Given the numerous reports in recent weeks of accidents at BSL4 labs, it is unconscionable to place this facility in such a densely populated, urban area without a full consideration of the real risks.

I also have serious questions about B.U.'s failure to comply with the requirement that there be an alternatives analysis of other potential locations for the laboratory. What criteria were used by University Associates in making the decision to locate the laboratory on Albany Street in Boston's South End. There are serious environmental justice considerations that need to be addressed.

I have been working with United for Justice with Peace as an ally of the ACE/Safety Net campaign in opposition to the lab. I have been appalled by BU's failure to provide information to the community. I am convinced that there must be an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks and to monitor the operations of the lab. I request that you require the creation of such an oversight group.

In my view, the materials submitted thus far do not begin to satisfy the MEPA process requirements. The potential dangers are too real and too serious to allow the laboratory to complete the process on the basis of this seriously flawed FEIR

Thank you very much for the opportunity to submit my concerns.

Sincerely,

Vicky Steinitz
Associate Professor

BG

**Boston Water and Sewer Commission**

980 Harrison Avenue
Boston, MA 02119-2540
617-989-7000

November 5, 2004

Ms. Ellen Roy Herzfelder, Secretary
Executive Office of Environmental Affairs
251 Causeway Street, Suite 900
Boston, MA 02144

Attn: Mr. William Gage, MEPA Office
EOEA No. 12021

Mr. Mark Maloney, Director
Boston Redevelopment Authority
One City Hall Square
Boston, MA 02201

Attn: Mr.John O'Brien, BRA

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Re: BioSquare Phase II – FPIR/FEIR

Dear Secretary Roy Herzfelder and Mr. Maloney:

The Boston Water and Sewer Commission (Commission) has reviewed the Final Project Impact Report/ Final Environmental Impact Report (FPIR/FEIR) for the BioSquare-Phase II Project. The BioSquare-II Project is located on the Boston University Campus in Boston's South End. The project site is bounded by the Massachusetts Avenue Connector to the south, BioSquare-Phase I to the west, Albany Street to the north and the Boston Flower Exchange and Frontage Road to the east.

On November 21, 2003, the Commission submitted a detailed comment letter to MEPA and the BRA. The letter highlighted two significant concerns; the proximity of one of the propose buildings to the East Brookline Street storm drain as well as the proximity of the Roxbury Canal Conduit, a very large combined sewer overflow pipe.

Last year, the Commission requested that the proponent address two major concerns: (1) a conflict in the location of a proposed building with a section of the existing East Brookline Street storm drain and (2) security issues posed by the size of the Roxbury Canal Conduit. The proponent agreed to develop an engineering plan to demonstrate the feasibility of relocating this storm drain, given the existing constraints in this area. The proponent also agreed to address the Commission's security concerns. The concerns about relocating the East Brookline Street storm drain and the security issues with the Roxbury Canal Conduit have been resolved.

The Commission looks forward to working with the proponent. The proponent should submit the relocation plans to Mr. Phil Larocque, Site Plan Review Engineer, Engineering Customer Service as soon as possible.

Thank you for the opportunity to comment on this project.

Yours truly,

John P. Sullivan, P.E.
Chief Engineer

JPS/pwk

c:

Joseph Kajunski – BU Medical Center
Susan St. Pierre – Fort Point Associates
Charlie Jewel – BWSC
Phil Larocque - BWSC

**Watertown Citizens for Environmental Safety**
**Post Office Box 1194 Watertown, MA 02471-1194**

November 5, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114



Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:

As residents of Watertown, we have grave concerns about the proposed facility discussed in this report. In the event of any accident, the impacts upon the entire metropolitan area could be devastating. The FEIR that has been submitted is in our view totally inadequate in that it does not cover the real and serious possibility of such accidents, as well as other required analyses. Specifically, a supplemental FEIR should be required for the following reasons:

1) The "worst case scenario" described significantly underestimates the disastrous impacts on the surrounding community of a release of anthrax or other deadly and incurable viruses and toxins from the proposed laboratory. This facility would be the first to be built in a densely populated area; a NIAID memo in 2000 stated that a BSL 4 lab should be well removed from major populations centers in order to reduce the possibility of an accidental release of an organism leading to a major public health disaster. The report should contain a site-specific release analysis and should fully consider the environmental impact of any release.

2) There have been documented cases of accidental releases of pathogens during transport to laboratories. The report fails to provide information about transport of hazardous agents to the laboratory and does not describe such a "worst case scenario."

3) The laboratory could be subject to intentional acts of sabotage, resulting in releases of pathogens into the surrounding community. There should be an analysis of vulnerability to an attack.

4) The report is inconsistent with the Massachusetts Environmental Justice Policy.

5) There should be an analysis of alternative locations for the laboratory. On what basis was the decision made to use the current location?

6) How will the laboratory comply with regulatory requirements, including the Boston regulation prohibiting recombinant DNA research requiring BSL4 containment?

7) How will the project proponent assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory?

8) The report fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.

We believe that there should be an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility. The committee should consider real worst case release scenarios, including releases from the lab (due to containment system breaches, escape of infected research animals, unknowing infection of lab workers etc.) and releases while the hazardous biological materials are in transport to the lab. The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR. Thank you very much for the opportunity to comment.

Sincerely,

Ernesta Kraczkiewicz

Ernesta Kraczkiewicz

WCES Planning Committee Member

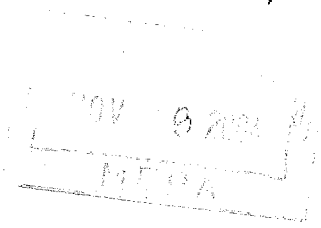
**William S. Grenzebach**
**9 Perry Street**
**Brookline, Massachusetts 02445**

66

November 5, 2004

#12021

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114



Re: Boston University Biosafety Laboratory

Dear Secretary Herzfelder,

I am writing in support of Boston University Medical Center's plans to construct the Biosafety laboratory as part of the BioSquare Research Park on Albany Street.

My twenty-five years of diverse engineering experience has provided me with a unique knowledge base to review this project. In addition to working in off-shore oil exploration and nuclear power plants, I also co-authored the six-volume Maine Yankee Power Plant probabilistic risk assessment for the Nuclear Regulatory Commission. More recently, as a certified lead assessor for both ISO 14001 Environmental Management Systems and ISO 18000 Health and Safety systems, I have evaluated both environmental and safety systems for a number of petrochemical, manufacturing and mining clients in North and South America and Western Europe.

Having reviewed the proposed Biosafety Lab building plans, I am certain that Boston University will set a new standard for safe and secure high containment laboratory facilities. The study of emerging infectious diseases will have a positive impact on the public health world wide. Having been confronted with the SARS issue in my own professional life, I can verify the importance of such research studies.

Since health care, biomedical research and biotechnology are major economic engines of the Massachusetts Economy, the Biosafety Laboratory will serve as a catalyst for continued growth of these industries by attracting additional research funds and staff. BU's community commitment to expand the Citilab program will provide new career opportunities for community members to acquire new skills and begin a research career.

In summary, I am certain that Boston University is committed to addressing every safety, environmental, employment and community issue for the Biosafety Laboratory and urge the BRA to approve this unique project which will maintain Boston's position as an innovator in biomedical research.

Sincerely,

William S. Grenzebach

William S. Grenzebach, Ph.D., M.S.G.E., M.S.I.E.

**Robina E. Folland**
**9 Perry Street**
**Brookline, Massachusetts 02445**

BG
11/2021

November 5, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: Boston University Biosafety Laboratory

Dear Secretary Herzfelder,

I am writing in support of Boston University Medical Center's plans to construct and manage the Biosafety laboratory as part of the BioSquare Research Park on Albany Street.

In my twenty years as a research administrator, I have worked with a number of infectious disease physician-scientists who utilized BL-3 high containment laboratories to study the organisms which cause HIV, plague, cholera, botulism, and similar maladies. Standard laboratory operating procedures and research protocols stress not only the fastidious nature of lab techniques but also the safety of the technical support personnel performing those techniques. In my experience, employee safety and security is of paramount concern to scientists with whom I have worked.

Many of the organisms which will be studied in the Biosafety Laboratory pose significant public health problems in large areas of the developing world due to the lack adequate sanitation and poor access to clean water. Development of vaccines to combat these diseases will significantly enhance the quality of life for third world citizens and will enable them to contribute to building more productive societies.

BU's community commitment to expand the Citilab program will provide new career opportunities for community members to acquire new skills and begin a research career in a growing industry. Research jobs provide higher salaries and better benefits than many service jobs currently held by members of the local community.

In summary, Boston University has committed significant resources to addressing every safety, environmental, employment and community issue for the Biosafety Laboratory. I strongly the BRA to approve this project which will contribute to the Boston economy for some time to come.

Sincerely,

Robina E. Folland

Robina E. Folland, M.B.A., R.H.I.A.

BG

SAFETY NET

ACE
alternatives for community & environment

*Building Power Together for Environmental Justice*

November 5, 2004

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MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:

These are the comments of the Safety Net and Alternatives for Community & Environment (ACE) on the Final Environmental Impact Report (FEIR) for Biosquare Phase II.

The Safety Net is comprised of public housing residents and others in Roxbury who came together in 2000 to develop a voice and vision for a sustainable Roxbury and equitable metropolitan development. Members of the Safety Net are concerned about BioSquare Phase II because the project is near their neighborhood and they believe that the project as proposed will have adverse environmental, health, safety, and economic impacts. Based in Roxbury, Massachusetts, ACE works in partnership with low income communities and communities of color to achieve environmental justice. The Safety Net and ACE are part of the Stop the BU Bioterrorism Lab campaign, a coalition of many persons and groups, both within and outside Boston, that believe that Boston University's proposed BSL4 Bioterrorism Laboratory[1] presents too many environmental, health, and safety risks to be located safely on Albany Street in Boston's densely populated South End.

A thorough review of the FEIR will demonstrate that the FEIR does not adequately describe the potential impacts of the bioterrorism laboratory project. We urge you to find the FEIR inadequate and to require University Associates to file a supplemental FEIR as authorized by 301 CMR § 11.08(8)(c)2 because the FEIR:

- Does not include a true or accurate "worst case scenario." Instead, the FEIR contains a purported "worst case scenario" that: 1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of

[1] The facility is a bioterrorism laboratory because under federal funding requirements the laboratory must give preference to biodefense research and other NIAID research programs for the first twenty years. The laboratory will host and perform experiments on some of the most dangerous and incurable diseases known, diseases that are easily transmissible, can cause public health crises, and can be used in bioterrorism and biowarfare.

c/o Alternatives for Community & Environment
2181 Washington St., Suite 301 / Roxbury, MA 02119
tel: 617-442-3343 / fax: 617-442-2425 / www.ace-ej.org

anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins[2] that, unlike anthrax, are highly contagious.

- Fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory.

- Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.

- Is inconsistent with the Massachusetts Environmental Justice Policy.

- Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End.

- Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.

- Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met, considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.

- Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report (hereinafter, the "Certificate"). It does not respond to many comments made on the DEIR, consequently denying agencies and the public the opportunity to review and comment on important issues that have a potential impact on the environment.

These inadequacies of the FEIR are discussed in more detail below.

## I. THE WORST CASE RELEASE SCENARIO SET FORTH IN THE FEIR IS NOT AN ACCURATE EVALUATION OF A WORST CASE RELEASE FROM THE PROPOSED BIOTERRORISM LABORATORY

[2] Select agents are biological agents and toxins that have a potential to pose a severe threat to public health and safety. The select agent rule is found at 42 CFR Parts 73 and 1003. The list of select agents and toxins, found at 42 CFR § 73.4 and 73.5, is based on criteria specified in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, including the effect on human health of exposure to the agent or toxin, the degree of contagiousness of the agent or toxin and the method by which the toxin is transferred to humans, and the availability and effectiveness of therapies and vaccines to treat and prevent an illness resulting from the agent or toxin.

The Certificate requires the FEIR to include, *inter alia*, an evaluation of a "worst case" safety event involving the loss of physical integrity of the laboratory's containment systems, noting that the draft EIR (DEIR) "did not include a detailed discussion of the potential environmental impacts of the biocontainment building." The Certificate also requires the FEIR to respond to the comments received, "in particular to the detailed comment letter submitted by Alternatives for Community and Environment" (hereinafter, "ACE"). ACE's comments noted that the lab DEIR "did not provide information about the environmental impact of a potential release of deadly agents from the laboratory" and the project proponent should include a comprehensive discussion of the impact of building a laboratory "with a BSL4 component that must perform federally required bioterrorism research on deadly organisms... Such discussion must describe and analyze... all aspects of the project, including... environment, health and safety...."

MEPA mandates that there be a complete assessment of a potential release from the bioterrorism lab so that "the nature and extent of the proposed project and its environmental impact" is described. MGL c.30 § 62B. A FEIR must "present a complete and definitive description and analysis of the Project and its alternatives, and assessment of its potential environmental impacts and mitigation measures...." 301 CMR § 11.07(4). A FEIR that understates the impact of the release, or fails to analyze the release of select agents and toxins with different properties, does not assess potential environmental impacts and, in this instance, is not protective of the public health, safety, and environment.

The FEIR contains a purported worst case release scenario based on a *Summary Report Hazard and Risk Assessment* (hereinafter, the "Summary Report") prepared by RWDI West, Inc., (University Associates' paid consultant) and contained in the September 24, 2004, Comments of Clarification on the FEIR. Whether the FEIR has adequately identified and analyzed the potential impacts to the public health and the environment in the event a select agent or other virus or toxin is released from the bioterrorism laboratory depends on whether the Summary Report is accurate and complete. As we discuss below, the Summary Report is seriously flawed and does not present a worst case release scenario. It is not a description of the potential environmental impact of the project.

Jeanne Guillemin, Ph.D., has reviewed the Summary Report. Dr. Guillemin, a Senior Fellow, MIT Security Studies Program, and Professor of Sociology, Boston College, works in the area of medical anthropology. Her teaching includes a seminar on Risk and Danger. She has more than twenty years of experience in the investigation of biological weapons controversies and has published broadly about them. She is the author of *Anthrax: The Investigation of a Deadly Outbreak* (University of California Press, 1999), the definitive account of the 1992 team research of the largest inhalational anthrax epidemic in recorded history, which in 1979 killed sixty-six people in the Soviet city of Sverdlovsk. Her interviews with the families of victims were the basis for the epidemiological map that proved an anthrax aerosol from a nearby military facility caused the outbreak and her data proved that the incubation period for inhalational anthrax can be as long as six weeks. She is also the author of the forthcoming book, *Biological Weapons; From the Invention of State-sponsored Programs to Contemporary Bioterrorism.* Dr. Guillemin's curriculum vita is available at http://www2.bc.edu/~guilleje/Homepage(Frames).html.

Dr. Guillemin has given us permission to include her review of the Summary Report in our comments. It is found in the appendix to these comments. In brief, Dr. Guillemin's conclusions about the Summary Report are that:

- The Summary Report contains serious mistakes that lead to the erroneous conclusion that an anthrax spore release caused by a laboratory spill would pose no risk to the public.
- The Summary Report ignores what would happen on a community level after a dangerous release.
- The Summary Report ignores contagious disease outbreaks that could result from BSL4 accidents.
- The Summary Report does not address workplace contamination even though the 2001 anthrax postal attacks and indoor simulations showed the ease with which anthrax spores disperse throughout buildings and cause health risks and the extreme difficulty, time, and expenses associated with building decontamination. A recent report concerning anthrax contamination at Ft. Detrick also raises concern about leaks from high containment laboratories.
- The Summary Report ignores environmental contamination even though any outdoor release brings with it the possibility of soil contamination.

Based on Dr. Guillemin's review of the Summary Report, we believe that the FEIR presents a best-case release scenario, not a worst-case release scenario required by the Certificate. The FEIR is inadequate because, in violation of 301 CMR 11.07(h), it fails to include an assessment of the negative potential environmental impacts of the laboratory. It is a critical failing of the FEIR on a most crucial issue and is reason alone to require a Supplemental FEIR. Relying on the erroneous conclusion that there will be no harm from a release, the FEIR then fails to describe and assess the mitigation measures it will institute in the event of a release, a MEPA requirement.

We request that you incorporate Dr. Guillemin's recommendations in your determination of the FEIR and that you require a Supplemental FEIR that includes a risk assessment report by the independent oversight committee recommended by Dr. Guillemin. We suggest that the Executive Office of Environmental Affairs convene and chair a meeting that would include the project proponent and those who commented on the FEIR's risk assessment to determine how such a committee should be constituted and the charge for the committee. To prevent a potential conflict of interest, the members of the committee should not be affiliated with BU or NIH, listed in BU's NIH funding application to construct the bioterrorism laboratory, or have an intention to operate or perform research in the laboratory.

Having a BSL3/4 bioterrorism laboratory in Boston and Massachusetts is unprecedented, presents unprecedented risks to the community, and requires a serious and unbiased review. We must have an independent committee to provide a risk assessment for the laboratory, including disease outbreak scenarios, and on future plans for biodefense research, so as to fulfill the mandate of MEPA that the impacts of the project be known, and mitigation measures identified and evaluated, before the project may go forward.

A recent study of the anthrax releases at Fort Detrick supports the need for a thorough and unbiased risk assessment of the proposed bioterrorism laboratory. We have included in the appendix an article in the October 14, 2004, USA Today reporting on the U.S. Army report on the anthrax releases from the Fort Detrick BSL3/4 laboratory. Three strains of anthrax escaped the supposedly secure BSL3 laboratory, which is designed to enable scientists to safely work with deadly microbes. Two of the strains were used in biodefense work. The report and statements of experts in the article serve to show that the FEIR is incorrect in its conclusion that there would be no human health or environmental damage from an anthrax release from the containment laboratory. Highlights of the article include:

> Researchers expressed relief that no one was hurt or killed in the episode, but Stephanie Loranger of the Federation of American Scientists asks, "Fort Detrick is one of the premier biodefense labs, and if they have problems, what does it mean for all the others?"
>
> "The good news is nobody got the disease (*i.e.*, anthrax)," says Alan Zelicoff, a biodefense expert who is now a consultant at ARES Corp., a risk analysis firm. "The bad news is that nobody got the disease because just about everybody near the BL-3 suite had been vaccinated."
>
> "The message here from a scientific and policy standpoint is profound," Zelicoff says. "Facilities that are medical and microbiological may not be suitably equipped for dealing with aerosolized versions of the organisms that they otherwise deal with in great safety. These facilities probably ought not be located in a heavily populated area. How do you contain smoke?"

We have also included in the appendix a December 15, 2000, memorandum obtained from NIH that acknowledges the risk of releases from BSL4 laboratories. In pertinent part, the memorandum reads that a reason to build a BSL4 laboratory in rural Montana, "well removed from major populations centers," is that "the location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster."

## II. THE FEIR MUST BE REQUIRED TO INCLUDE AN ANALYSIS OF A RELEASE WHEN SELECT AGENTS ARE IN TRANSIT TO THE LABORATORY AND OTHER ESSENTIAL INFORMATION ABOUT THE TRANSPORT OF HAZARDOUS BIOLOGIC AND TOXIC AGENTS TO THE LABORATORY

The FEIR fails to contain any assessment of a release of a select agent when in transit to the laboratory. Instead, the FEIR discusses the protocols it will use for shipment of biological materials and claims, without any support, that "the risk to the community from transport of infectious agents or other biological derived material is negligible." (FEIR 5-26.) That is inconsistent with 301 CMR § 11.07(6)(h) and the Certificate, which require the FEIR to "address safety considerations related to any transport of potentially hazardous biological agents to and from the biocontainment facility." Simply stating that the risk is negligible, without any support whatsoever for that statement, does not address the safety considerations of what would occur if

there were a release during transport or allow agencies and the public to determine whether the level of risk asserted in the FEIR is accurate.

Two recent accidents when shipping infectious agents show that there is indeed a risk to the public from shipping and consequently the proponent must be required to analyze that risk. First, earlier this year a laboratory accidentally shipped live, rather than dead, anthrax from Maryland to California. The mistake was discovered only when laboratory animals in California died from anthrax and the researchers using the anthrax found that the dead anthrax that they had ordered was alive and virulent. The laboratory shipping the anthrax has admitted the error. Second, last year a package containing West Nile virus exploded at the Federal Express facility in the Port Columbus International Airport, Ohio, forcing the evacuation from the facility of about fifty workers. Fortunately, no persons died from these accidents, but they show that there is a real and substantial risk of errors in shipping that may put the public at risk.

In addition to the two recent shipping accidents, the federal government itself has acknowledged the vulnerability of shipping biological agents, writing that infectious agents such as anthrax may pose a security risk in transport and that it needs to determine if addition federal rules are necessary to assure the safety of hazardous materials in transit. 67 Fed.Reg.157, p.53131 (August 14, 2002).

Further, the FEIR provides no information on designated transport routes. The only reference is that "the receiving and shipping location(s) for select agents will have a designated route to and from BUMC and will be accessed and egressed to the site only by the local highway system (presumably Frontage Road)." Yet, the Massachusetts Turnpike Authority prohibits the transport of hazardous materials in all its tunnels, including the tunnel under the Prudential Center, and the Central Artery, Callahan, Sumner, and Ted Williams tunnels. 730 CMR 7.10. Hazardous materials are those defined and listed in 49 CFR Chapter 1, Subchapter C, which include infectious materials. Because designated routes are not mentioned in the FEIR, other than noting access and egress by the local highway system, it is unknown whether the project proponent is aware of or has considered the prohibition and how the routes will be adjusted accordingly. Because vehicular traffic to the project site may be primarily from Frontage Road, it is essential that the public and regulatory agencies are fully aware and have the opportunity to comment during MEPA review on the routes of transport of select agents to the site.

We request that the recommended oversight committee include an analysis of risk during transport of biological agents to the laboratory and that you require a report on transit risks as part of a Supplemental FEIR.

## III. THE FEIR MUST BE REQUIRED TO INCLUDE A THREAT AND VULNERABILITY ANALYSIS FOR A TERRORIST ATTACK ON THE LABORATORY AND AN ANALYSIS OF A RESULTING RELEASE OF SELECT AGENTS AND OTHER DAMAGES TO THE SURROUNDING COMMUNITY.

The bioterrorism laboratory will house and perform experiments with select agents that can be used in bioterrorism and biowarfare. It is generally acknowledged that terrorists in the possession of such agents could do great damage but terrorists cannot make such agents and

would need to obtain them from a source such as the laboratory. Richard Ebright of Rutgers University recently wrote, "The simplest, most likely, path for a sub-state adversary, such as Al Qaeda, to acquire bioweapons capability is to obtain bioweapons agents and training by penetration of a biodefense research project in a US laboratory." Terrorists will view the bioterrorism laboratory as a source of bioweapons materials or a facility to destroy. An attack on, or infiltration of, the laboratory could result in the release of pathogens or the escape of infected insects or animals, with deadly results. An attack on the lab that did not release pathogens might nonetheless cause damage to nearby communities.

As noted in the FEIR, in recognition of the threat of terrorism, the facility will be constructed with an outdoor security perimeter, limited and controlled access points, and an anti-scale fence that will serve as a vehicle and pedestrian barrier. There also will be internal laboratory controls designed to limit access to select agents. Inexplicably, however, the FEIR fails to analyze the threat of a terrorist attack or the consequences of a pathogen release caused by an attack. In public meetings, the project proponent has claimed that any attack would destroy the stored pathogens, but that analysis must be provided in a Supplemental FEIR for review and comment. Further, as noted in the FEIR, the facility will be infecting insects and animals, including non-human primates, with infectious diseases for which there is no known cure. Infected insects and animals could be released as a result of terrorism and spread disease to other insects and animals, including humans, outside the laboratory yet the FEIR contains no analysis of those risks.

The FEIR's failure to consider and analyze the risks of a terrorist attack on or penetration of the laboratory, and its failure to assess the impact of a pathogen release caused by terrorism is a significant failure of the FEIR to comply with the mandate of MEPA that the FEIR must assess the direct and indirect potential environmental impacts from all aspects of the project. 301 CMR 11.07(6)(h). It is reason alone to reject the FEIR as inadequate.

We request that the recommended oversight committee include an analysis of the risk of a terrorist attack on or penetration of the laboratory, the risk that such attack could release pathogens, including infected insects and animals, and the impact of such a release on human health and the environment.

## IV. THE FEIR IS INCONSISTENT WITH THE MASSACHUSETTS ENVIRONMENTAL JUSTICE POLICY

The proposed location of the laboratory is within one mile of an Environmental Justice population and within a few blocks of a large public housing complex and the Suffolk County House of Corrections. The Massachusetts Environmental Justice Policy recognizes that residents of EJ communities live side by side with numerous undesirable and dangerous facilities that can pose risks to public health and the environment and consequently its statement of purpose is that environmental justice shall be an integral consideration in the implementation of all EOEA programs. The EJ policy defines environmental justice as "the equal protection and meaningful involvement of all people with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies and the equitable distribution of environmental benefits." The EJ Policy defines "meaningful involvement" as meaning that "all neighborhoods

shall have the right to participate in partnership with government in environmental decision-making including needs assessment, planning, implementation, enforcement, and evaluation...."

Notwithstanding these statements, there has been no involvement of the nearby EJ community in planning for the bioterrorism laboratory. Instead, Boston University applied for federal funding for the laboratory without EJ community involvement, and many government agencies and officials have assisted University Associates in the project without any input from or apparent regard for the nearby EJ communities.

As noted in Dr. Guillemin's comments, socio-economic factors (*e.g.*, language barriers, access to health insurance and services) may increase the vulnerability of EJ communities to the types of public health emergencies that may result from releases from the laboratory and yet there is no consideration of those factors in the FEIR. In addition, the proposed laboratory will add yet another burden to an EJ population that already has much more than its fair share of undesirable facilities in its community, yet that issue is not analyzed in the FEIR even though MEPA regulations require an analysis of the cumulative impact of the project with other work or activity in the area. 301 CMR 11.07(6)(h).

Further, there are many instances, as set forth throughout these comments, in which the FEIR does not provide sufficient information to allow for meaningful public participation and comment (*e.g.*, not including a detailed analysis of alternative locations for the laboratory). Failure to provide that information deprives the affected EJ community of the opportunity to review and comment fully on a dangerous facility proposed for its community.

Thus, we strongly urge you to require a Supplemental FEIR that analyzes the EJ implications of having a BSL3/4 bioterrorism laboratory in an EJ community.

## V. THE FEIR MUST INCLUDE A DETAILED ANALYSIS OF ALTERNATIVE LOCATIONS FOR THE BIOTERRORISM LABORATORY

Our comments on the DEIR noted that a deficiency of the DEIR was its failure to include a discussion of alternative sites for the bioterrorism laboratory and alternative development at the site that does not include a BSL4 bioterrorism laboratory. In the Certificate, you required the FEIR to respond to the detailed comments that we submitted on the DEIR. Nonetheless, the FEIR does not contain any discussion of alternative locations for the bioterrorism laboratory. Instead, buried in the FEIR's response to comments, appendix 1-30, is the statement that a separately issued Environmental Impact Statement has been developed that includes an alternative analysis.[3]

The failure to include an alternatives analysis in the FEIR is a violation of 301 CMR 11.07(6)(f), which requires, unless otherwise indicated by the Secretary, a description and analysis of

[3] We received the NEPA DEIS on October 28, 2004. It analyzes a no-build option, but does not analyze any alternative locations. (One rationale given for not analyzing other locations is the same flawed RWDI Summary Report used in the FEIR.) If the project proponent intends to rely on the DEIS to fulfill a MEPA requirement, then the DEIS must be submitted under MEPA as part of a Supplemental FEIR so that it is subject to MEPA review.

alternatives to the project, including, "all feasible alternatives..." as well as "the alternative of not undertaking the Project...." To our knowledge, you have not indicated otherwise.

Compliance with MEPA requires that the FEIR include an analysis of all reasonable locations for the laboratory, all feasible alternatives, and the principal differences between the alternatives. 301 CMR 11.07(6)(f). This analysis is critically important, considering that the project proponent proposes to locate a bioterrorism research laboratory that will host and manipulate bioterrorism and biowarfare agents and may be a terrorist target in a densely populated urban Environmental Justice community, near a major hospital used by inner city residents that might be unavailable in the event of a release from or attack on the laboratory, and close to major roadways. A true alternative analysis is necessary so that other options may be considered and the option chosen is one that minimizes risk to the public and environment. Without the analysis of reasonable alternative locations, as required by MGL c.30 § 62B, the mandate of MEPA is not met.

We request that the proponent be required to submit a Supplemental FEIR that includes the criteria it used for locating the laboratory in a densely populated EJ community, the other locations it considered for the laboratory, including population density and characteristics of those locations, why it rejected those other locations, and how the current site meets those criteria. To the extent proximity to researchers at Boston University and at the NIAID Regional Center for Excellence is a criterion, the Supplemental FEIR must explain why the project proponent did not consider or rejected other locations in less densely populated areas within a one hour drive of Boston.[4] The Supplemental FEIR must also explain how the decision considered risks to public health and safety and the environment and how a decision could have been made on siting before the RWDI Summary Report was completed.

## VI. THE FEIR FAILS TO IDENTIFY ALL STATUTORY AND REGULATORY STANDARDS AND REQUIREMENTS AND THE MEASURES TO BE TAKEN TO ASSURE COMPLIANCE WITH THOSE STANDARDS

MEPA regulations require the FEIR to contain a "list of any Permit, Financial Assistance, or Land Transfer that is or may be required, and a brief description and analysis of the applicable statutory and regulatory standards and requirements thereof and the measures to be taken to ensure due compliance therewith." 301 CMR § 11.07(6)(i). In our comments on the DEIR, we noted that the DEIR failed to describe the performance standards for each state permit and approval and how the project would meet the standards. Notwithstanding the regulatory requirement and the Certificate's requirement that the FEIR respond to ACE's comments, the FEIR does no more than list, page 1-8, the anticipated required permits and approvals but again provides no information on the standards or the measures to be taken to ensure compliance.

[4] To the extent the project proponent did not consider other locations, the Supplemental FEIR should identify and consider other locations. We anticipate that the project proponent will say that it chose the location at least in part because it owned the land. That, however, would be an inadequate rationale for three reasons. First, that is not an acceptable rationale under MEPA for not undertaking an alternatives analysis. Second, the project proponent did not own the land when it applied to NIAID. It acquired the property later, after negotiations with the state and BRA. It could have identified other properties, including perhaps at or adjacent to closed or currently operating military bases, which it could have acquired for the project. Third, federal requirements allow the land to be leased.

Instead, in violation of the regulatory requirement and the Certificate, it notes in the response to comments section that during the state permitting process it will "demonstrate compliance with all relevant performance standards." The project proponent may prefer that method of proceeding, but that is not the MEPA requirement and does not give the public the opportunity to comment during the MEPA process on the proposed measures to ensure compliance. That is especially important for those permits and requirements that have no public participation process, where the public does not know of the permit application, or may be unable to monitor compliance.

For example, the Boston Public Health Commission regulation on recombinant DNA (rDNA) use contains an important standard not noted in the FEIR. It prohibits rDNA use requiring BSL4 containment. Modern biological research requires rDNA use and one would expect rDNA use in the BSL4. Notwithstanding, the FEIR fails to list this critical standard or describe how the laboratory will comply with the standard.[5]

The FEIR, page 5-13, also notes that the facility will generate up to 10-15 pounds of radioactive waste each month, that long-lived isotopes will be shipped off site and short-lived isotopes will be held on site for up to two years and nine months while they decay before being discharged to the sewer. The FEIR, however, fails to list at page 1-8 the requirements and standards for radioactive waste. That information must be made available to the public, regulatory agencies, and MEPA.

We urge you to require a Supplement FEIR in which the project proponent is required to meet the standard set forth in 301 CMR § 11.07(i), including how the laboratory would assure compliance with the Boston rDNA regulations.

## VII. THE FEIR DOES NOT INCLUDE A DISCUSSION OF HOW THE PROJECT PROPONENT WILL ASSURE THAT ITS HEALTH AND SAFETY OPERATING PROCEDURES ARE MET CONSIDERING THAT THE FEDERAL GOVERNMENT HAS NOT YET CHOSEN THE ENTITY THAT WILL OPERATE THE LABORATORY AND THAT MANY OUTSIDE RESEARCHERS, INCLUDING STUDENTS WITH NO BSL4 EXPERIENCE, WILL USE THE LABORATORY.

Our comments on the DEIR noted that the federal government had not yet chosen the operator of the laboratory and that the operator chosen might not be BU. Consequently, we asked how BU could assure safe operation of the laboratory. We also asked whether the research in the laboratory would be subject to federal secrecy requirements and, if so, how that would affect state and local environmental, health, and safety oversight of the laboratory.

The FEIR response is found in its appendix, 1-30. It claims that the "building will be owned and operated and research to be undertaken will be directed by Boston University Medical Center University." It provides no documentary support or evidence for that statement. We have enclosed in the appendix the pertinent pages from the Request for Proposals and Applications (RFPA) under which BU is being funded to build the laboratory, showing that BU must compete

[5] The FEIR also misstates the regulation as requiring project registration whereas the regulation requires a permit.

for an operations contact. There is no evidence that BU has been chosen for the operations contract.

The FEIR also claims that various committees in the laboratory will "authorize research." Yet, the RFPA requires that the laboratory "must give priority to Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities."[6] The FEIR does not explain whether and how it can ignore those priorities set forth in the RFPA -- both as to the type of research to be performed and the entities expected to perform research.

Finally, the FEIR is silent on whether federal secrecy requirements apply and if so how they would affect state and local environmental, health, and safety oversight of the laboratory. Considering that the laboratory must give priority to biodefense work, there is a high likelihood of secret research.

These important issues go to the heart of whether the laboratory will have an adverse environmental and health impact on the community. The FEIR claims that BU will have procedures and practices in place to assure that the laboratory will experience no health or safety failures, but has provided no information showing that BU will have the authority necessary to implement and enforce those procedures and practices. It also fails to address the real possibility that the secrecy of the research to be conducted in the laboratory will prevent necessary oversight by regulatory entities.

The FEIR was required to have responded to these issues, but failed to do so. We urge you to require a Supplemental FEIR that responds to these issues.

## VIII. THE FEIR FAILS TO COMPLY WITH THE REQUIREMENTS OF THE CERTIFICATE

The FEIR fails to comply with the Certificate for many issues in addition to those noted above. Those others that require the preparation of a Supplemental FEIR because the FEIR's failure to analyze them prevents important opportunities for agency and public review and comment on matters that have a potential environmental impact include:

- The Certificate required the FEIR to include an analysis of how the proponent would meet any applicable inflow and infiltration (I/I) requirements. The FEIR does not address Inflow and Infiltration (I/I) removal requirements.
- The Boston Transportation Department's (BTD) comments on the DEIR asked for details about truck routes into and out of the site, including turning templates. The FEIR does not provide any.
- BTD's request for pedestrian information is ignored. On page 8 of 11 of its letter, BTD asks for "A graphic showing all existing and proposed pedestrian paths and crosswalks (with a distinction for unsignalized crossings) between Harrison Avenue, the Mass. Ave. Connector (MAC), East Canton Street and East Concord St., a detailed pedestrian internal circulation

[6] We have included in the appendix the pertinent pages from the RFPA and a January 28, 2003, letter from BU to NIAID that acknowledges that the laboratory will be "devoted exclusively to biodefense research and other NIAID-defined research programs...."

plan for the Site that shows all sidewalks, paths and pedestrian entrances..." The only relevant graphic in the FEIR is Figure 2-19 (which is the same as Figure 4-18) and which does not provide the required information. Noticeably absent from the figure is that there is no pedestrian connection between the MAC and either East Concord St., East Newton St., or East Brookline St. In fact, there is no connection from the site to the MAC. The proponent's response is: ""No connection to the South Bay Harbor Trail will be provided through the campus rather, access to the trail will be afforded from Massachusetts Avenue and Albany Street." Yet, the site does not even extend to Mass. Ave. and Albany St. but the proponent claims a 10% reduction in trips because of a TDM program. Few employees would bike west on Albany St. to go east on the Harbor Trail.

- Our comments, page 5, on the DEIR, compared the project to Executive Order 385, noting that the roadways and intersections near the site were at or above capacity and requesting that the proponent describe how the lack of roadway capacity is adequate infrastructure. We also asked whether the sewer system in the area contributes to a Combined Sewer Overflow and, if so, how that is adequate infrastructure. The FEIR, appendix 1-31, concludes that the project is consistent with E.O. 385, but fails to demonstrate how increasing traffic on already overburdened roadways aids adequate infrastructure. Further, its failure to address I/I requirements means that one cannot assess whether its discharge would increase the frequency or severity of CSO activations or the costs of necessary sewer improvements elsewhere.
- Our comments, page 8, on the DEIR traffic study, noted that the DEIR analyzed traffic data, collected at different locations on different dates, as a single comprehensive data set, that most intersections were measured on one day only, and that several of the traffic study dates were after the end of the academic year, likely resulting in traffic undercounts. We suggested that the proponent generate the traffic numbers again. The FEIR response is that the data collection and traffic count times and locations were approved by BTD and are standard practice. That does not show that the data is correct or representative. It is incumbent on the proponent to generate representative traffic data, which cannot be done by measuring most intersections on only one date and many intersections on a day when school is not in session -- especially near the project site, where many roadways are at or near capacity and where it proposes to construct a 1,400 car parking garage. There should be a new traffic study, generated on the multiple same dates at each intersection during days when schools are in session.
- Section 1.2 of the BTD Scope requested a complete analysis of all parking facilities in the area. The FEIR, appendix 1-32, states that BTD modified the scope to include only parking on the BUMC/BioSquare campus. Although the BTD narrowed the scope of its request, to adequately assess parking supply and demand, the proponent should be required to evaluate all nearby parking facilities, including BioSquare, BUMC, BWSC, Crosstown, and the proposed Dudley Garage, Renaissance Park, and Northeastern University's Master Plan. The FEIR's parking discussion, pages 4-43 - 4-44, proposes to satisfy parking demand through leased satellite parking lots at Northeastern University. The FEIR fails, however, to discuss the traffic and environmental impacts resulting from an additional 900 parking spaces at Northeastern University and from shuttle buses. Those impacts must be studied to determine the level of service provided by the local and regional roadways caused by the increase use and how to mitigate the impacts.

- Our comments on the DEIR noted that a 25% subsidy for MBTA passes may be insufficient to encourage public transit use and requested that BUMC analyze the impact of providing free passes. We also requested review of whether a single zipcar space is sufficient, 32 carpool spaces are appropriate, and how the proponent might comply with the DEP ridesharing regulation that requires a reduction of customary commuting vehicles of 25% from the base date. The FEIR, appendix 1-32, responds merely by referring to the Transportation Demand Management (TDM) at §§ 4.3.8, 4.4. Section 4.3.8 does not exist in either the DPIR or the FPIR. Section 4.3.7 provides a cursory discussion of TDM. Section 4.4, does not explain why a 25% subsidy for employees, and a 0% subsidy for students adequately encourages public transit. Instead, it merely states that the MBTA subsidy costs BUMC $120,000 per year, without stating the amount of money it saves BUMC in terms of automobile infrastructure, such as reducing the number of additional parking spaces, fewer roadway improvements and less maintenance, and less congestion. The FEIR, at 4-50, states that there are 2 Zipcar spaces located at Lot A, but does not indicate whether those spaces will be included in the proposed inconvenient parking garage. The FEIR, at 4-49, does not explain why BUMC chose 32 spaces for carpoolers, or describe the location of these 32 spaces, but claims that they are in a central location. The FEIR does not explain how the BUMC carpool program meets the DEP ridesharing regulation.
- Our comments on the DEIR, pages 10-11, included that the parking evaluation is inadequate because the proponent failed to analyze parking needs fully. The FEIR, app. 1-32 states that parking is discussed at Section 4.3.5. It does not, however, explain how BUMC chose 1,400 as the number of parking spaces needed. It does not explain the number of employee and visitor spots that will be needed. It states that prior studies indicate that the turnover rate for patients and visitors at BUMC is about 4.0, and that the average parking duration is 1.5 to 2 hours but does not cite those studies. It states that the continued increase in parking fees and reduction in overall supply are expected to decrease single occupant vehicle use, but does not state how a net increase of 800 parking spaces (200 more spaces at the Phase II garage and 600 satellite spaces at Northeastern University) will do so, particularly in light of the 800 person waiting list. Finally, it claims that the original 1999 scope that required a parking needs assessment for the entire South End Medical Area was limited in May 2002 to BUMC and BioSquare facilities. Consequently, it does not discuss parking needs for the South End Medical Area.
- Our comments on the DEIR, page 11, noted that the ENF required a discussion of construction period traffic impacts, quantification of associated truck trips, and any necessary coordination with the Central Artery/Tunnel construction activities in the project area but none were provided. The FEIR, app. 1-32, states that construction impacts are discussed in Section 4.7, and that a detailed Construction Management Plan will be filed by project contractors, subject to approval by BTD. Section 4.7 states that "[t]he developer of each building will submit a detailed Construction Management Plan to BTD as a condition of obtaining a building permit." Thus, even though a discussion of construction period traffic impacts is required, the FEIR merely states that it will provide analysis at a later date.
- Our comments on the DEIR, page 13, noted that the Mesoscale Air Quality Analysis failed to consider the increased use of light trucks and SUVs, thus undermining a key assumption in the analysis and requested that the analysis be rerun with no assumed reductions in motor vehicle emissions. As far as we can determine, the FEIR does not respond to this.

- Our comments on the DEIR, page 13, noted that northwest winds would blow emissions into residential areas of Roxbury and Dorchester and stated that the potential impacts should be addressed. We also noted that the proponent needed to evaluate the necessity of filters and scrubbers and discuss their usage in greater detail. The FEIR did not respond to these comments.

In addition, there are a number of comments that we made on the DEIR relating to security for the building that have no response in the FEIR or for which the proponent claims it will consult or coordinate with others at a later date. We believe these issues are important because they may affect the safe operation of the laboratory and require a response in a Supplemental FEIR so that they are subject to agency and public review and comment. They include: 1) Methods to protect infrastructure (from terrorist activity relating to the lab); 2) capacity and adequacy of utility systems (*e.g.*, gas, electric, and steam) serving the building and the building's energy requirements. They should be discussed in the FEIR.

## IX. CONCLUSION

The FEIR is woefully inadequate. It presents a critically flawed release scenario that seriously understates the potential impact of a release from the lab, thus presenting a best-case release scenario rather than worst-case release scenario. It omits critical information such as an alternative locations analysis. It ignores that the laboratory will be a terrorist target and that a terrorist attack or infiltration could release deadly pathogens into the community. It fails to consider environmental justice issues. It does not describe the existing regulatory standards for the laboratory and how the laboratory will meet those standards. It does not provide the required and necessary assessment of its negative impacts and its alternatives or any mitigation measures. It fails to comply with the Certificate and with MEPA regulations. It evinces a significant disregard for the requirements of MEPA and the right of the public to review and comment on important aspects of a project that presents a significant potential environmental risk.

We urge you to find that the FEIR is inadequate for the reasons set forth in these comments and to require a Supplemental FEIR that responds to the issues we have raised herein. We also urge that you facilitate the creation of an independent committee to review and report on a true risk assessment.

Thank you for the opportunity to comment. For follow up on these comments, please contact Eugene B. Benson, Staff Attorney, ACE, at 617-442-3343 x226 and gene@ace.ej.org.

Respectfully submitted,

Alternatives for Community & Environment
Safety Net

APPENDIX TO
COMMENTS OF ACE AND SAFETY NET
ON THE
FINAL ENVIRONMENTAL IMPACT REPORT
BIOSQUARE PHASE II, EOEA # 12021

1. October 24, 2004, memorandum by Dr. Jeanne Guillemin: Comments on Final Environmental Impact Report/Anthrax Aerosol Release Models

2. October 14, USA Today article: *Anthrax Slip-Ups Raise Fears about Planned Biolabs*

3. December 15, 2000, memorandum: constructing a BSL-4 building at Rocky Mountain Laboratories (2 page cover letter and 3 page memorandum. See page 2 of the memorandum for the relevant statement about a release from the laboratory.)

4. Selected pages from the Request for Proposals and Applications to which Boston University applied for construction funding for the bioterrorism laboratory (RFPA) and Amendment #1 to the RFPA, showing that:
    - The laboratory "must give priority to Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities."
    - BU must compete for an operations contract.
    - The entity may own or lease the land on which the laboratory is located.

5. January 28, 2003, letter from BU to NIAID that acknowledges that the laboratory will be "devoted exclusively to biodefense research and other NIAID-defined research programs...."

From: Jeanne Guillemin
Date: October 24, 2004
Re: Comments on Final Environmental Impact Report/Anthrax Aerosol Release Models

The report by RWDI West Inc. uses three potential anthrax release scenarios to "provide an estimate of the maximum possible risk of exposure." The report contains serious mistakes that lead to the erroneous conclusion that an anthrax spore release caused by a laboratory spill would pose no risk to the public.

In its conclusion and in its methodology, the RWDI report also ignores the question of what would happen on a community level after a dangerous release. The 2001 anthrax postal attacks revealed "an unacceptable level of fragility" in public health and hospital response that remains unaddressed (Gursky, Inglesby, and 0'Toole 2003: 97). Difficulties (including unpredicted fatalities) in administering the 2003 federal smallpox vaccination campaign pointed to serious shortfalls in defending the public and to increased risks to public health (Hillel, Gould, and Sidel, 2004).

In addition, the report ignores contagious disease outbreaks that could result from BSL-4 accidents. Smallpox and plague outbreaks, widely discussed in the Homeland Security literature, could pose serious threats to the public.

Before addressing these problems, I want to offer some background on what we know about anthrax as a disease and about anthrax spores.

*About Anthrax*

Anthrax as a disease originated thousands of years ago in grazing animals and only later passed to humans who came in touch with infected livestock carcasses, from butchering or eating infected meat or in industrially processing skins, wool or hair.

The anthrax spore is about one micron in diameter and forms as a protection after the bacterium is exposed to air. Research on anthrax aerosols to attack enemy civilians is fundamental to the history of state biological weapons programs (Guillemin 2005). That history begins with the French in the 1920s, followed by the Japanese Imperial Army in the 1930s. Anthrax spores for use in bombs and spray generators were most extensively developed by the United States from 1943 until it abandoned biological weapons in 1969. From 1975 to 1992, anthrax bacteria were secretly researched and produced by the USSR. A main goal was to increase the virulence of anthrax spores, which could be done by passing the disease through successive animal hosts and also by new methods in biotechnology.

Inhalational anthrax is an extremely rare disease. Most of what we know about it comes from military research, from the 1979 Soviet outbreak in the city of Sverdlovsk, and from the 2001 postal anthrax attacks (WHO 2004: 229-243). The Sverdlovsk outbreak, the largest of its kind in recorded history, was later shown to have resulted from an outdoor

spore release from a military facility in the city (Abramova, Yampolskaya, and Walker 1993; Meselson et al. 1994; Guillemin 1999). Sixty-eight people died in the outbreak, from what is estimated as a gram or less of spores disseminated in a plume that blew over a local neighborhood. The released spores killed livestock as far as 30 miles from the source of the emission.

The optimal size of any particulate for inhalation in the human lung is 1-10 microns. Although anthrax spores can clump into larger particle sizes, weapons research showed that spores can easily be separated into the small particle sizes that would increase the chances of infecting the enemy under attack.

A single anthrax spore can cause inhalational anthrax if it is inhaled deep into the lungs and subsequently reaches the lymph nodes. Even small amounts of lethal anthrax spores are dangerous, such as the trace amounts that cross-contaminated letters during the 2001 anthrax attacks.

The early symptoms of anthrax infection are flu-like (not those of the common cold as the RWDI report states on page 2) and can easily lead to misdiagnosis. After symptoms commence, death often occurs within two to three days from massive internal inflammation and hemorrhage (Dixon et al. 1999). Antibiotics can prevent infection in those exposed but once symptoms begin, saving the patient is difficult. An 80-90% fatality rate is associated with inhalational anthrax.

The Sverdlovsk outbreak strongly suggested that, in some cases, the spores can remain dormant even after being inhaled and infection can be delayed as long as six weeks. For this reason, during the 2001 postal attacks, those at high risk of exposure were advised to remain on antibiotics for as long as three months (Jernigan et al. 2002).

The current anthrax vaccine is presumed to be an adequate defense against inhalational anthrax, although, because the disease is so dangerous, the vaccine has never been tested on humans. A large dose of anthrax spores could overwhelm the protection afforded by a vaccine.

Although workplace contamination is not addressed in the RWDI report, the 2001 anthrax postal attacks and indoor simulations showed the ease with which anthrax spores disperse throughout buildings and cause health risks and also the extreme difficulty, time, and expense associated with building decontamination (WHO 2004: 98-108; DRES 2001). The recent report concerning anthrax contamination from Fort Detrick's BSL-3 laboratory also raises concern about leaks from high-containment laboratories (US Army 2004).

Environmental contamination is also not a part of the RWDI report, but any outdoor release brings with it the possibility of soil contamination. Sunshine can eventually degrade anthrax spores but they are otherwise impervious to extremes of heat or cold. They have been known to survive in arid soil for as long as 140 years and to cause repeated animal outbreaks for decades after soil contamination.

*The RWDI Report on a Potential Anthrax Release*

The central problems in the RWDI report concern:

1) the estimated number of spores that could be released
2) human dose response to anthrax
3) the dispersal of spores in the urban environment.

**The Estimated Number of Spores Released**

For each of its three scenarios, the RWDI report concludes that the maximum number of spores likely to be inhaled by an individual at ground level in the center of a plume is less than one. "Since the release and inhalation of a partial spore is not feasible, this number may be considered as zero." A serious mistake, though, appears to have been made in reckoning the number of spores released.

The US and Canadian military and other authoritative sources commonly calculate that there are around a trillion anthrax spores per gram (Meselson et al.1994, He and Tebo 1998, Meselson 2002, DRES 2001). In contrast, the RWDI report (p.3) relies on just ten billion spores per gram.

The RWDI report also relies on a reported NIH simulation calculating that 400,000 spores (per ten billion) or 4% would be "respirable", that is, in the 1-10 micron range. The 4% estimate might be reasonable; but for a gram of anthrax (a trillion spores) 4% would mean 40 billion spores in the respirable range would be released.

This increased amount would likely change the "zero" conclusion about the predictable number of spores inhaled to some whole number.

That said, the attempt to calculate risk in terms of a single individual positioned in the center of an anthrax plume fails to capture the way in which anthrax affects different individuals and also the collective nature of the impact of an anthrax release.

**Human Dose Response**

The RWDI emphasis on the lone exposed individual ignores the importance of human dose response as it depends on individual susceptibility. We like to average risk assessments, but we must remember that some people are more vulnerable to infectious diseases than other.

For example, in Sverdlovsk, we estimated that the number of inhaled spores per victim was nine and, based on the number of people exposed, around 5000, it was possible to estimate a 2% fatality rate (or, in military terms, attack rate) from the release.

Yet among the victims, older people were more susceptible to inhalational anthrax than younger people or children. No one under age 24 in Sverdlovsk contracted the disease, although many were exposed. Those who contracted inhalational anthrax during the 2001 postal attacks were also in their forties or older. It could be that older people and perhaps those afflicted with respiratory or lung diseases would have increased risks of infection from an anthrax release. For that reason, beyond even any accurate models RWDI might construct, census data and figures on health and disease are necessary to predict potential harm to the local population.

**The Dispersal of Anthrax Spores in the Urban Environment**

The RWDI emphasis on a lone exposed individual located at ground level oversimplifies the physical and temporal conditions that affect urban aerosol dispersal. An anthrax aerosol flowing through an urban environment would expose *all those in its path*. That path, if from a single source, would gradually expand, like a cone growing both larger and longer.

Depending on wind velocity and direction and on atmospheric conditions, an anthrax aerosol emission could expose people at a range of altitudes, not only at street level but on different floors in apartment, hospital, office or factory buildings. Even if windows are closed, anthrax spores could penetrate indoors. (Note that in the anthrax postal attacks, spores penetrated the paper of the envelopes in which they were mailed. Such ordinary paper has apertures up to 3 microns in size.)

Population density is, of course, crucial in calculating the risks of exposure. In Sverdlovsk, the neighborhood near the military facility was much less densely populated than more northerly area of the city, where fatalities would have been higher. Within the afflicted neighborhood, the most crowded workplace in the path of the plume, a large ceramics factory employing thousands, lost 19 employees to inhalational anthrax. Equally large industries on either side of the projected plume were unaffected by it.

Although it used models for different weather conditions, the RWDI report could have modeled a potential release in Boston (as opposed to some other metropolis) as a real-time dispersal with impact on communities rather than on a standard individual.

The understanding of the importance of distinct urban characteristics is well represented in US military research on anthrax aerosols. In 1953, the US Army chose three North American cities (Minneapolis, St. Louis, and Winnipeg) for their similarities in population density and climate to Soviet industrial cities targeted for biological attacks (US Army 1954). Since anthrax spores have a tendency to stick to surfaces on impact (like the sides of buildings, trees, or the ground), a city's distinctive topology affects how a plume would spread. Using anthrax simulants, its researchers conducted repeated year-round aerosol release experiments to gauge dispersal in different parts of these cities. Whether a city area was built up or open, had parks, high buildings, highways or

waterways made a difference, along with atmospheric conditions, in the plume's potential impact.

Boston is a northeastern port city with predictable prevailing winds and seasonal variations in temperature and daylight hours, which affect the direction and altitude of a potential anthrax plume. The area immediately around the proposed BUMC building has a distinctive topology for which models of aerosol dispersion could be made, in order to estimate the paths of potential anthrax plumes and their impacts on local populations.

*Contagious Disease Scenarios*

The WHO has recently published guidelines on responses to outbreaks of diseases caused by biological weapons agents (WHO 2004: 53-85). A main point of the WHO guidelines is that a community's existing "well-designed public health and emergency-response system" should be able to handle a medical emergency from any source. On-going community-level disease surveillance should be part of that capability, to identify unusual disease outbreaks as early as possible.

But how should gaps in the system be identified? The WHO strongly advises the use of scenarios involving different agents to pinpoint problems:

> The level of threat that exists is also a function of the potential vulnerability of the community concerned. Vulnerability analysis will identify potential scenarios as well as weaknesses in the system...and will determine the current ability to manage the emergency. (2004:58)

Regarding biological weapons, even when public health systems are effective, there are limits to medical interventions to protect against select agents. Although we want to believe in "magic bullet" defenses, none exist that would protect the public without risk. The possible short-term and long-term effects of the anthrax vaccine have been an on-going source of controversy in the US military (Sidel, Nass and Ensign, 1998; Guillemin 2000, 2003a; Institute of Medicine 2002). The 2003 smallpox vaccination campaign faltered quickly after five first responders over age fifty died from heart problems aggravated by the vaccine. Nor should individuals with skin diseases, compromised immune systems, or other medical vulnerabilities be vaccinated against smallpox. The biodefense initiative aims to invent better protections, but in the meanwhile an exposed public has to be vigilant about risks and hazards.

**Contagion Scenarios and Smallpox**

Worst-case scenarios involving highly contagious disease outbreaks from select agents, (such as those for smallpox, pneumonic plague, tularemia or one of the hemorrhagic fevers, such as Ebola virus) would necessarily reveal complexities that can be avoided in models of a single-point source anthrax emission. Unlike scenarios for inhalational anthrax, which is not transmitted human-to-human, a contagion scenario requires calculation of how a disease is introduced into and can proliferate in a community and

possibly beyond, and what public health measures are either in place to contain the epidemic or are insufficient or lacking.

In the simplest scenario, a single index case contacts and infects others who in turn pass on the disease. How many people an individual is likely to infect is called the contagion rate, which can vary by the virulence of the disease and the relative immunity or susceptibility of those exposed. If contagion began with an aerosol release, the number of vectors could be multiplied with catastrophic consequences. Modern travel has also accounted for the rapid spread of dangerous infectious diseases like AIDS, smallpox, and SARS.

Smallpox, highly communicable and, with anthrax, a disease of great national security concern, is the most likely candidate for a worst-case contagious disease scenario. Officially eradicated from the world in 1981, long after it was a serious threat in North America, smallpox causes fear because of reduced immunity in the general population. Those under twenty-five are unlikely to be vaccinated and older people who are vaccinated may have only residual immunity or none at all. Only two reserves of smallpox strains now exist, at two WHO reference laboratories, one at the Centers for Disease Control and Prevention (CDC) in Atlanta and the other at Vektor, the Russian research center in Novosibirsk. Intermittent research that exposes animals, including primates, to smallpox aerosols is currently conducted at the CDC. Concerns have been raised about security at the Vektor facility. In the run-up to the 2003 invasion of Iraq, rumors that Saddam Hussein might attack the US with smallpox were rampant and affected public opinion about a vaccination campaign (Blendon et al. 2002).

The World Health Organization summary of its eradication campaign includes descriptions of the laboratory accidents that caused outbreaks in the United Kingdom in 1966, 1973, and 1978 (WHO 1988:1095-1101). Following early misdiagnoses, all were contained by public health intervention. The earliest and latest epidemics were apparently caused by insufficient ventilation precautions between a Birmingham medical school laboratory and the floor above it. The 1973 outbreak was started at the London School of Hygiene and Tropical Medicine when a laboratory assistant, vaccinated as a child and again in 1972, nevertheless contracted smallpox after briefly visiting the poxvirus laboratory. Safety measures are more stringent today but, should smallpox return, its consequences could be not only national but international.

Experts concerned with bioterrorist attacks have differed with each other about a likely contagion rate, should a smallpox outbreak occur in the United States. Authors of the well-known table-top exercise "Dark Winter," relying on information from the 1972 smallpox outbreak in Yugoslavia, postulated a 1:12 rate of transmission (O'Toole, Mair, and Inglesby 2002). They also conjectured 3000 initial cases, an especially virulent smallpox strain, and a shortage of smallpox vaccine, which in the exercise led to an international pandemic in a matter of weeks.

Others have argued that a ratio of 1:2-3 is more in line with past epidemics (Meltzer et al. 2001; Ganl and Leach 2003). Historically, the mortality rate associated with smallpox

also varies, from 12% to 30% of those who contract it. Those most at risk for secondary infection and death would be small children and pregnant women, along with those with suppressed immune systems, malnourished, elderly, or sick with other diseases.

**Public Trust and Communication Failures**

Experts agree that the successful containment of a contagious disease from any source depends on the public's trust, cooperation and understanding of risks (Levy and Sidel 2003). Transparency is vital. To protect themselves, people need information about the nature of the disease threat, the kinds of protective interventions that are available, and how to access those interventions. Any disease outbreak model for Boston should reckon beforehand the main obstacles to trust and communication and therefore increase the vulnerability of communities.

Two such obstacles are predictable: 1) existing social barriers; and 2) secrecy surrounding biodefense research.

Social barriers to communication based on differences in education, ethnicity, race and language can hinder diagnoses and increase the dangers of any outbreak. Boston's population is both diverse and, in many instances, segregated. To what extent would this hinder communication in an unusual disease outbreak?

When a biological weapons agent is involved, services can break down along existing racial divides even when government agencies are technically prepared for an emergency. During the 2001 anthrax postal attacks in Washington, DC, the 97% African-American postal workers where two of the contaminated letters were processed were only belatedly warned of their risks and given antibiotics, while the government early on distributed antibiotics to other, mainly white employees.

State secrecy regarding dangerous epidemics has been a repeated source of danger to the public (Guillemin 2003b). We saw this most recently with China's reluctance to admit to the SARS epidemic. In 1972, Iraq kept silent about the smallpox epidemic in Baghdad that later spread to Yugoslavia and in the early 1990s India denied epidemics of plague affecting its cities.

The 1979 Sverdlovsk anthrax outbreak was an extreme instance of state secrecy; the Soviet military never admitted its responsibility for the aerosol release and the affected community remained ignorant of the source and nature of the disease. By the time antibiotics and treatment were available, nearly half the victims had died or were beyond help.

Defense research on weapons seeks innovative advantages in anticipation of what an enemy might acquire and strives to keep these innovations secret. We should expect that is no less true for biological weapons than for other weapons, even though offensive development is banned by international treaty. For example, in early 2001, the US secret development of a vaccine-resistant anthrax strain was leaked to the press (Miller,

Engelberg, and Broad 2001: 231). Critics pointed out that such weapons development is forbidden by the 1972 Biological Weapons Convention and, moreover, that it dangerously stimulates less powerful nations to emulate American flaunting of the treaty (Wright 2002: 15-16). The line between offensive and defensive research, though, has been historically difficult for military and intelligence agencies to draw.

Most microbiologists working in this country have not had their work classified or restricted as "sensitive." Open review and publication in medical research have led to altruistic advances for the general benefit of humanity. Yet there are pressures now on scientists funded to do secret biodefense research in the name of US national security, like physicists who work on nuclear weapons programs. In reaction, a recent National Research Council commission report urges scientists become vigilant about the risks of research on select agents and recommends against secrecy: "Given the increased investments in biodefense research in the United States, it is imperative that the United States conduct its legitimate defensive activities in an open and transparent manner." (NRC 2003:9)

The secrecy around biodefense research that could erode the altruistic goals of medical research could also pose a risk to local vulnerable communities if they are kept in the dark about potential disease threats.

*Recommendations*

Models for assessing the health risks of a BSL-4 laboratory to Boston and surrounding communities should be more complex and various and meet the WHO guideline for identifying community vulnerability and gaps in public health response systems.

Scenarios for anthrax and other aerosols should take into account the demography of communities that could be affected, as well as the particular atmospheric, weather, and topological characteristics of Boston and its suburbs.

Scenarios for contagion should involve two sources: a) outdoor aerosol release; and b) a BSL-4 employee or visitor to the building as an index case.

Around 40 select agents are commonly listed as dangerous to humans (WHO 2004: 230-231). Many more exist which affect animals and crops. Those in charge of modeling scenarios should consult with Boston University Medical Center and NIAID about the agents likely to be researched in the proposed BSL-4 laboratory.

For transparency on a local level, to protect the public in the Boston area, BUMC should immediately agree to an independent oversight committee to consult on risk assessment for the BSL-4 laboratory, including disease outbreak scenarios, and on future plans for biodefense research. The members of this committee should not be affiliated with Boston University or NIH. The committee should include knowledgeable scientists and Boston community residents most likely to be affected by the laboratory.

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# *Anthrax Slip-Ups Raise Fears About Planned Biolabs*

***If it happened at top Army lab, it may elsewhere, some fear***

By Dan Vergano and Steve Sternberg, USA Today

Bruce Ivins was troubled by the dust, dirt and clutter on his officemate's desk, and not just because it looked messy. He suspected the dust was laced with anthrax.

And he was in a position to know. Ivins, a biodefense expert, and his officemate were deeply involved in Operation Noble Eagle - the government's response to the Sept. 11, 2001, attacks that killed almost 3,000 Americans and the anthrax attacks that killed five more less than a month later.

It was December 2001. Ivins, an authority on anthrax, was one of the handful of researchers at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Md., who prepared spores of the deadly bacteria to test anthrax vaccines in animals. He knew enough to grow alarmed when his officemate complained, as she had frequently of late, about sloppy handling of samples coming into the lab that could be tainted with anthrax.

"I swabbed approximately 20 areas of (her) desk, including the telephone computer and desktop," Ivins later reported to Army investigators. Half of the samples, he found, "were suspicious for anthrax," betraying the clumpy brown appearance of anthrax colonies under a microscope.

Rather than reporting contamination to his superiors, Ivins said, he disinfected the desk. "I had no desire to cry wolf," he later told an Army investigator.

Months later, Army investigators would see Ivins' desk cleanup as the first sign of an alarming anthrax contamination at the nation's most renowned biodefense laboratory. A 361-page U.S. Army report on the events of that winter and the following spring, recently obtained through a Freedom of Information Act request, opens a rare window into the government's guarded biodefense establishment.

Today, the view from that window frightens critics of the government's plans to establish similar labs in urban centers throughout the country. They say it's too dangerous to bring deadly microbes into populated areas. In July, hundreds of Boston-area scientists and activists marched to oppose plans to construct a biodefense lab at Boston University. Supporters say such facilities are needed to fight bioterrorism.

But the new safety concerns echo fears expressed in late 2001 and early 2002 after anthrax spores, too small for the naked eye to see, escaped from a supposedly secure lab suite and into the scientists' offices. Within USAMRIID, 88 people were eventually tested for exposure to anthrax. The incident also raised fears that anthrax had leaked into nearby Frederick, Md.

Anthrax spores are infectious, and they're potentially deadly for years. When spores get into the skin, they cause pus-filled blisters that burst to form black scabs. Hence the name anthrax, from the Greek word for anthracite coal. Untreated skin infections are fatal about 25% of the time. Spores can be ingested in spoiled meat or inhaled in the air. Without prompt treatment, gastrointestinal and inhalation anthrax will kill you.

Researchers express relief that no one was hurt or killed in the episode, but Stephanie Loranger of the Federation of American Scientists asks, "Fort Detrick is one of the premier biodefense labs, and if they have problems, what does it mean for all the others?"

December 2001 was almost two months after the inhalation-anthrax death of tabloid photo editor Bob Stevens in Atlantis, Fla. Stevens' death was the first from five anthrax-laced letters that infected 22 people, hobbled the U.S. postal system and shut down the Hart Senate Office Building in Washington after Sen. Tom Daschle, D-S.D., received one of the letters. The person who sent the deadly envelopes has never been caught.

It was a frantic time at the biodefense lab. The criminal investigation, dubbed Amerithrax by the FBI, was in full swing and USAMRIID was the only national laboratory giving authorities round-the-clock biodefense analysis, spokeswoman Caree Vander-Linden says.

The six-member team that worked in the lab equipped to handle anthrax had swollen to a staff of 85. Most had to learn how to handle the bacteria "on the fly," says USAMRIID's commander Col. Erik Henchal, who headed the forensic effort. As many as 70 researchers slept in cars or on cots as they scrambled to keep up with a deluge of specimens flooding the lab.

Over roughly eight months, USAMRIID researchers ran tests on 30,000 suspect envelopes, packages and other items that arrived at the lab.

They also tested about 320,000 environmental samples from such places as the Hart Senate Office Building and Washington, D.C.'s Brentwood postal center, which lost two employees exposed to the lethal letters. (In addition to the Florida victim and the postal workers, an elderly woman from Oxford, Conn., and a Vietnamese immigrant from New York City were killed.)

"They were running just fantastic numbers of (anthrax) samples," says biodefense expert D.A. Henderson of the University of Pittsburgh. "I'm not sure what they have accomplished is appreciated."

In April 2002, four months after Ivin's initial suspicions, the contamination resurfaced. A microbiologist spotted the liquid slurry in which anthrax is grown leaking from flasks inside a secure lab suite. He reported the episode up the chain of command, which set off alarms throughout the lab. Ivins did more tests.

This time he found that three strains of anthrax had escaped the supposedly secure "Biosafety Level 3," or BL-3, laboratory, which is designed to enable scientists to safely work with deadly microbes. Two of the strains were used in biodefense work. One of them may have come from the envelope sent the previous October to Daschle's office.

Powdered anthrax from the Daschle envelope so readily surfed currents of air that it frightened USAMRIID experts who opened the envelope.

"The good news is nobody got the disease," says Alan Zelicoff, a biodefense expert who is now a consultant at ARES Corp., a risk analysis firm. "The bad news is that nobody got the disease because just about everybody near the BL-3 suite had been vaccinated."

It was during that period, as the anthrax investigation gained momentum, that Ivins' officemate "repeatedly expressed concern to (Ivins) that she may have been exposed to anthrax spores when handling powder," according to the Army's report.

The leak inside the BL-3 lab was found on April 8. Over the next two weeks, Ivins and other researchers tested lab surfaces to confirm the extent of the contamination. Eighteen lab workers were tested for anthrax exposure. Nasal swabs from one of them tested positive for anthrax. Army officials acknowledged the incident in an April 19 press release.

Anthrax was found in three places outside the containment lab. Colonies of two anthrax strains were found in the "clean change room" where male scientists disrobe before showering and donning sterile suits to enter the secure lab suite. The strains were Sterne, a benign form used in inoculations, and Vollum 1B, once Fort Detrick's signature bioweapons strain. Vollum 1B was grown from the blood of lab microbiologist William Boyle, who died after inhaling anthrax in a 1951 lab accident, hence the B in the name.

Further away from the lab suite, researchers found three strains of anthrax in the office called B-19 that Ivins and his colleague shared: Sterne, Vollum 1B and Ames. Ames is now the preferred strain for biodefense research and was the strain found in the Daschle letter.

Their tests also found more than 200 colonies of Ames strain on the lab's "passbox." The passbox is a 2-foot-square ultraviolet-bathed portal - a blue glow emanating around the edges of its door - used for safely passing potentially contaminated material into and out of the laboratory suite.

As the investigation continued, word was leaking out. On April 20, USAMRIID officials got irate calls from Frederick's mayor and a visit from local U.S. Rep. Roscoe Bartlett, R-Md., who told Army investigators that he thought the incident was being "blown out of proportion" and "gives the terrorists an advantage."

Bartlett also wanted his nearby horse farm tested for anthrax. One day later he showed up at the lab, bearing a soil sample from his farm, which turned out to be negative for anthrax. He now says the public was never at risk and the lessons learned from the episode have made USAMRIID's safety standards stronger.

Fear that spores had escaped into the community in USAMRIID's dirty laundry prompted officials to dispatch technicians to the base's laundry at the Jeanne Bussard Center, a rehabilitation center for the developmentally disabled in Frederick.

One laundry worker's doctor had already called the base to query about the

exposure risk. On April 20, the team collected 32 samples to test for possible anthrax contamination. Nothing was found.

The formal probe of how the contamination occurred began April 24, led by an Army investigator from Walter Reed Army Institute of Research. In 20 interviews over two weeks, investigators learned that some lab workers had been concerned about possible exposure for months, beginning with the botched handling of the Daschle letter that sent 16 people to the infirmary for preventive antibiotics.

By the time the investigation drew to a close, about 1,120 sites in the lab, the off-site laundry and the laundry's delivery vans had been tested. About 90 people had been evaluated for exposure, and many of them treated with preventive antibiotics. No one became ill and no other traces of anthrax were found.

Military investigators concluded that the Sterne and Vollum 1B colonies had probably persisted in Building 1425 for years, perhaps as far back as the U.S. offensive biowarfare program ended by President Richard Nixon in 1969. The Ames strain likely escaped the lab because workers didn't thoroughly decontaminate shipping containers with fresh bleach. USAMRIID's Henchal suspects that a researcher who handled a poorly decontaminated container may have spread the Ames spores outside of the containment area.

A question the report leaves unanswered is whether that Ames strain came from the Daschle letter, which would elevate the episode to a higher level of concern. "It is a little ambiguous," says C.J. Peters, of the University of Texas Medical Branch at Galveston, formerly one of USAMRIID's experts on deadly microbes. "If this is from the (Daschle) powder, it could be re-aerosolized and somebody could get hurt really bad. If it's from ordinary culture, it's not that dangerous."

Lt. Col. Jeffrey Adamovicz, who was then deputy chief of bacteriology at USAMRIID, says it's unlikely that the contamination stemmed from aerosolized spores, noting that spores would have been found in air filters throughout the building. They were not.

Henchal insists that the contaminating anthrax never posed an airborne threat to anyone. Despite acknowledging that the FBI has genetically typed the Ames strain found outside the containment lab, as well as the Daschle letter anthrax, Henchal declined to say whether the two were the same. "I'm not convinced I know the source of the contamination," he says.

No one was disciplined for the contamination. Ivins couldn't be reached for comment. USAMRIID declined to permit interviews with staff mentioned in the report. Henchal says lessons from the incident have been used in a revamped biosecurity program. "We're not going to take any shortcuts on safety," he says.

That such a slip-up occurred in the research center that pioneered safety procedures now used worldwide to deal with lethal microbes raises broader questions, experts say.

"The message here from a scientific and policy standpoint is profound," Zelicoff says. "Facilities that are medical and microbiological may not be suitably equipped for dealing with aerosolized versions of the organisms

that they otherwise deal with in great safety. . These facilities probably ought not be located in a heavily populated area. How do you contain smoke?"

About 50 maximum-containment labs nationwide harbor the deadliest of bacteria, viruses and toxins. Forty more biodefense research labs are planned in cities such as Atlanta and Boston. In addition to the furor over the plans in Boston, opponents have also taken aim at a lab to be built at the University of Texas Medical Branch in Galveston, citing concerns about excessive secrecy and biosafety.

Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, which is building its own facility at Fort Detrick, notes that accidents are rare and that planned labs are unlikely to be as deluged with the flood of samples that arrived at USAMRIID as part of the anthrax investigation.

"Most scientists do things in a very careful way," Fauci says. "The chance that they'll be working in the same rushed atmosphere they faced at Fort Detrick is very small."

Ultimately, the unsolved 2001 anthrax killings still shadow Fort Detrick. The Ames strain of anthrax used in the letters, and found in the contamination incident, was first used in biodefense studies there.

For that reason, the FBI briefly shut down parts of the lab this July to look for more clues, searching for stray spores that might match those used in the attack. In August, FBI investigators carted away more lab equipment for analysis, looking for clues that may reveal a link of some kind between the lab and the attacks that can be presented to a grand jury.

Army investigators concluded that years of sloppy practices at the lab resulted from neglect of safety procedures, compounded by the pressure of a high-profile criminal case. One researcher described a common room in the lab area as a "rats' nest." And experts say the "sloppiness" documented in the report may complicate prosecution if the anthrax killer is ever caught, especially if defense lawyers can cast doubt on USAMRIID'S reliability.

"Any defense lawyer should read this report carefully and keep it in mind when DNA results are being quoted against his (or) her client," says Martin Hugh-Jones of Louisiana State University, a leading expert on anthrax. "I now understand why the FBI (anthrax) letter team is so fascinated by USAMRIID."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
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Bethesda, MD 20892

January 9, 2003

James Miller, President
Friends of the Bitterroot
P.O. Box 442
Hamilton, MT 59840

FOI Case No. 27890

Dear Mr. Miller:

This is a final response to your August 13, 2002, addressed to the National Institute of Allergy and Infectious Diseases, and received in this office August 19, 2002. You had requested the following information:

1) The memo(s) or other documents selecting Rocky Mountain Laboratory site or the county in which the laboratory is located, Ravalli County, to be the site for the new Biolevel 4 laboratory.

2) The minutes of the meeting and list of participants in which appears the decision to place a Level 4 lab in the Rocky Mountain Laboratory or the county in with the laboratory is located, Ravalli County.

3) A copy of any memos, emails, or other notes in which the Director of National Institute of Health (NIH), Assistant to the Director, or staff or other persons acting on behalf of the Director directed or suggested the selection of the Level 4 lab site.

4) A copy of any analyses or records of discussion of the tradeoffs in the location of the level 4 laboratory.

5) For the previous seven (7) years, a copy of complaints, reports, emails, memos or other documentation received by your offices of actual or alleged incidences regarding the Rocky Mountain Laboratory of:

- Accidents involving hazardous material with the laboratory.
- Unauthorized access to hazardous material.
- Release of biological agents to the air, water, land, wildlife, fish, or humans outside the boundaries of the Rocky Mountain Laboratory, as well as unintentional releases within the site.

- Failure to follow safety, control or security procedures.
- The inadequacy of safety, control, or security procedures.

We located 68 pages responsive to your request, most of these responsive to your Question # 5. These are enclosed. Although it does not fit specifically under any of the questions you asked, included also is a copy of a memo, developed in December 2000 by the Director of NIAID's Division of Intramural Research, expressing the need for the construction of a BSL-4 building at the Rocky Mountain Laboratories location. For your further information, I have also enclosed a memo I received from NIAID staff describing the responsive documents; this memo is organized according to each item outlined in this request, as well as to your other request (#27891). I hope that this memo is helpful to you in putting these responsive documents in context. It is the policy of the Department of Health and Human Services to expunge confidential commercial or financial information, evaluative material, EIN numbers, personal information such as social security numbers, and individual salaries. Such information has been redacted accordingly. If you feel that this information should not be excluded from the material, please write to me and I will consult with the NIH Freedom of Information Officer.

Sincerely,

Paul A. Marshall
Freedom of Information Coordinator
National Institute of Allergy
and Infectious Diseases
6610 Rockledge Drive, Room 6053
MSC 6605
Bethesda, MD 20892
Phone: 301-451-5109

Enclosures

## I. PROJECT TITLE.

Construction and Operation of an Infectious Disease Biosafety Level-4 Building at NIH, NIAID, DIR, Hamilton, Montana Campus

## II. PROJECT DESCRIPTION

It is proposed that a new building be constructed on the NIAID Hamilton, Montana campus (Rocky Mountain Laboratories, RML) to meet the research and diagnostic challenges caused by emerging and reemerging diseases national and internationally. The facility will also contribute to challenges caused by the threat of bioterrorism and other illegitimate releases of microbial pathogens. The primary purpose of the new building will be to house a biosafety level-4 facility and associated conventional research and support space. The Infectious Disease Biosafety Level-4 Building should include state-of-the-art engineering to permit safe use and manipulation of biosafety level-4 pathogens. The facility will also contain laboratory space suitable for rapid identification and the study of the molecular mechanisms of transmission, pathogenesis, and prevention. The Infectious Disease Biosafety Level-4 Building should also contain under one roof a vivarium capable of housing arthropod vectors, and small and large research animals, including non-human primates.

All other laboratory space in the building should be capable of biosafety level-3 research. Each laboratory should be compartmentalized to permit maximum safety during use and to facilitate shut down, cleaning, sterilization, and other maintenance. Access to this restricted building should be limited to qualified personnel by retina scanners, thumbprint readers, or like devices.

It is proposed that the building include approximately 26,000 sq. ft. of research and support space, or about 60,000 gross sq. ft., and consist of 3 floors.

## III. PROJECT JUSTIFICATION.

Biosafety level-4 laboratory space in the United States is currently limited to three facilities located in Bethesda and Frederick, Maryland, and Atlanta, Georgia. One additional facility is planned for construction in Galveston, Texas. The Bethesda, Atlanta, and Galveston facilities are located in or nearby major metropolitan areas with very large human populations. There are currently no biosafety level-4 laboratories located in the western United States. Although growth of the NIH budget and new construction on the NIH Bethesda campus is occurring at an

unprecedented rate, there is national and international concern that the United States has a critical shortage of biosafety level-4 laboratory space, and personnel trained to work with biosafety level-4 pathogens. Concern about this shortage has been magnified by a clear and present danger posed by the daily threat of human and agricultural bioterrorism and other illegitimate releases of microbial pathogens, accidental importation of level-4 pathogens, and emergence and reemergence of organisms capable of rapid pandemic spread or untreatable with available antimicrobial agents.

The overall national shortage of biosafety level-4 laboratory space, and its total lack in reasonable proximity to major population centers in the Western United States can detrimentally effect public health. Moreover, efforts to discover treatments and novel containment strategies for the world's most dangerous microbes, several capable of rapid and widespread human depopulation, are now significantly limited by lack of adequate numbers of trained personnel and laboratory infrastructure.

There are many advantages and few disadvantages to construction of biosafety level-4 laboratory space and related support facilities at the RML campus in Hamilton, Montana. First, although the RML campus comprises 33 acres, well over one-half of the space is not yet built on. Hence, unlike the Bethesda campus, adequate and readily-identifiable space exists for significant expansion. Second, there are personnel already at the facility with extensive biosafety level-3 expertise, which means that in principal these individuals represent a pool of talent who could be upgraded to biosafety level-4 capability with reasonable ease. Third, the RML campus is located in rural western Montana, well removed from major population centers. The location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster. Fourth, RML enjoys a longstanding collegial and harmonious relationship with Hamilton and the surrounding population living in the Bitterroot Valley. It is therefore anticipated that following appropriate public discourse, the community would be receptive to its construction and supportive of its daily use. Fifth, RML is located far closer to west-coast cities such as Seattle, San Francisco, and Los Angeles than existing biosafety level-4 facilities in the eastern United States. In the event of a proven or presumed biosafety level-4 pathogen event, this proximity avoids undue delays that could define the difference between successful rapid containment and identification, and pandemic and consequent public health disaster. Sixth, a biosafety level-4 facility and investigative capability would complement ongoing RML research and available expertise on biosafety level-3 agents, arthropod vector biology, large-scale microbial genomics, human and pathogen DNA microarray strategies, and emergent and reemergent pathogens. Seventh, research on biosafety level-4 pathogens is far more expensive, on average, than laboratory work with other infectious agents. This means that given appropriate support, it is possible that research and discovery on biosafety level-4 pathogens could proceed at an accelerated pace relative to the extramural research environment.

The NIAID has one of the largest intramural programs at the NIH and infectious disease research is at the heart of its mission. World-class programs are in place in many areas of contemporary host-pathogen research. However, research on biosafety level-4 pathogens is notably absent from the NIAID intramural research portfolio. Construction of the proposed facility at RML would be an important first step toward filling this void and enhancing the currently inadequate national infrastructure in the critical area of biosafety level-4 pathogen investigation. Construction of the facility at RML would also provide geographically strategic placement of biosafety level-4 capability in the western United States.

# SECTION 1

# INFORMATION APPLICABLE TO APPLICANTS/OFFERORS APPLYING TO BOTH RBLs and NBLs

# BACKGROUND

The Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Center for Research Resources (NCRR) and the National Institute of Allergy and Infectious Diseases (NIAID) are collaborating on the subject Broad Agency Announcement. The NCRR and NIAID encourages the submission of grant applications and contract proposals for the establishment of Biocontainment Laboratories in order to further the research capabilities of the Division of Microbiology and Infectious Diseases (DMID), NIAID, to conduct research on pathogens that are considered to be of significant research importance for biodefense.

In order to focus attention on those agents that pose the greatest risks to civilian populations in the event of a bioterrorist attack, the NIAID compiled a list of Category A, B, and C priority pathogens (http://www.niaid.nih.gov/dmid/bioterrorism/bandc_priority.htm). In February 2002, NIAID developed a strategic plan for biodefense research in consultation with a Blue Ribbon Panel to accomplish short- and long-term goals aimed at protection of the United States and the world population against attacks by these agents. The NIAID strategic plan emphasizes both basic research and the application of that basic research to the development of products such as diagnostics, therapeutics, and vaccines.

The NIAID Blue Ribbon Panel further identified a critical need to expand the availability of research resources to support implementation of the Biodefense Research Agenda of NIAID (http://www.niaid.nih.gov/dmid/bioterrorism/). Since one of the major challenges in meeting the goals of the Agenda is the serious shortage of high-level biocontainment laboratories, NIAID has established a comprehensive approach that includes both grants and contract awards to help provide the facilities needed. Important components of NIAID's Biodefense plans are a network consisting of: 1) Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs); 2) Regional Biocontainment Laboratories (RBLs); and 3) National Biocontainment Laboratories (NBLs).

The overall goal of the RCE Program, which is currently being solicited via a grant mechanism (RFA-AI-02-031 is located at http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-02-031.html), is to develop and maintain strong infrastructure and multi-faceted research and development activities that will provide the scientific information and translational research capacity to make the next generation of therapeutics, vaccines and diagnostics against the NIAID Category A, B, and C Agents, with particular emphasis on Category A.

NIAID and NCRR are currently soliciting by this BAA proposals/applications for the construction of Regional and National Biocontainment Laboratories. The RBL Program (Part A of this BAA), which will be funded through a grant mechanism, will provide support for building and/or renovating Biosafety Level 3 (BSL-3) facilities and the necessary associated BSL-2 laboratories, animal facilities, and research support space. The NBL Program (Part B of this BAA), which we anticipate will be funded through a contract mechanism, will provide support for constructing state-of-the-art, comprehensive facilities, including Biosafety Level 3 and 4 containment (BSL-3/4) capabilities plus other required facilities. NBL and RBL operations and management activities are not a subject of this BAA. Awards under this program are contingent on availability of appropriated funds and NIAID appropriations authority provided at the discretion of Congress.

## PURPOSE OF THIS BAA

With this BROAD AGENCY ANNOUNCEMENT (BAA), NIAID and NCRR invite offerors/applicants to submit proposals/applications for the planning, design, and construction (including large-scale alteration, modernization and renovation activities) of high-level biocontainment research facilities. The facilities must be used for biomedical research and research training, with the specific goal of supporting the NIAID Biodefense Research Agenda.

This BAA consists of the following two parts:

### Part A -- Regional Biocontainment Laboratories (RBLs)

The overall objective of the RBL construction program is to provide funding to design, construct, renovate, commission, and install and certify fixed equipment into state-of-the-art BSL-3 biocontainment laboratories and the necessary associated BSL-2 labs, animal facilities, and research support space. RBLs must preferentially support the research activities of NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE), as well as other NIAID funded biodefense and emerging infectious diseases research. RBLs will be part of the NIAID RCE Biodefense Network and will serve as a regional resource for research institutions in the area. In addition, RBLs must be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.

### Part B -- National Biocontainment Laboratories (NBLs)

The overall objective of the NBL construction program is to provide funding to design, construct, renovate (if needed) and commission and install and certify fixed equipment into comprehensive, state-of-the-art BSL-4 biocontainment laboratories and the necessary associated BSL-3 labs, BSL-2 labs, animal facilities, insectary facilities, clinical facilities and research support space. NBLs will serve as a national resource for efforts in conducting clinical and laboratory (*in vitro* and *in vivo*) research and testing on hazardous biological agents in support of the NIAID's Biodefense Agenda. NBLs must preferentially support the research activities of NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE), as well as other NIAID funded biodefense research. NBLs will be part of the NIAID RCE Biodefense Network and will serve as a national resource. In addition, NBLs must be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.

Offerors/applicants may submit Proposals for Part A and/or Part B. Part A and B offerors/applicants must be associated with or linked to existing or planned Regional Centers of Excellence (RCE) in order to be eligible for an award.

Part A and Part B have both common and specific objectives (see below). If an offeror/applicant plans to respond to both Parts A and B, then a separate proposal/application should be submitted for each part to allow for separate reviews.

The NIAID plans to fund 1-2 NBLs and commit approximately $100 million of FY03 funds and approximately $175 million of FY04 funds. The NIAID plans to commit approximately $50 million to fund approximately 4-6 RBLs in FY03 and an additional approximately $50 million for approximately 4-6 more RBLs in FY04. The nature and scope of the activities proposed in response to this BAA may vary; it is anticipated that the size of awards will vary.

The length of time for which funding is requested should be consistent with the nature and complexity of the proposed construction project. The maximum period acceptable is five (5) years. No facilities and administrative (F&A) costs will be awarded for grants. Awards are expected to be made between the months of September and November, 2003. All funds must be obligated within 5 years from the date of award. Funds may not be used for the acquisition of land, for building "shell space" or for off-site improvements.

Facility construction that may be supported under this program includes construction of new facilities, additions to existing buildings, completion of previously-built uninhabitable "shell" space in new or existing buildings, and major alterations and renovations. The acquisition and installation of fixed equipment such as casework, fume hoods, large autoclaves, or biological safety systems is allowed. Large equipment essential for basic functions of the building may also be requested.

Since this award is not renewable, it is assumed that recipients of RBL awards will have or acquire other support for research conducted in the RBL facilities and for on-going management and operations expenses. Users of the facilities may be charged appropriate fees. Recipients of NBL awards may compete for anticipated operations contracts to support on-going costs. Awards pursuant to this BAA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

The NIAID anticipates making award decisions based on technical merit of proposals, available funding and programmatic balance and priorities. In addition, other considerations for award include: the needs of the institution, with special consideration given to institutions or consortia designated as RCEs; the commitment of matching funds by the institution; program objectives; achieving desired scope of facilities at a national level; availability of facilities to conduct the desired scope of biodefense research at the national level; national geographic distribution; and the expectation that facilities will be finished and available for use as rapidly as possible.

# BAA-NIH-NIAID-NCRR-DMID-03-36
# Amendment #1 (Questions & Answers)
# "FINAL POSTING"

This Amendment provides questions submitted by potential applicants/offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated at least weekly to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #1 for additional Q&A.

All offerors are advised to revisit the original solicitation package as it incorporates some minor edits effective November 5, 2002. http://www.niaid.nih.gov/contract/archive/RFP0336-0.pdf

## "Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL)"

| | |
|---|---|
| **Amendment to Solicitation No.:** | BAA-NIH-NIAID-NCRR-DMID-03-36 |
| **Amendment No.:** | 1 (FINAL Posting) |
| **Issue Date:** | November 5, 2002 (Questions 1 – 21)<br>November 7, 2002 (Questions 22 – 27)<br>November 25, 2002 (Questions 29-42 and Revised Question 27)<br>December 4, 2002 (Questions 43-46)<br>December 16, 2002 (Questions 52-61)<br>December 31, 2002 (Questions 62-63)<br>February 4, 2003 (Questions 64-70) |
| **Proposal Due Date/Time:** | February 10, 2003, at 4:00 P.M., EST |
| **Issued By:** | Kristen Mistichelli<br>Contracting Officer<br>CMB/DEA/NIAID/NIH/DHHS<br>6700-B Rockledge Drive, Room 2230,<br>Bethesda, Maryland 20892-7612 |
| **Points of Contact:** | km359d@nih.gov<br>Kristen Mistichelli, Contracting Officer<br><br>**Please also cc:**<br>bs92y@nih.gov<br>Barbara Shadrick, Sr. Contracting Officer |

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**Applicants/Offerors must acknowledge receipt of this Amendment #1, for each posting, on each copy of the application/proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your application/proposal.**

**The hour and date specified for receipt of applications/proposals HAS NOT been extended.**

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The following answers are provided concerning a number of inquiries we have received for the above numbered acquisition:

**Question 1** It is my understanding from reading the RFP that the parties that are awarded the contracts will own 100% of the building; however, NIH would control 100% of the activity in the building for 20 years. If a contractor contributes 25% of the cost of the building should the contractor be able to control 25% of the work done in that building?

*No. See page 7, item 6 of the BAA. Additionally, the priorities for usage of the facilities are described on page 5, first paragraph of Parts A and B.*

**Question 2** Will the contractor be allowed to charge a profit on the construction of the building?

*No. This solicitation has been issued to eligible non-profit organizations. Please note that any subcontract issued to for-profit construction companies can contain a reasonable fee/profit on the subcontract.*

**Question 3** Can the contractor stipulate in the proposal that it is contingent upon being awarded the operating contract?

We have significant concerns about building a facility and then having another contractor be awarded the contract to operate a facility on our campus. If we are responsible for security, safety and the overall operations then another company operating a facility we own is an issue.

The BAA is silent regarding an operations contract for the NBL except for pg 6 where it states that the awardee may "compete" for an operations contract. Previous information from NIAID had indicated the intent to award an operations contract simultaneously with the construction contract. Is this still the intent? If not, is it contemplated that the operations contract might be awarded to an institution that did not build the facility? When will the solicitation be released?

*NBL awardees will be eligible to submit a separate proposal for support activities related to the operation and maintenance of the NBL.*

**Question 4** Can the government provide any assurance as to the level of contracts/grants placed in the RBL/NBL over the next 20 years?

*No.*

**Question 5** If the contractor elects to propose on a RBL (grant based) instead of the NBL (contract based) how will it get a return on its investment through the grants?

*See Question #2, above.*

**Question 6** Will the arrangement be that the contractor leases the building to NIH?

*No.*

**Question 7** Will the contractor be able to depreciate the building and include that in their indirect rates?

*The contractor should follow good accounting practices in accordance with that organization's approved accounting procedures and applicable laws and regulations.*

**Question 13** How does this solicitation change previously issued information in the Notice of Intent and at the August 8th meeting? I am specifically interested in the number of NBL awards (previously announced 5-7) and the budget (up to $100 million in construction). Is there any guidance regarding the number of RBLs vs NBLs?

*The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. The BAA indicates "One (1) or two (2)" potential NBL awards, and four (4) to six (6) RBLs in FY '03 and four (4) to six (6) RBLs in Fy'04. See page 5, paragraph 6, of the BAA anticipated funds available.*

**Question 14** The BAA refers to a cost share of 25% for the awardee (pg 7, para. 2). Does this provision apply to the construction cost of the NBL? The operation of the NBL?

*Yes, for construction costs. The details of the separate operations and management contract have not been determined and are not within the scope of this BAA.*

**Question 15** Should there be escalation of construction costs, justified claims, force majeure, etc., during the construction phase; what is NIAID's commitment to cover these costs that are above the original project estimate?

*It is anticipated that the prime contractor will negotiate a construction contract that is legally sound and that limits the liability of the purchaser. Please review the FAR Clauses contained in the solicitation for General Clauses that are required to be in subcontracts issued under the prime. These FAR clauses include provisions for Claims and Acts of God or nature. NIAID will commit to a maximum amount authorized for construction subcontracts. Therefore, a "Guaranteed Maximum Price" may be negotiated between the prime and subcontractors. Changes to the maximum amount authorized for a subcontract must be negotiated in advance. The following clauses will more than likely be included in any resultant contract:*

*FAR 52.236-1 Performance of Work by the Contractor*
*FAR 52.236-2 Differing Site Conditions*
*FAR 52.236-4 Physical Data*
*FAR 52.236-5 Material and Workmanship*
*FAR 52.236-7 Permits and Responsibilities*
*FAR 52.236-8 Other Contracts*
*FAR 52.236-10 Operation and Storage Areas*
*FAR 52.236-11 Use and Possession Prior to Completion*
*FAR 52.236-12 Cleaning Up*
*FAR 52.236-13 Accident Prevention*
*FAR 52.236-15 Schedules for Construction Contacts*
*FAR 52.236-18 Work Oversight in Cost-Reimbursement Construction Contracts*
*FAR 52.236-21 Specifications and Drawings for Construction*
*FAR 52.236-27 Site Visit*
**FAR 52.246-12 Inspection of Construction**

**Question 16** The BAA states that "The facility must be utilized for biomedical research projects as determined by NIAID program needs" (pg. 7, para. 6). Our Institution has biodefense contracts from several Federal agencies. Can this work or similar work be performed in the NBL? Or only work funded/approved by NIAID? What specific restrictions on the use of the facility are contemplated?

*The facility must give priority to Regional Centers of Excellent for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities. See page 5, paragraphs 2 and 3 of the BAA.*

c. *Architectural and engineering services.*
d. *Bid advertising.*
e. *Bid guarantees, performance and payment bonds.*
f. *Contingency fund.*
g. *Filing fees for recording the Notice of Federal Interest.*
h. *Inspection fees.*
i. *Insurance.*
j. *Legal fees related to obtaining a legal opinion regarding title to site.*
k. *Preaward costs: Project management.*
l. *Relocation expenses.*
m. *Sidewalks necessary for use of the facility.*
n. *Site survey and soil investigation.*
o. *Site clearance (as long as reflected in bid).*

*Unallowable costs:*

a. *Bonus payments to contractors, including guaranteed maximum price contracts.*
b. *Construction of shell space designed for completion at a future date.*
c. *Consultant fees not related to actual construction.*
d. *Damage judgment suits.*
e. *Equipment purchased through a conditional sales contract.*
f. *Fund-raising expenses.*
g. *Land acquisition*
h. *Legal services not related to site acquisition.*
i. *Movable equipment.*
j. *Off-site improvements.*

*See OER, NIH Grants Policy Statement, Part III, Construction Grants (http://grants1.nih.gov/grants/policy/nihgps/part_iii_1.htm) for details.*

Question 27 On-Site/Off-Site (Revised Response: 11/25/02)

1) Can the grant be for 20 years of lease costs instead of building costs?

2) Can the "Building" be virtual, such that animal facilities for the building could be at one institution, and two other institutions could each put in for BSL-3 space to fit each sites needs?

3) Would a university owned and operated facility on land obtained by long term lease (longer than the 20 year life of the facility) from the U.S. Army be eligible for an NBL or would it be non-responsive as it is off-site?

*The grant/contract covers construction but not the cost of a lease.*

*The facility may be built on land that is leased by the applicant institution. Applicants must include an opinion from acceptable title council describing the interest the applicant organization has in the site and the building and certifying that the estate or interest is legal and valid. If there is a lease, the legal opinion must provide evidence of the existence of a lease agreement which covers a time period sufficient for the usage requirement (20 years beyond completion or occupancy of the project) and that a Federal interest in the building will be recorded for the period of the usage requirement.*

*The facility may be built on property that is owned by the applicant institution but may be situated at a location other than the main campus. However, it is not possible to apply for one award for construction at multiple sites owned by either the same organization or multiple institutions. Each institution would have to apply for a separate award that would define each individual "construction project".*

BAA-NIH-NIAID-NCRR-DMID-03-36
Klempner, Mark S.

Boston University
School of Medicine

715 Albany Street
Boston, Massachusetts
02118-2526

January 28, 2003

Barbara Shadrick
Senior Contracting Officer
Contract Management Branch, DEA
NIH: National Institute of Allergy and Infectious Diseases
6700B Rockledge Drive, Room 2106
Bethesda, MD 20892-7612

Re: BAA-NIH-NIAID-NCRR-DMID-03-36
National Center for Emerging Infectious Diseases and Biodefense
Certification that facility will be used for the purpose for which it was constructed.

Dear Ms. Shadrick,

We are writing to assure the NIH that should we receive funding to build a National Center for Emerging Infectious Diseases and Biodefense, the facility would be devoted exclusively to biodefense research and other NIAID-defined research programs for 20 years, beginning 90 days after completion of construction.

We understand that NIH staff will periodically review the type of research being carried out in the building to ensure compliance with this requirement.

Sincerely,

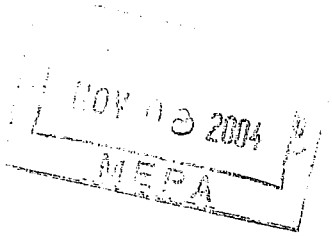
Aram V. Chobanian, M.D.
Provost, Medical Campus
Dean, BU School of Medicine

Elaine S. Ullian, M.P.H.
President and CEO
Boston Medical Center

BG

November 5, 1004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office, attn: EOEA #12021
100 Cambridge St. Suite 900
Boston, MA 02114




Dear Secretary Ellen Roy Herzfelder:

I am writing to oppose the BU bio lab 4 Project.

It is now scheduled to be built in a most populated area of Boston. This is openly racist and very dangerous. It is to be in an area populated by majority people of color.

It is dangerous because in an age of terrorism this lab is to be in a place that can easily be bombed from the highway. I have heard doctors testifying to working in labs and they claim they are safe. Much evidence points to the contrary. Furthermore, they were working in these labs before 9/11.

There is also ample evidence, Defense Department , funding etc. that these labs are developing biological weapons along with so called cures.

As co-chair of Boston Women's International League for Peace and Freedom I strenuously object to BU's plans for this bio 4 laboratory.

Sincerely, Joan Levin Ecklein

Joan Ecklein, Co-Chair of WILPF
Sociology Professor, (retired) University of Mass./Boston

BG


# CITY OF NEWTON, MASSACHUSETTS

Department of Planning and Development
Michael J. Kruse, Director

David B. Cohen
Mayor

Telephone
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E-mail
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November 5, 2004

Secretary Ellen Roy Herzfelder
EOEA, **Attn: MEPA Office**
Commonwealth of Massachusetts
100 Cambridge Street, Suite 900
Boston, MA 02114

Director Mark Maloney
Boston Redevelopment Authority
One City Hall Square, 9th Floor
Boston, MA 02201

**Re: BioSquare Phase II, EOEA No. 12021**

Dear Secretary Herzfelder and Director Maloney:

This letter responds to your requests for comments regarding University Associates Limited Partnership's proposal for "BioSquare Phase II," and the proponent's proposal to locate and operate a Biosafety Level 4 Laboratory (BSL-4) in Boston's South End. Such laboratories raise unique safety, health, and environmental issues for the entire metropolitan region.

The City of Newton has the following concerns:

- **The proponent should revise the FPIR/FEIR to further elaborate on the amounts of agents, including Anthrax, Plague, Ebola, and Smallpox, to be stored on-site and limits should be set and monitored.** This would be the first BSL-4 lab to be built in a densely populated urban area. Although high level safety and security procedures are proposed to be installed in the facility, accidents of an unknown magnitude are possible. Releases could occur through many means and consequences could be deadly. The lab could be a potential target for terrorists, and transportation of pathogens and/or waste to and from the site pose a risk for the entire metropolitan region.
- **The proponent should revise the FPIR/FEIR to further analyze the potential benefits and impacts of the proposed lab, how this lab will be monitored, and if there is room for community oversight of research conducted in the lab.** The lab may not be operated in an open and transparent manner with a public health agenda. For twenty (20) years the federal government can mandate the research to be conducted in the lab and require classified research, thus preventing any state or local oversight. There should be clearly stated public benefits that outweigh the potential negative impacts to this project, and potential secrecy and lack of oversight may prevent this from occurring. On-going communications with neighboring communities about risk factors

and appropriate response measures is critically important in case of accidental or intentional release. Additionally, we would expect that permanent limits be placed on the level of risk in this facility.

- **Further discussion of the regional impact of a release and "worst-case scenarios" should be included in the FPIR/FEIR.** The safety of the region should not be compromised to construct a BSL-4 laboratory. Policies and procedures on a regional level to respond to a potential release of a deadly agent have not been addressed in the FPIR/FEIR. The proponent should be expected to present further analysis regarding the potential release of any hazardous agent in a "worse-case" scenario. Water contamination, hijacking of transportation or waste disposal vehicles, animal carcass disposition, or losses of the laboratory's containment systems also represent potential scenarios that should be further analyzed, as they represent a concern to the City of Newton. The FPIR/FEIR should be revised to describe evacuation strategies and the chain of command on a regional level, and to explain how regional roads, hospitals, and airports would be affected in the event of an emergency.
- **Emergency evacuation of the building should be discussed in the FPIR/FEIR.** In the event of an emergency, there may not be adequate time for the evacuation and/or proper decontamination of employees. The FPIR/FEIR should be revised to analyze how an emergency evacuation could take place expediently to ensure employee safety, and how such an evacuation would affect surrounding communities.

In light of these concerns, the City of Newton respectfully recommends that the Executive Office of Environmental Affairs and the Boston Redevelopment Authority require the proponent to prepare a revised final FPIR/FEIR with additional analyses that are responsive to the issues articulated above.

Finally, should this project be approved we urge the creation of an independent community oversight group to monitor all aspects of construction and ongoing facilities management to include Fire and Public Health officials from neighboring communities. Thank you for your consideration.

Sincerely,

Michael Kruse, Director

Cc: Mayor David B. Cohen
R. Lisle Baker, President, Board of Aldermen
David Naparstek, Newton Commissioner of Public Health
Joseph LaCroix, Newton Fire Chief
Joseph A. Russo, Boston Redevelopment Authority
William Gage, Massachusetts Environmental Policy Act Office
Susan St. Pierre, Fort Point Associates, Inc.

BG

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston, MA 02114

November 7, 2004



Mr. John O'Brien
Mr. Jay Russo
Boston Redevelopment Authority
One City Hall Plaza, 9th Floor
Boston, MA 02201

Re: Comments on the Final Project Impact Report and Planned Development Area Review for BioSquare Phase II

Dear Ms. Herzfelder and Messieurs O'Brien and Russo,

We are two longtime South End residents, one of whom is a native Bostonian, who live in the Worcester Square Area Neighborhood, the neighborhood immediately abutting the proposed Bio Safety Lab Level 4 (BSL4). One of us, Ms. Stoner, owns and occupies one of two houses that will be the closest residences (approximarly 300 feet ) to the BSL4. We are writing in opposition to the location of the BSL4 in our neighborhood and indeed in any densely populated neighborhood.

We will attempt to address our concerns within the context of the Final Project Impact Report (FPIR), dated July 30, 2004. It should be noted, however, that we feel severely hampered in evaluating the FPIR because of the unfair process of the developers. For months, we and others have asked the developers to hold a public debate and forum with knowledgeable and credible scientists, both in support and in opposition to the project. This has not happened, with the absurd response being how difficult it would be to set this up. In addition the Worcester Square Area Neighborhood Association (WSANA), of which we are members, asked in July for, among other things, funds to hire an independent consultant to help us evaluate the FPIR and the entire project. It is only recently that there has been any meaningful response to our request from the developers, not timely enough to hire a consultant before this response was due. So, we will do our best to respond without the tools we feel we need to properly evaluate the FPIR.

Since there are no guarantees that accidents could not occur at this facility, we are deeply concerned about the way in which the consequences have been explained in the documents. Not having access to independent consultants, we are unable to assess the accuracy of their scenarios or whether in fact they are the proper ones to use. As a result of this we do not feel any comfort in their use of the word negligible in

describing the risks associated with any mishap that might occur at the facility or any potential release of infectious agents. We also question why the worst case risk scenario only refers to the release of anthrax spores. There must be other risk scenarios with other pathogens that have not been studied. The proponents should be required to do this.

There is insufficient discussion in the documents of the use of human volunteers. Where will these volunteers come from? We are in a neighborhood of homeless people and people who come to the neighborhood for drug and methadone treatment. In addition, the Suffolk County House of Corrections is nearby. The developers should be required to set out where they will get their human volunteers from, and how they will ensure an informed consent from the volunteers and that ethical guidelines will be implemented for dealing with them. Finally, what is the risk to the community that these volunteers will cause?The developers should be required to clearly set this out. We are ever mindful of the Tuskegee syphyllis study and the unethical way in which it was conducted.

In addition, the document is not always truthful, causing one to not trust their assertions. For example, in Section 5.7.2 on page 5-24, the proponents state in the last paragraph that in February of 2004 there was an Ebola Virus needle stick, that the staff member was isolated, and there was no risk to the community. What they have conveniently left out is that the staff member went home that day and only reported the needle stick the next day. I assume she went home to the "community." Similarly, in Appendix 10 in the list of abutters they do not list any of the abutting residential streets, East Brookline and East Concord, or its residents, one of which is Ms. Stoner. Also, in the list of Community meetings, one meeting with the Project Advisory Committee never took place. How many other inaccuracies are there concerning these meetings? Finally, the document omits any reference to the Cooperation Agreement for BioSquare construction projects.

At the recent public BRA meeting, the issue was raised about a City of Boston ordinance that prohibits the use of recombinant DNA research in the City of Boston. Although the proponents admit in Section 15.3 of Appendix 1-30 that they will be conducting recombinant DNA research within the facility, it does not state how this comports with the City of Boston ordinance.

In case of an accident at the facility, how will the community be notified and in fact will we be notified? Will we be quarantined? Will we be given treatment and what is the priority of treatment for the hospital and the community? The FPIR sets out none of this. Again, we are mindful of the recent flu vaccine shortage where our esteemed congress people made sure that they (and probably their families) received the vaccine. Although in Section 5-5 the proponents talk about a disaster plan, we have lived in this community for over 20 years and never have we been informed of any disaster drill or plan. When will we find out? When the disaster happens? The proponents should be required to lay this out and have practice drills.

We feel that because of a lack of a good faith process and a lack of a process with integrity, we have been intentionally put in an untenable and vulnerable position that compromises our ability to respond adequately to the FPIR.

Thank you,

Helaine Simmonds

Helaine Simmonds
49 East Springfield St.
Boston, MA 02118

Cinda Stoner

Cinda Stoner
107 East Brookline St.
Boston, MA 02118

BC


# Metropolitan Area Planning Council

60 Temple Place, Boston, Massachusetts 02111 617-451-2770 fax 617-482-7185 www.mapc.org

*Serving 101 cities and towns in metropolitan Boston*


November 8, 2004

Ellen Roy Herzfelder, Secretary
Executive Office of Environmental Affairs
Attention: MEPA Office
William Gage, MEPA # 12021
100 Cambridge Street, Suite 900
Boston, MA 02114



RE: BioSquare Phase II, Final EIR, EOEA # 12021

Dear Secretary Herzfelder:

The Metropolitan Area Planning Council regularly reviews proposals deemed to have regional impacts. MAPC reviews these projects for consistency with MetroPlan, the regional policy plan for the Boston metropolitan area, MAPC's Smart Growth Principles, and the Commonwealth's Sustainable Development Principles, as well as for their impacts upon the environment. MAPC has reviewed the project's Final Environmental Impact Report (FEIR) and the Comments of Clarification on the FPIR/EIR.

The project is the second phase of the BioSquare Research Park and will be located on a 9.3 acre parcel on Albany Street in the South End/Roxbury section of Boston. The project includes:

- A 7-story, 194,000 square foot Level IV National Biocontainment Laboratory;
- An 8 to 11-story, 234,700 square foot medical research facility; and,
- An 8-level parking garage providing 1,400 parking spaces.

MAPC acknowledges the critical nature of this project in establishing a state of the art research facility that will be help establish Boston and the region as a key center for the emerging biotechnology sector. However, based on our review, we must conclude that the intent of MEPA has not been met by the FEIR, and that additional information and mitigation is necessary before a MEPA Certificate can be issued on this project. This letter elaborates on these concerns.

**1. MAPC is concerned that the MEPA review process for this project has failed to serve the public interest and intent of MEPA.** Section 11.01 of the MEPA regulations states that "The purpose of MEPA and 301 CMR 11.00 is to provide meaningful opportunities for public review of the potential environmental impacts of Projects for which Agency Action is required..." MAPC's concerns are related in part to the fact that the project has substantially changed since the proponent filed the ENF five years ago. Changes since the ENF include:

- The addition of the Level IV National Biocontainment Laboratory;
- The design and use of buildings F through K has been changed;
- The traffic, water, air, wind, shadow and visual impacts of each building and the entire project have changed;
- The proposed bike path, which, according to the ENF, would have continued the "Bike to the Sea" trail from the South End in Boston to the Fort Point Channel, has been eliminated; and,
- The ENF offered 166,050 square feet of open space and this may also have changed. It is unclear if this amount has been reduced and how much of this open space will be enclosed behind a non-scaleable 8-foot high perimeter fence.

To further complicate the situation, the proponent was not required to issue a notice of project change and the DEIR included a vague description of project changes (see Section 2.4 of the DEIR). For example, the list of changes does not state that a Level IV national laboratory was added. It states that "To accommodate the safety and security requirements of the NBL facility, (Building F), additional land area was required to establish a 150-foot buffer." The summary does not explain what "NBL" stands for, does not specify that it is a Level IV facility, and the wording implies that the buffer was added – rather than facility itself. These are not mere technical oversights. Rather, the addition of the NBL facility entirely changes the character of the development and calls for significantly new review as well as new strategies for mitigation.

There were additional changes from the DEIR to the FEIR. These include:

- Site access via the Massachusetts Avenue Connector has been eliminated, with unknown traffic impacts on Albany Street and other local roadways. It is unclear from the FEIR if and how traffic previously using the Massachusetts Avenue Connector was reallocated;
- The proposed through connection between East Concord Street and the Mass Avenue Extension has also been eliminated as part of this redesign; and
- Buildings F-1 and F-2 have been eliminated.

In addition to these changes, the FEIR introduces critical new information and analyses. New information includes a description of operational safety and security measures (27 pages of description and two appendices with additional procedures), a worst-case risk assessment, and information on the characteristics of diseases that will be studied. We also learn for the first time in the FEIR that the project will alter the proposed Urban Ring route – this is a regionally important transportation project. The introduction of such a substantial amount of new information should not eliminate the requirement for the proponent to address concerns or questions raised by the public on these new items.

We believe that not requiring a Notice of Project Change, not clearly explaining project changes, and the addition of substantial new information in the final review phases is contrary to the intent of MEPA and does not allow adequate public input.

MAPC is also concerned that this project is concurrently undergoing review under NEPA, but there is no apparent coordination between the NEPA and MEPA reviews.

**2. There are numerous items that still need to be addressed or clarified by the proponent.** Our concerns are described in detail below:

- Since the DEIR, site access from the Massachusetts Avenue Connector has been eliminated. Page 1-2 of the DEIR contained the following summary: "The introduction of new access to and from the regional roadway system [via the Mass Avenue Connector], combined with the changes to East Concord, East Canton, East Newton, and East Brookline Streets will reduce traffic impacts on Albany Street and deter traffic cutting through the site from the adjacent neighborhood to the Interstate Highway system." The impacts on Albany Street and the local streets are now reported in the FEIR to be negligible, despite the fact that no changes are indicated in the numbers of trips generated from the DEIR analysis. There is no explanation of how a connection previously deemed necessary to reduce traffic impacts can be removed from the proposal without a concurrent increase in traffic impacts on the local street network..

- Issues of the Urban Ring routing remain unresolved. The proposed site access plan does not allow the MBTA's Urban Ring BRT 7 route as planned. The proponent has proposed an alternative route, using Albany Street. That proposal has been on the table since October 2002, but the MBTA's comments on the DEIR from November 2003 would suggest they still do not agree that the alternative route is acceptable. The FEIR should have shown how the proponent's alternative route (the only route possible under the current design) would have impacted the route, travel time, and schedule adherence. Unfortunately, the FEIR did not do this.

- The DEIR contains an inventory of existing parking supply and demand in the area, but no real estimate of future demand at the site. The existing 1,000 car garage built as part of Phase 1 and the proposed 1,400 car Phase 2 garage are described as necessary to supply all the parking for the site. Demand is simply estimated at 1.25 spaces per gross square foot. However, the NBL is expected to have both smaller numbers of employees and much reduced numbers of visitors versus the other medical buildings in the area. New supply and demand at the adjacent Crosstown site under development were also not included in this analysis. The FEIR should have provided parking demand numbers tied to the intended uses and proposed supply at the site. It does not do this.

- The phasing of the parking is also being mixed with the phasing of the buildings. When all development is completed, most of the visitors to the entire site will be directed to park in the already constructed Phase 1 garage. Very few visitors are expected for the NBL, which will be located at the opposite end of the site from the Phase 1 garage. Eventually the Phase 2 garage will be the primary parking for all employees at the site (both phases), even the "low employee" NBL .

To accommodate some of the parking needs of employees in existing buildings during construction, 600 parking spaces will be rented by the proponent off site at Northeastern. This means that at least 600 employees currently working on site but parking off-site during construction will begin driving to the site when the Phase 2 garage opens. Those 600 trips should be added to the trip generation figures for Phase 2 and factored into the LOS calculations.

- No issues on the transportation of hazardous materials to and from the site have been addressed. The Transportation section of Chapter 5, Operational, Safety, and Security Issues, merely notes that federal regulations and protocols are in place and will be followed. Regardless of how safe the laboratories themselves are, the hazardous materials must be shipped to, and eventually away from, the facility using the local and regional street network. Since crashes en route and even assault on the vehicles are a possibility, some discussion of containment practices during these trips, and hazardous transport issues in general, should be included in the FEIR.

  While shipment will be according to "strict federal guidelines" there is no information on how these guidelines apply to this specific Boston location. For example, in the section on packaging, the outer package must comply with a "drop test of 1.2 m", and "a temperature tolerance range of 40 -131 degrees F." A crash on one of our numerous overpasses/bridges could result in a fall well over 1.2 meters, and the temperature does occasionally fall below 40 degrees Fahrenheit here. Again, the FEIR should demonstrate that the anticipated hazardous materials can be safely transported in Boston.

- Potential emissions from the facility are not analyzed. In Appendix I, page 20, the proponent states, "A risk analysis of the laboratory operations will be performed as part of the Federal Environmental Impact Statement for the Project. This analysis will provide useful information on potential biological and chemical emissions from the laboratory and their potential impacts at nearby locations." In other words, this FEIR provides no analysis of operational air quality impacts and therefore mitigation cannot be proposed. The Comments of Clarification notes that Volatile Organic Compounds (VOCs) will be emitted but does not provide an analysis of the amount. Given that the EOEA has designated much of the area within one mile of the project site as Environmental Justice areas and that air quality emissions are an impact under MEPA, this analysis must be conducted before EOEA issues a final certificate for this project.

- During an emergency or heightened security, would air space, nearby roads and the interstates be affected? Have areas around other facilities been restricted or shut down for any amount of time? If the answer to either of these questions is "yes" – or even "maybe" – a plan must be introduced to cope with such circumstances.

- According to the project funder's (NAIAD) website, the Division of Safety at the National Institute of Health oversees the planning and design of these facilities. Has the division approved of the proposed design? If so, evidence of the approval should be submitted. If not, what changes may be required to obtain the division's approval and how will these changes affect the proposed plan?

- According the to the Standard Operational Procedures for a Level IV facility (as found the in the EIS for the Rocky Mountain Laboratory), in the event of an evacuation due to a "Bomb Threat/Incident," personnel must locate to an area at least 300 feet upwind of the facility. At the proposed Boston facility, 300 feet extends off-site and includes off-site roadways and buildings. Would the roadways be closed down during an incident and would occupants of those buildings be evacuated? If the 300 foot rule does not apply here, why not?

- The Comments of Clarification provides a rendering of the non-scaleable fence. Figure 2 illustrates a 6-foot or 8-foot fence while Figure 3 illustrates a 9-foot fence. What height will the fence be? Has the NIH approved this fence and is this type of fence used at other facilities? Is it a possibility that barbed wire will be required? What impact will such a fence have on the surrounding community and how will it be designed to minimize such impacts?

- Figure 5-1 shows the security fence going though two buildings. The FEIR does not discuss what measures will be in place to ensure that these buildings also serve as a security barrier. For example, could a person bypass security by going into the building on the non-secure side and existing on the secure side?

- In addition, we wonder if additional security measures are warranted. A Level IV NBL will be constructed at the Rocky Mountain Laboratories in Montana. At that site, according to NAIAD's website, the entire 33-acre campus will have observation cameras, new lighting, and card readers. The NBL proposed in Boston only calls for a 150 foot security area. The proponent should describe why the same level of security measure is not needed here. A security shed was proposed in the DEIR, but has been removed. What functions did this security shed provide and, if they are still deemed necessary, how are those functions replicated in the final plan?

- Neither the DEIR nor FEIR explain the methodology/rationale for determining the expected number of jobs during construction and operation. Unless the proponent can explain the basis for these numbers (2,100 new jobs during construction and 1,400 permanent jobs), these numbers should not be included as a Community Benefit. Comment 15.7 in Appendix 1 of the FEIR further confuses our understanding of this analysis. Here, the proponent provides a figure of 660 new jobs based on an industry standard of 3 employees per 1,000 square feet. It is unclear how this number relates to the 1,400 noted elsewhere. In addition, the transportation analysis states that a density of 3 employees per 1,000 square feet is too high for the proposed use. The proponent should clarify these figures,

clearly explain its methodology and ensure that the same assumptions apply to the transportation analysis.

- Will the good-faith efforts of the proponent to employ Boston residents during construction and operation be hampered by the skills required for workers at this unique facility? If yes, what steps will be taken to overcome such difficulties?

- Section 5.7, Risk Assessment, discusses the protocols if an infected animal escapes. Protocols for insect escapes are not provided.

- Neither the DEIR nor FEIR described the project's consistency with the regional plan, *MetroPlan 2000*, as required by MEPA. While at face value, the project is likely consistent with many aspects of MetroPlan, the proponent must look carefully at the project's consistency with the regional plan.

**3. Mitigation measures are lacking and it is unclear to which measures the proponent is committing.** The Secretary's December 1, 2003 Draft EIR Certificate clearly states that the proponent should include a summary of all mitigation measures. Section 1.5 and the Draft Section 61 Findings list a handful of measures – nowhere near all of the items suggested as mitigation throughout the document. It also is unclear what measures mentioned in the ENF or DEIR carried over to the FEIR.

We suggest that the proponent commit to at least the following mitigation strategies:

- The proponent notes in Section 4.3.5, Parking, that "BUMC representatives have met with nearby community groups to agree on mitigation measures." But these measures are not disclosed. A list of the agreed-upon mitigation measures should be provided, along with evidence of the acceptance by the City of Boston and or community groups.

- In terms of local emergency response, the FEIR notes that the Boston Public Health Commission will be providing free training via its Boston Emergency Preparedness Training Institute. This training will include response to bioterrorism, disaster and large-scale emergency response. The proponent should commit to offering resources, including financial resources, to assure that specific groups that must be trained are in fact trained. City-wide preparedness for a potential incident at the NBL is critical. The FEIR also notes that the NBL will "partner with state agencies such as the Department of Environmental Protection, the Massachusetts Water Resources Authority, the National Guard and Fire Services to increase reporting efficiency and develop a more uniform context for action relating to emergency response triage, public health decision-making and external communications." We urge the proponent to provide the financial resources and training needed for these agencies to take on these responsibilities. We also believe that the regional public health district and the Executive Office of Public Safety should be part of this partnership.

- The results of the wind analysis are dependant upon the proponent planting appropriately placed conifer trees. This should be added to the mitigation list.

- We would like to see a firmer commitment to green building measures. The project's architect for the NBL, CUH2A, Inc., has vast experience in green buildings – their expertise should be tapped to reduce the project's water and energy usage. In addition, the water conservation measures offered in its response to comments 8.14 and 8.15 should be listed in the mitigation section.

- The proponent should commit to DEP's diesel emission mitigation program, as outlined in DEP's comment letter on this project. As noted, the area contains Environmental Justice populations and lessening air quality impacts should be of critical importance.

- Section 2.4 of the FEIR notes that "...the site will consist of pedestrian paths, open spaces and landscaped areas." However, Figure 2-19 indicates that most of the open space is within the 150-foot secured perimeter of the NBL and the proponent clarifies in the Comments of Clarification that indeed most of the open space will be inaccessible to the public. The proponent will create a pocket park that will be surrounded by security fencing on three sides. It is unfortunate that the public benefit of open space has been eliminated aside from the pocket park. We hope the proponent will work with the neighborhood to ensure a functional design of the park and rethink the need to provide more benefits to the community.

- The response to Comment 15.36 notes that "the proponent has proposed a number of specific mitigation measures to help reduce project-related motor vehicle emissions as detailed in the Draft PIR/EIR." These measures are not listed in the Mitigation Section nor in the Draft Chapter 61 Findings.

- It is unfortunate that the proponent has withdrawn its support of the South Bay Harbor trail. Given the fact that much of the surrounding community is defined as belonging to Environmental Justice populations, the proponent should give more thought to mitigation. Assisting with the construction of this path would be a start.

In sum, the proponent should address the concerns and questions above, and develop additional mitigation strategies to satisfy these concerns.

**Recommendations**

It is MAPC's conclusion that EOEA does not have adequate information or adequate input from affected communities to make a determination on this critical project. The proponent must clarify its mitigation commitments, and we ask the Secretary to consider our additional suggestions for mitigation measures. But more importantly, additional

analysis and public review must occur before a decision is made. Without full public disclosure of all potential impacts, those impacts cannot be properly mitigated.

We therefore urge you to make a finding under 301 CMR 11.07 that the FEIR does not adequately and properly comply with the Massachusetts Environmental Policy Act, and require that the proponent submit a Supplemental Final EIR that addresses the concerns raised in this letter as well as those of other commenters. An SFEIR will also provide the opportunity for coordination between the NEPA and MEPA reviews.

Given the juxtaposition of such critical issues within an area defined by EOEA as including Environmental Justice populations, MAPC further suggests that the best way to achieve a satisfactory outcome from further review of this project would be to establish a Special Procedure under 301 CMR 11.00. A Special Procedure can be used to facilitate the "coordination or consolidation of MEPA review with other environmental or development review and permitting processes; and establishment of a CAC" (Citizens Advisory Committee). In this case, a Special Procedure could be used to coordinate MEPA's review of outstanding issues along with the NEPA review that this project must still complete.

MAPC stands ready to provide input into the scope of a Supplemental Final EIR to ensure that it meets the needs of the community and the region. Thank you for the opportunity to comment on this important project.

Sincerely,

Marc D. Draisen
Executive Director

cc: Rebecca Barnes
Tom Kadzis
Douglas Foy
Stephen Burrington

27 Hereford Street
Boston, MA 02115

November 8, 2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA #12021
100 Cambridge St., Suite 900
Boston MA 02114
Via e-mail

Mr. John O'Brien, Project Manager
Boston Redevelopment Authority
One City Hall Plaza, 9th floor
Boston, MA 02201
Via e-mail

Re: BioSquare Phase II
Final Environmental Impact Report and Final Project Impact Report/PDA comments

I submit the following comments on the FEIR/FPIR and PDA for the Boston University Level 4 Lab proposed on Albany Street in BioSquare.

In summary: The FPIR/FEIR is not adequate, and the proponent should be required to file a revised document.

1. The FPIR/FEIR Risk Assessment analysis is seriously deficient:
   a. To my understanding, it does not represent the way that anthrax has usually been accidentally disseminated. A literature review of anthrax infection episodes should be provided to document the nature of the likeliest anthrax escape.
   b. It does not consider any of the other microorganisms that the Lab is expected to study, which may be dispersed in different ways, and which most likely are not as treatable as anthrax.
   c. It does not even attempt to consider the microorganisms that the Lab may later undertake to study, including those that may result from experiments in recombinant DNA (the local prohibition on which is not acknowledged). This lab is to occupy 25% (not 15% as implied all along) of the active lab space; and increases in this proportion, and changes in subjects studied, are likely to be defense secrets, made without public information. The future operation of the lab will not be in local hands, but under Federal control, in military fashion. No risk assessment in 2004 is predictive without specific inviolable limits on the lab's scope, limits which are not forthcoming. We will truly have no idea what will be happening here in the middle of this heavily populated area once the structure is built.
   d. It does not consider environmental contamination, only individual human infection. In addition to the usual air, soil, and vegetation issues, we are a peninsula, surrounded by river, bay and ocean waters the contamination of which could transfer serious harm very widely.
   e. It does not examine transportation-related risks, either in product delivery/disposal, nor in emergency escape.
   f. It does not consider the risks of terrorist attack, which such a facility invites, and the possible collateral damage to surrounding neighborhoods.

2. ***"At the heart of the MEPA process stands the requirement to evaluative feasible alternatives to a proposed project, to ensure that all state agencies can find, pursuant to Section 61 of the statute, that all feasible means to avoid, reduce, or mitigate environmental damage have been considered and incorporated into the project design."*** (quote from a recent EOEA certificate, #13365). The most basic evaluative element, a study of alternative sites for the lab, has not been attempted, despite repeated and widespread public demand. This is the only such lab in the United States to be located in a dense urban environment, which I suspect is not by accident; is this not an indication of an issue that at least bears examination? In addition to the extraordinary public health risks of this siting, there is a lost opportunity for community benefit. This site was previously to hold a mix of institutional and commercial uses, which could provide a more diverse economic development base, without risk to life and limb. Further, the prison-like urban design environment of this lab is likely to impede the City's contemplated development of the BU surroundings as "neighborhood fabric." It is absolutely unacceptable that such a decision be made without even an attempt to consider other sites.

3. The City and BRA transferred the land for this purpose to the proponent, without the required Urban Renewal processes and at a huge financial subsidy, without public hearings or City Council oversight as both Urban Renewal and City tax expenditure require. This information is still not available, despite repeated questions from the public and from City Councilor Chuck Turner.

The PDA designation itself requires a balance of private and public benefit. Without a sophisticated and comprehensive Risk Assessment, a comparative evaluation of alternative sites, and an honest disclosure of the public financial subsidy to the proponent, this designation cannot be made.

I fear that a true risk assessment, alternatives consideration and cost-benefit analysis basic to the decision to site the building here has been deliberately compromised by the proponent with the complicity of the City administration, which supported the project before it was even publicly known. This project is extremely politicized; public information has been withheld or distorted. The political connections between the proponent and the City administration are well known. And the City's vision of becoming the "biotech capital" of the country, as an economic development strategy, appears be leading to an expedited approval process that imposes unexamined risks on the surrounding neighborhoods (and beyond) and the natural environment. The City administration, the University and the developer, R.F. Walsh, are celebrating the capture of this financial and status "prize," but the long-term price may not be known for some time, and would be paid by others who have no such immediate benefits to reward their future risks.

Once again, as often before, we depend on the state to do what the City and BRA will not do, to protect the public from impacts of ill-considered development. But in this case, the stakes are extraordinary.

The proponent is a step behind in the review process, having omitted the Level 4 lab from the Draft evaluation documents. Certainly, it is time to catch up on this process. A genuine Final EIR/PIR should be required that fulfills the MEPA requirements for alternatives study and in-depth impact assessments.

Thank you for considering my comments.

Shirley Kressel

# Old Dover Neighborhood Association

15 Waltham Street B302, Boston, MA 02118-2115

November 8, 2004

RECEIVED
NOV. 10 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

#

Re: Comments on Biosafety Lab — 12021

Dear Ms. Herzfelder:

I am writing to convey the concerns of the Old Dover Neighborhood Association (in the South End, centered around Washington Street and East Berkeley) about BU's proposed Biosafety Lab.

It is fair to say that the feelings of individuals vary from support, based on a confidence that safety issues can and will be addressed adequately, to strong opposition, based on the potentially devastating consequences of a safety failure, no matter the probabilities.

Everyone understands the economic and scientific benefits that are possible. However, on the cost side, supporters and opposition alike share the same concerns, which include:

- The obvious extreme health risks, should there be any lapse of containment, either by mistake or intention. Based on our understanding of the project, the lab will work with and research certain biological agents against which there are currently no known defenses.
- Whether, even with the best intentions, adequate, effective safeguards and training will actually find their way into the construction of the lab building and the long-term operating standards of this facility.
- The possibility that the lab, because of its research and the agents it contains, could become the target of a terrorist act. Even an explosion (for example) that did not breach the lab could potentially be a disaster for a very large number of local residents and employees.
- A building design that doesn't fit contextually with the surrounding neighborhood, looking more appropriate to an isolated location rather than an urban residential and institutional setting.

In order to address these concerns, we have several requests of the city and the project proponent:

- An ongoing program of neighborhood/area public outreach and information should be established that is a part of BU's ongoing program relative to their operation of this facility. We should not be the "last to know" what is going on in the neighborhood. This should continue not only during development, but throughout operation.
- A set of plans that do not rely on voluntary compliance or secrecy for their adequacy. The facility needs to be invulnerable to sloppiness or an intruder familiar with its systems.

- A known response plan, for both the occupants and the surrounding neighborhood, in the event of a problem, accidental or otherwise.
- A building that acknowledges the context of the historic South End neighborhood in which it is being built. All other structures are subject to design and neighborhood review, and this should be no different.

Generally, there have been many broad assurances that all possible safety concerns will be addressed by design and training, but the details have been limited. The decisions have to be driven by the possible consequences, not simply the likelihood of a mishap. (A minimal chance of a huge disaster must be driven by the magnitude of the disaster, not the small probability of its occurrence.) These require exceptional conservatism and redundant safety in the plans, designs, and training.

Without being cynical, we expect that, in spite of the strong and vocal local opposition, the lab is likely to go forward. Therefore, it is of the utmost importance to satisfy the above concerns, both to validate the supporters and to satisfy the opposition, that the developers are not only willing, but also able, to reduce the local threat to virtually zero.

Sincerely,

Roger Wellington

Roger Wellington
President

BG

RECEIVED

NOV 9 – 2004

MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:
I am writing in comment on the FEIR and Boston University's proposed bioterrorism laboratory. I have read the FEIR as well as BU's application to the NIAID for their proposed BSL4 lab. I have undergraduate degrees in biochemistry and microbiology and a graduate degree in biology. I have been working in biomedical research labs for the past 20 years, so I am quite familiar with the laboratory environment and the projects that BU is proposing. I believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR for the following reasons.

1) The assessment of a worst-case release is extremely superficial at best. RWDI West Partners have chosen anthrax as their released organism. In assessing the plume of contamination that would be released from the lab, they measure the exposure of individuals at a single point at ground level. A true assessment of the exposure must include a 3-D model of dispersal in the area, taking into account buildings and the presence of people at many elevations throughout the plume. Localized wind patterns may lead to concentrations of anthrax spores in discreet spots within the neighborhood.

2) The danger posed to community depends not only on the nature of the released organism, but also on the health and available healthcare of the resident population. It is known that the population around the proposed site suffers abnormally high incidences of asthma and other respiratory diseases. The population is also under-insured and may not have access to medical care. These factors must be taken into account to get a realistic picture of the risk posed by this lab to the neighborhood.

3) The choice of anthrax as the studied organism does not take into account the much greater danger posed by a true contagion. Accidental or intentional release of an organism that is spread from person to person poses a very different set of very serious health risks. This must also be included in a true assessment of a worst-case release.

4) The FEIR does not look at the dangers posed by transport of infectious agents through the neighborhood going to and from the lab.

5) There is no assessment of alternative sites for the proposed lab. The fact that the $128 million dollar grant from NIAID to BU was contingent on the lab being placed in this site places huge monetary pressure on the outcome of this site comparison. Public safety concerns appear to be a secondary consideration.

6) Boston Public Health Commission has an existing restriction on using recombinant DNA (RDNA) in a BSL4 lab. In reviewing BU's list of proposed projects for the lab, over half of those projects would require RDNA at some point. Either BU plans on violating the existing restriction or they will be constantly shuttling these infectious agents to other labs to try and circumvent this restiction. This will greatly increase the risk of exposure to the community.

7) Lack of transparency in this lab will actually lead to suspicions that biological weapons research is being conducted in this facility. Whether or not that is the case, it will fuel the push for an international bioweapons arms race that will lead to decreased biosafety.

8) Research in this lab will bring into existence highly infectious organisms that can themselves be appropriated for a bioterrorism attack. The anthrax attacks in 2001 were carried out with weaponized anthrax stemming from a U.S. biodefense facility.

9) This neighborhood should not be strapped with yet another facility that it does not desire. Community input has not been sought in deciding on this project.

I also request that you require the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous biological materials are in transport to the lab.

The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR. Thank you very much for the opportunity to comment.

Sincerely,

Marc Pelletier
8 Glade Ave. #2
Jamaica Plain, MA

## Gage, Bill (ENV)

**From:** Susan St. Pierre [sst.pierre@fpa-inc.com]
**Sent:** Tuesday, November 09, 2004 5:30 PM
**To:** Williaml Gage (ENV)
**Cc:** Jamie Fay; Richard Towle; Donna Camiolo; Dick Galvin; Jane Howard; Jim Greene
**Subject:** BioSquare

Bill Gage Response 11-8-04.doc...

Bill,

Attached please find a list of community benefits with associated cost estimates. We have not been able to put any numbers on the TDM measures.

Also, just for your information, there are City of Boston benefits also being provided including a recently announced $1,000,000 scholarship Grant Program for entry level lab technician training for Boston residents and PILOT payments to City of Boston will be continued. BUMC currently makes PILOT payments in excess of $300,000 per year and Boston University makes annual PILOT payments of $3,200,000 and tax payments of $3,000,000.

Please call if you have any further questions.

Susan

1. **Infiltration/Inflow** Currently, BWSC uses the following formula to determine the level of mitigation needed:

   Average daily flow (gpd) * 4 = I/I burden (gpd). The acreage of separation required is calculated at 1-acre/37,000 gallons. Once the acreage has been calculated a BWSC construction costs for required piping of $70,000/acre is then calculated.

Based on the current estimate of 63,452 gpd of sewage flow, the I/I burden would be 253,808 gpd or a removal acreage of 6.86 which totals a construction cost $480,000. Please note that this amount is subject to change during final design if the estimated flows are changed.

2. **Transportation**
   - a Improve East Newton/Albany Street as a 4-way intersection at a cost of $100,000 - $200,000. The modification of the East Newton Street at Albany Street will include, as necessary, installation of new equipment to update this intersection to the current design standards. This will include new curbing, sidewalks, mast arms and signal posts, LED pedestrian and vehicle indications, interconnect conduit and a traffic controller.
   - b Pavement markings along Albany Street including lane striping and crosswalks at a cost of $35,000 to $60,000.
   - c Installation of Fiber Optics along Albany Street at a cost of $20,000 to $25,000.
   - d Provision of two variable message boards for real traffic information to BTD at a cost of $52,000.
   - e Provision of directional way finding signage around site at a cost of $25,000.
   - f Provision of safe and secure bicycle storage for 140 bikes in various sites, including the new garage and building entrances on site at a cost of $20,000.
   - g Shower facilities in Boston Medical Center buildings will be made available to BioSquare cyclists as necessary at no cost.

3. **Other Project benefits**
   a. Creation of a pocket park along Albany Street at a cost of $246,000.

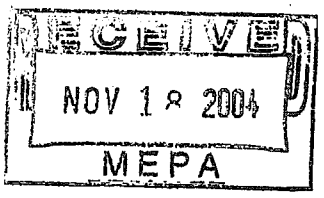
# The Commonwealth of Massachusetts

William Francis Galvin, Secretary of the Commonwealth
Massachusetts Historical Commission

BG

November 9, 2004

Secretary Ellen Herzfelder
Executive Office of Environmental Affairs
251 Causeway Street, 9th Floor
Boston, MA 02114-2150




RE: BioSquare Phase II, Boston; MHC# 12021

Dear Secretary Herzfelder:

The Massachusetts Historical Commission has reviewed the Final Environmental Impact Report for the above referenced project. The proposed project site is adjacent to the South End Landmark District and is within the South End Landmark Protection Area (administered by the Boston Landmarks Commission).

The proposed project involves new construction on a 14.5 acre parcel on Albany Street, including 2 buildings and a parking garage.

The MHC looks forward to receiving and reviewing additional designs for the proposed project as they are revised in response to the South End Landmark District Commission's review and approval process.

These comments are offered to assist in compliance with M.G.L. Chapter 9, Section 26-27C, as amended by Chapter 254 of the Acts of 1988 (950 CMR 71.00) and MEPA. Please do not hesitate to contact Ann Lattinville of my staff if you have any questions.

Sincerely,

Brona Simon

Brona Simon
Deputy State Historic Preservation Officer
Massachusetts Historical Commission

xc: BLC
Fort Point Associates

220 Morrissey Boulevard, Boston, Massachusetts 02125
(617) 727-8470 • Fax: (617) 727-5128
www.state.ma.us/sec/mhc

The Commonwealth of Massachusetts
Executive Office of Transportation and Construction
Ten Park Plaza, Boston, MA 02116-3969

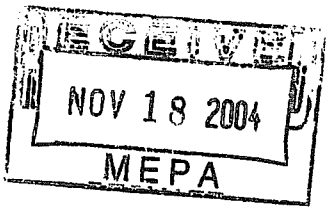
Mitt Romney
Governor

Kerry Healey
Lieutenant Governor

Daniel A. Grabauskas
Secretary of Transportation

B6

November 9, 2004




Ellen Roy Herzfelder, Secretary
Executive Office of Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114-2150

RE: Boston – BioSquare Phase II – FEIR
EOEA #12021

ATTN: MEPA Unit
William Gage

Dear Secretary Roy Herzfelder:

On behalf of the Executive Office of Transportation, I am submitting comments regarding the BioSquare Phase II project, as prepared by the Office of Transportation Planning. If you have any questions regarding these comments, please call J. Lionel Lucien, P.E., Manager of the Public/Private Development Unit, at (617) 973-7341.

Sincerely,

Astrid Glynn
Deputy Secretary

AG/ksm

cc: Luisa Paiewonsky, Assistant Secretary
John Blundo, P.E., Chief Engineer
Kenneth S. Miller, P.E., Director, Office of Transportation Planning
Patricia Leavenworth, Acting District 4 Director
William R. Bent, P.E., State Traffic Engineer
Stanley Wood, P.E., Highway Design Engineer
Public/Private Development Unit files
Dennis DiZoglio, Director of Real Estate Planning, MBTA
Joseph Cosgrove, Director of Planning, MBTA
Peter Calcaterra, Urban Ring Project Manager
Planning Department, City of Boston
Metropolitan Area Planning Council
Central Transportation Planning Staff

COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF TRANSPORTATION
OFFICE OF TRANSPORTATION PLANNING

# MEMORANDUM

TO: Astrid Glynn, Deputy Secretary
Executive Office of Transportation

THROUGH: Kenneth S. Miller, P.E., Director
Office of Transportation Planning

FROM: J. Lionel Lucien, P.E., Manager
Public/Private Development Unit
Joseph Cosgrove, Director of Planning
Massachusetts Bay Transportation Authority (MBTA)

DATE: November 9, 2004

RE: Boston – BioSquare Phase II – FEIR
(EOEA # 12021)

The Office of Transportation Planning has coordinated the review of the Final Environmental Impact Report (FEIR) for the proposed BioSquare, Phase II project in Boston. The project entails the construction of a mixed-use development consisting of a 457,700 square of biomedical research and office space, with associated parking facilities that will provide 1,400 parking spaces. The site also includes a 5,600 square foot utility building and a small security building to service the biomedical institutions in the area. The project will be located on ±9.3 acres between Albany Street and the Massachusetts Avenue Connector in Boston. According to information contained in the FEIR, Phase I and II of the project will generate approximately 6,952 vehicle-trips on an average weekday. A Massachusetts Highway Department (MassHighway) permit will be required for access to the I-93 the Frontage Road-South. The project is categorically included for the preparation of an Environmental Impact Report (EIR).

The BioSquare Phase II FEIR conforms generally to the EOEA/EOTC Guidelines for EIR/EIS Traffic Impact Assessments. The project proponent and the City of Boston have met in several occasions with the Executive Office of Transportation, the MBTA and MassHighway to discuss the request for the new access points along the I-93 South Frontage Road and the Massachusetts Avenue Connector (MAC), as well as access schemes for the Urban Ring project. We believe that the FEIR has addressed most of MassHighway concerns on the DEIR, even though some issues associated with the Urban Ring project still remain to be resolved. MassHighway and the MBTA offer the following comments.

**MassHighway:**

1. The proponent has proposed a list of measures that include roadway improvements to mitigate the impacts of the Biosquare II project. The proposed roadway mitigation measures consist of the construction of a right-in/right-out driveway to Southbound Frontage Road; and the modification of the signalized intersection of East Newton Street and Albany Street as a four-way intersection. Based on our review of several traffic study submissions and the proponent's FEIR, we believe that MassHighway can support a break in access for a right-in, right-out driveway at the I-93 southbound frontage road. The proponent should work closely with MassHighway during the permitting process to address the following issues. The site driveway design should provide for enough acceleration lanes to facilitate merging onto Frontage Road and maximize the driveway location to increase the weaving distance between the site driveway and the Southbound Frontage Road/Southeast Expressway off-ramp intersection. The proponent should also modify the traffic signal timing of this intersection to minimize queue length that may block the site driveway.

2. The proponent has indicated in the FEIR that the proposed MAC access will not be pursued at this time, and further stated that the Proposed Project can be accommodated under any of the access schemes analyzed. MassHighway has expressed both in correspondences and meetings with the proponent, its concerns regarding the proposed signalized intersection along the MAC. Due to the design of the connector roadway, the observed vehicle speeds, and the length of weaving distances along the connector, a new signal will have significant impacts on traffic operations and safety. We have reviewed Alternative II and believe that the access along Frontage Road south, in addition to proposed and local street accesses, can safely accommodate the project without severely impacting the local roadway system.

3. The FEIR included discussions of several possible BRT routings for the Urban Ring service that could be accommodated under the BioSquare project access alternatives. The MBTA has previously indicated preference for access along the MAC to allow Urban Ring Phase 2 BRT7 buses to continue their routing via an extension of East Concord Street. As proposed in this FEIR, MassHighway will have the same safety and traffic operations concerns regarding access along the MAC. As the MBTA continues to develop plans for the Urban Ring 2 FEIR/S, MassHighway will cooperatively reevaluate access plans proposed in this FEIR, as well as evaluating additional safe access schemes along the state highway system to accommodate the Urban Ring bus routing.

**MBTA:**

1. The MBTA's November 5, 2003 comment letter on the Draft EIR pointed out that the project's proposed internal roadway connection with the Massachusetts Avenue Connector (MAC) failed to accommodate the Urban Ring's planned routing to and from the MAC via East Concord Street. Since that time significant changes have been made in the roadway and circulation plan for BioSquare Phase II, most notably that it no longer

includes any direct connection between the internal BioSquare roadways and the MAC. Section 4.2.3 in Chapter 4 of the Final EIR document for BioSquare Phase II discusses the Urban Ring in the context of the revised BioSquare roadway and access plan. For reasons described below, the MBTA remains concerned with the adequacy of the Urban Ring routing options available under the BioSquare Phase II plan.

2. MAC Connection

The revised BioSquare Phase II roadway and circulation plan no longer connects directly with the MAC, and instead will rely on the South Frontage Road as its connection with the regional highway system. The concern expressed in the MBTA's November 5, 2003 comment letter on the Draft EIR remains with the current roadway and circulation plan, though the MBTA is encouraged that the proponent does state in its response to the Boston Transportation Department in the Appendix 1-11 that "The current design of the East Concord Street Extension/Mass. Ave. Connector does not preclude a future connection or median break in the future." While other issues may prevent the final recommended Urban Ring routing in this area from using the MAC connection, the BioSquare Phase II project should be required to accommodate two-way Urban Ring routing along East Concord Street in the future should that routing ultimately be recommended for the Urban Ring project.

3. BRT7 Routing

Page 4-35 quotes an October 1, 2002 memo with Boston University Medical Center's (BUMC) suggestions for the BRT7 routing, but it should be noted that BUMC's suggested routing would utilize I-90 and I-93 and be entirely in mixed traffic. Analysis of the above routing during the Urban Ring Phase 2 DEIR/S showed it to be slower and, more importantly, less reliable in the peak hours. If the East Concord Street connection to the MAC were not available to the Urban Ring the MBTA' s preferred routing of the BRT7 would utilize Albany Street.

4. BRT7 Station Location

Page 4-36 summarizes three station location options considered by the MBTA early in the Urban Ring DEIR/S process in 2002. The location shown in Figure 4-16 was dropped from further consideration by the MBTA some time ago because it is less accessible to the transit users in the area and is less flexible than an Albany Street location for routing and connections with other services. The Urban Ring Phase 2 DEIR/S uses the location shown in Figure 4-15, which provides maximum flexibility for routing options, though the MBTA could consider a location slightly further east as shown in Figure 4-14 if it provides greater opportunity for joint development of the station with BUMC and BioSquare. This can be addressed during the FEIR/S for the Urban Ring Phase 2.

5. BRT6 Routing

Pages 4-35 and 4-36 describe two options for the BRT6 routing in this area identified in 2002. It should be noted that subsequent analysis of those options during the Urban Ring DEIR/S showed that routing the BRT6 as described in the second bullet on page 4-36 would add considerable time and delay to the route and result in a major net loss of

ridership. The Urban Ring DEIR/S routing of the BRT6 is as described in the first bullet, and will provide for connecting service to BUMC/BioSquare from the Albany Street/Hampden Street BRT station.

6. Figure 4-17
The bottom of page 4-36 states that a commenter suggested using the routing shown in Figure 4-17. Please note that the MBTA has not suggested this routing and is concerned that its depiction in Figure 4-17 with the title "Revised Urban Ring Bus Routing through BioSquare" may be misconstrued as the preferred routing. In the absence of the MAC connection via East Concord Street the MBTA's preferred routing in this area would be via Albany Street/Frontage Road for both the eastbound and westbound movements, and would not utilize internal BioSquare roadways and the modified signalized 4-way intersection at Albany/East Newton Street for the eastbound move unless it can be shown that it would be faster and more reliable than Albany Street.

The FEIR included a more detailed description of the TDM program, and we believe that the program will reduce site trip generation. The project proponent will work with the established area TMA Transportation Solutions for Commuter (TranSComm) to implement the TDM program. Elements of the program will include parking management and pricing, transit subsidies for both employees and students, shuttle bus services to MBTA stations, bicycling, car sharing, and flex time. The project proponent should provide an annual report to evaluate the success of the program.

The project proponent should submit a letter of commitment to implement the above traffic mitigation measures for this project, and should describe the timing and cost of their implementation based on the phases of the project, if any. MassHighway will issue a Section 61 findings for the project based on this letter of commitment. If you have any questions regarding these comments, please contact Lionel Lucien of Public/Private Development Unit at (617) 973-7341 or Joseph Cosgrove of the MBTA Planning Department at (617) 222-4400.

BG

260 Chapman Road
Barre, MA 01005



11-3-2004

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
Attn: MEPA Office
William Gage, EOEA No. 12021
100 Cambridge St., Suite 900
Boston MA 02114

Re: Comments on the Final Environmental Impact Report for BioSquare Phase II
EOEA # 12021

Dear Secretary Herzfelder:

These are my comments on the FEIR and the proposed bioterrorism laboratory. I believe that the FEIR is inadequate and that you should require the project proponent to file a supplemental FEIR because the FEIR:

- Does not include a true or accurate "worst case scenario." Instead, the FEIR contains an inaccurate and incomplete "worst case scenario" that: 1) contains serious mistakes in analysis that cause a significant underestimate of the potentially devastating and deadly impact of a release of anthrax from the proposed bioterrorism laboratory; 2) fails to perform a site-specific release analysis, 3) fails to consider the environmental impact of the release; and 4) fails to analyze an accidental or intentional release of the deadly and incurable viruses and toxins other than anthrax that may be present in the lab, including select agents and toxins that, unlike anthrax, are highly contagious.
- Fails to include a worst case release scenario for when a select agent is in transit to the laboratory or provide other essential information about the transport of hazardous biological and toxic agents to the laboratory.
- Fails to include a threat and vulnerability analysis for a terrorist attack on the laboratory and resulting release of select agents and other damages to the surrounding community.
- Is inconsistent with the Massachusetts Environmental Justice Policy.
- Does not include an alternatives analysis of other potential locations for the laboratory or provide the criteria used by University Associates to base its decision to locate the laboratory on Albany Street in Boston's South End.
- Does not include an explanation of how the laboratory will comply with regulatory requirements and fails to list the Boston regulation that prohibits recombinant DNA research requiring BSL4 containment in the City of Boston.
- Does not include a discussion of how the project proponent will assure that its health and safety operating procedures are met considering that the federal government has not yet chosen the entity that will operate the laboratory and that many outside researchers, including students with no BSL4 experience, will use the laboratory.
- Fails to comply with the requirements of the December 1, 2003, Certificate of the Secretary of Environmental Affairs on the Draft Environmental Impact Report.

I also request that you require the creation of an independent advisory committee comprised of residents and scientists not associated with BU or NIH to advise on the risks associated with the facility, including real worst case release scenarios from the lab and while the hazardous biological materials are in transport to the lab.

The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the MEPA process on the basis of the seriously flawed and inadequate FEIR.

Thank you very much for the opportunity to comment.

Sincerely,

Helen M Rayshick

Helen M. Rayshick

The CBR Institute for Biomedical Research

The CBR Institute for Biomedical Research, Inc.
800 Huntington Avenue
Boston, Massachusetts 02115
t: 617.278.3000
f: 617.278.3493
www.cbr.med.harvard.edu

13G

Wednesday, September 15, 2004

RECEIVED
SEP 17 2004
MEPA

Secretary Ellen Roy Herzfelder
Executive Office of Environmental Affairs
MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

EE
12021

Dear Secretary Herzfelder:

I am writing about Boston University Medical Center's proposed Biosafety Lab, as detailed in the Final Project Impact Report/Environmental Impact Report filed with the Boston Redevelopment Authority in July, 2004.

As a scientist working on rapid pathogen diagonostics, I strongly support the proposed laboratory. There is critical need for such facilities. There is not enough Level 4 laboratory space to accommodate the work that needs to be pursued if we are to develop treatments and vaccines to deal with both emerging and re-emerging infectious diseases.

Challenges to public health continue to emerge. Some examples include HIV/AIDS, West Nile virus, SARS and annual outbreaks of influenza. We know too that terrorists are interested in using biological agents against us and so scientists must be able to understand the biology of these disease-causing agents, develop assays to detect them and methods to neutralize outbreaks. This type of work can only be done in specially designed, safe laboratory facilities like the one proposed for BUMC.

I support Boston University Medical Center's solid proposal for a biosafety laboratory that will save lives and be constructed and operated to the highest safety standards.

Sincerely,

Robert J. Mandle, Ph.D.
Investigator
The CBR Institute for Biomedical Research, Inc.

Dear Secretary Herzfelder, EIR 12021

BG

I am writing to support Boston University Medical Center's plans to build the Biosafety laboratory as part of the BioSquare development on Albany Street.

This laboratory will save lives and the development of the lab will enable Boston to maintain its lead in the emerging bio-technology industry. This laboratory is an important economic development project that will create 1,300 construction jobs and over 600 permanent jobs

After reviewing the plans, I am convinced that Boston University will construct and operate the most secure biosafety lab in the world.

I am confident that Boston University has addressed every relevant community and environmental issue and urge your agency to approve this worthwhile project.

FROM:

Name Shawn Levine MD

Address Boston Medical Center

City Boston

State MA Zip 02118

RECEIVED

SEP 10 2004

MEPA

# Appendix 5

# RESPONSES TO COMMENTS ON THE NPC AND PHASE ONE WAIVER REQUEST

# APPENDIX 5: RESPONSES TO COMMENTS ON THE NOTICE OF PROJECT CHANGE AND PHASE ONE WAIVER REQUEST

This Appendix provides a response to the comments which were submitted to the Secretary regarding the filing of the Notice of Project Change and the Phase One Waiver request to the extent that they are relevant to the Remand Certificate on the FEIR (the Remand Certificate). The Remand Certificate was issued prior to Boston University's request for a Phase One Waiver to allow operation of the NEIDL at BSL-2 and BSL-3 research levels. The Proponent requested a Phase One Waiver to allow the commencement of BSL-2 and BSL-3 research to commence prior to the completion of the Final Supplementary Risk Assessment (FSRA) and the SFEIR. Comment letters pertained primarily to the advisability of issuing a Phase One Waiver in response to the Proponent's request to commence BSL-3 research prior to completion of the FSRA and the SFEIR, and the commenter's desires for EOEEA to hold a public hearing during the MEPA comment period.

A thorough review of the comment letters submitted following the filing of the Phase One Waiver request was undertaken by EOEEA. Of the 680 letters and cards received, 95 expressed concerns or opposition to issuance of the Phase One Waiver. Of the 585 letters and cards expressing support for the issuance of the Phase One Waiver, the majority cited the fact that numerous institutions in the Commonwealth and in the city currently undertake BSL-2 and BSL-3 projects safely. These projects are regulated in Boston by the Public Health Commission, a nationally recognized leader in regulating BSL-3 laboratories. The facility and the Phase One Waiver request received widespread support from the local and scientific community, as evidenced by the 585 letters and cards.

After considering the comment letters received, as well as the information submitted by the Proponent, and conferring with state permitting agencies, the Secretary found that "…the Waiver Request for BSL-2 Laboratory research has merit and that the proponent has demonstrated that the proposed project meets the standards for all waivers at 301 CMR 11.11(1)." In addition, the Secretary found that "…the potential environmental impacts of Phase I (utilization of BSL-2 Laboratory research), taken alone, are insignificant." The Secretary determined that Research at the BSL-3 level could not commence prior to completion of the FSRA and the SFEIR, and the issuance of a Certificate on the SFEIR.

This section also includes copies of individual comment letters, an example of a form letter and an example of form cards received.

## RESPONSES TO COMMENTS

Table A5-1 presents a list of the individual comment letters received on the NPC and Phase One Waiver Request. Table A5-2 provides a response to each comment which is relevant to the Remand Certificate and the SFEIR, and meets the requirements of the Remand Certificate on the FEIR in that it adds to or differs from the individual comments on the FEIR. Where appropriate, sections of the Supplemental Final Environmental Impact Report and its Appendices are cited for reference.

**Table A5-1: MEPA Comment Letters**

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Research at BioSafety Levels should not commence without completion of the Final Supplementary Risk Assessment and full MEPA review** | **MEPA Public Hearing Should be held** | **BU has not provided full disclosure of incidents/ communication with the community** | **Location of NEIDL should not be in Boston or "other"** |
| 8/30/11 | Fort Point Associates | **N** | | | | |
| 8/30/11 | AICUM | **S** | | | | |
| 8/31/11 | Boston Public Health Commission | **S** | | | | |
| 9/1/11 | Lynn Klotz | **O** | X | | | |
| 9/1/11 | Conference of Boston Teaching Hospitals (COBTH) | **S** | | | | |
| 9/2/11 | Michele Maniscalo | **O** | X | X | | |
| 9/4/11 | Caroline Attardo Genco, PhD | **S** | | | | |
| 9/6/11 | Associated Industries of Massachusetts (AIM) | **S** | | | | |
| 9/7/11 | Greater Boston Chamber of Commerce | **S** | | | | |
| 9/8/11 | Boston City Councilor Maureen Feeney | **S** | | | | |
| 9/8/11 | Elizabeth R. Simons, PhD | **S** | | | | |
| 9/9/11 | Lehigh University | **S** | | | | |
| 9/9/11 | Dana-Farber Cancer Institute/Brigham and Women's Hospital | **S** | | | | |
| 9/9/11 | Harvard University (Office of the Provost) | **S** | | | | |
| 9/10/11 | ALBANY LLC | **S** | | | | |
| 9/12/11 | Francisco Tapia | **S** | | | | |
| 9/13/11 | Shirley Kressel | **O** | X | X | X | |

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Research at BioSafety Levels should not commence without completion of the Final Supplementary Risk Assessment and full MEPA review** | **MEPA Public Hearing Should be held** | **BU has not provided full disclosure of incidents/ communication with the community** | **Location of NEIDL should not be in Boston or "other"** |
| 9/13/11 | Brigham and Women's Hospital/Harvard Medical School | **S** | | | | |
| 9/13/11 | Ronald B. Corley | **S** | | | | |
| 9/13/11 | Harbor Health Services, Inc | **S** | | | | |
| 9/13/11 | Alexis Brubaker | **S** | | | | |
| 9/14/11 | Dot Walsh | **O** | | | | Origins of Lyme Disease |
| 9/14/11 | Gregory A. Viglianti, PhD | **S** | | | | |
| 9/15/11 | Boston University Henry M. Goldman School of Dental Medicine | **S** | | | | |
| 9/15/11 | Michael Wilson, MD | **S** | | | | |
| 9/15/11 | Sandra Silver, PhD | **S** | | | | |
| 9/15/11 | Boston University Public Safety Department | **S** | | | | |
| 9/16/11 | Kenney Development Company | **S** | | | | |
| 9/19/11 | Boston City Councillors Tito Jackson, Felix Arroyo, Charles Yancey, Ayanna Pressley | **O** | X | X | | |
| 9/19/11 | Dr. Kath Hardcastle | **S** | | | | |
| 9/19/11 | Karsten Olejnik | **S** | | | | |
| 9/19/11 | BU Boston Medical Center | **S** | | | | |
| 9/20/11 | Kenneth King | **O** | X | | X | |
| 9/21/11 | Samuel M. Bauer | **O** | X | X | | |

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Research at BioSafety Levels should not commence without completion of the Final Supplementary Risk Assessment and full MEPA review** | **MEPA Public Hearing Should be held** | **BU has not provided full disclosure of incidents/ communication with the community** | **Location of NEIDL should not be in Boston or "other"** |
| 9/23/11 | Jeremy Gruber (Council for Responsible Genetics) | **O** | X | | X | |
| 9/23/11 | Linda K. Lukas | **S** | | | | |
| 9/23/11 | Steven P. Burgay | **S** | | | | |
| 9/26/11 | Massachusetts Water Resources Authority (MWRA) | **N** | | | | |
| 9/26/11 | Boston Imaging Core Lab | **S** | | | | |
| 9/26/11 | South Boston Community Health Center | **S** | | | | |
| 9/26/11 | Karen Freund, MD MPH | **S** | | | | |
| 9/27/11 | Conservation Law Foundation (CLF) | **O** | X | X | X | X |
| 9/27/11 | Spillane & Spillane, LLP | **S** | | | | |
| 9/27/11 | Metropolitan Area Planning Council (MAPC) | **N/O** | X (for BSL-3 and BSL-4 Research) | | | |
| 9/28/11 | Commonwealth of Massachusetts House of Representatives (Charles A. Murphy) | **S** | | | | |
| 9/30/11 | Representative Thomas A. Golden, Jr. | **S** | | | | |
| 9/30/11 | Representative Harold P. Naughton, Jr. | **S** | | | | |
| 10/4/11 | Alliance Detective and Security Service, Inc. | **S** | | | | |
| 10/4/11 | College Bound Dorchester | **S** | | | | |

| | | | Concerns Expressed | | | |
|---|---|---|---|---|---|---|
| **Date Received** | **Sender** | **Support Oppose Neutral** | **Research at BioSafety Levels should not commence without completion of the Final Supplementary Risk Assessment and full MEPA review** | **MEPA Public Hearing Should be held** | **BU has not provided full disclosure of incidents/ communication with the community** | **Location of NEIDL should not be in Boston or "other"** |
| 10/4/11 | Primitiva Tapia | **S** | | | | |
| 10/4/11 | MassHousing | **S** | | | | |
| 10/4/11 | Kimberly K. Russell-Lucas | **S** | | | | |
| 10/4/11 | Pat Augustine | **S** | | | | |
| 10/5/11 | Boston University School of Medicine & Metropolitan College Biomedical Laboratory and Clinical Sciences et. al. | **S** | | | | |
| 10/5/11 | Jian Huan Wu | **S** | | | | |
| 10/6/11 | Senator Sonia Chang-Diaz | **O** | X | | | |
| 10/11/11 | Seth D. Jaffe | **N** | | | | |
| 10/14/11 | Representative Gloria Fox | **O** | X | | | X |
| 10/19/11 | Anderson Kreiger, LLP | **O** | X | | X | |
| 10/20/11 | Representative Byron Rushing | **O** | X | X | | |
| N/A | Watertown Citizens for Environmental Safety | **O** | X | | X | |
| Various | Form Letters Opposed to Project (81) | **O** | | | | |
| Various | Form Letters in Support of Project (118) | **S** | | | | |
| Various | Cards in Support of Project (421) | **S** | | | | |

**Table A5-2: Response to individual MEPA Comment Letters in opposition to the NPC/Phase One Waiver Request**

| | | | | |
|---|---|---|---|---|
| 9/1/11 | Lynn Klotz | BSL-3 level research should not begin until court approves a risk analysis. BSL-1 and -2 research is an attempt to conduct BSL-3 research. | BSL-3 and BSL-4 research will not be conducted until the final Record of Decision on the Final Supplementary Risk Assessment is issued, and the MEPA SFEIR process is completed. BSL-1 and BSL-2 research is differentiated from BSL3 and BSL-4 research on many regulatory and procedural levels. Please see Appendix 11, Final Supplementary Risk Assessment (FSRA). | 01 |
| | | Allowing stimulant (sic) studies of non-contagious diseases will prove nothing, as they cannot mimic a lab worker spreading a contagious disease outside the lab.<br><br>[Attached an NRC article documenting escape of SARS virus from a worker in a BSL-3 lab.] | The *Culture of Safety* and numerous other protective measures have been adopted specifically to avoid an event where a lab worker could spread a "contagious disease" outside of the Laboratory.<br><br>Studies conducted at the NEIDL are subjected to a rigorous screening process, which includes public review. The established processes and regulatory requirements related to the selection and approval of research topics is described in the FSRA, and in Appendix 8 of the SFEIR. Studies at BSL-2 through BSL-4 must be approved by the CDC, Boston Public Health Commission and other agencies prior to commencement. | 02 |
| 9/2/11 | Michele Maniscalo | Hazardous nature of the pathogens to be studied and the density of the population surrounding the lab make it extremely risky to grant waivers without full review. | A thorough review of this matter has been conducted. The NIH FSRA document includes an exhaustive evaluation of the potential outcomes of siting the NEIDL in less densely populated areas. See Appendix 11.The Project Alternatives are also | 03 |

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| | | | discussed in Chapter 3 of the SFEIR. | |
| 9/13/11 | Shirley Kressel | BU has a history of laboratory safety violations, including the tularemia outbreak of 2004 and a history of misrepresenting facts about the NEIDL project to the community. | See Response 02 and Response 05 | 04 |
| | | [BPHC report on Tularemia outbreak in Boston attached to comment letter.] | BU has incorporated the recommended monitoring and oversight, as described in the report provided by Ms. Kressel. | 05 |
| | | Opposed to BU's efforts to open a bio-weapon research facility. | The NEIDL will not be operated as a bioweapons research facility. | 06 |
| 9/14/11 | Dot Walsh | Origins of Lyme disease need to be factored into MEPA's decision about the lab. | Lyme disease is classified by the CDC as BSL-2 research. The EOEEA granted Boston University a Phase One Waiver to begin BSL-2 research. See Response 02. | 07 |
| 9/13/11 | Nancy Seymour | Waiver would invite other developers to bypass the MEPA review process. Public hearing should be held for South End and Roxbury communities. | See Response 01. | 08 |
| 9/15/11 | Cat Bryant | BU has a history of circumventing community involvement. | See Response 02. | 09 |
| 9/19/11 | Boston City Councillors Tito Jackson, Felix Arroyo, Charles Yancey, Ayanna Pressley | As the NEIDL is an integrated laboratory facility with BSL-1 through BSL-4 lab spaces, work done in non-BSL-4 spaces could easily involve much more high risk material than would be the case at lower level security labs. BU has not provided any specific information on its waiver request about which pathogens would be studied at the NEIDL and what | The FSRA and the SFEIR include information about research that may be conducted at BSL-1 through BSL-4 levels. As mandated by Federal and State regulations, as BSL categorization increases, so does regulatory oversight and disclosure by the laboratory. See Response 02. | 10 |

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| | | work would be done by various labs that it contains. | | |
| 9/23/11 | Jeremy Gruber, Council for Responsible Genetics | Proliferation of BSL-2 labs does not justify a waiver; rather, they pose a great hazard due to the fact that they employ the largest number of researchers of any BSL, conduct research on the largest variety of organisms and pathogens, employ the least stringent training programs of any kind of biolab, and do not document or standardize their working practices. | Federal, State and local regulations govern the operation and safety of BSL-2 laboratories. | 11 |
| | | Tularemia in question is a Category A agent according to the CDC and a viable bioweapons agent, having been part of the US, Russian, and Japanese biological warfare programs. | See Response 02 and Response 05 | 12 |
| | | There have been no assurances from Boston University that BSL-3 research will not take place in BSL-2 facilities | Boston University will not conduct BSL-3 research until all permits and environmental reviews have been obtained and completed. All laboratory spaces will be utilized in accordance with these and existing approvals and any applicable Federal, State and local regulations. | 13 |
| | | General concern that BU is not open about activities and incidents at the NEIDL. | The "Culture of Safety" and many other measures implemented to ensure safe operation of the NEIDL laboratories are described in the FSRA and in the SFEIR. See Response 02. | 14 |

| | | | | |
|---|---|---|---|---|
| N/A | Watertown Citizens for Environmental Safety | The funding for these labs came through a program requiring research on bio-weapons agents. | This statement is false. See Appendix 11, and Chapter 2 of the SFEIR for a discussion of the history of the funding for the NEIDL project. | 15 |
| 9/27/11 | Conservation Law Foundation | BU has shown utter disregard for environmental and safety regulations. | See Response 02 and Response 05 | 16 |
| | | There has not been a good faith effort to produce a valid risk assessment. | The NIH has completed an exhaustive Supplementary Final Risk Assessment (SFRA). BSL-3 and BSL-4 research will not commence until the MEPA process and all other reviews have been completed and permits have been issued. | 17 |
| | | BU has failed to meet the regulatory requirement for issuance of a Phase One Waiver. | EOEEA issued a Final Record of Decision which approved a Phase One Waiver, and allowed research at BSL-2 levels to proceed with no further MEPA review. | 18 |
| | | The issuance of a Waiver for this project contravenes EOEEA's Environmental Justice Policy. | This notice was published in the Environmental Monitor. The comment period on the NPC/Phase One Waiver was extended. The MEPA process for the BioSquare Phase II NPC/Phase One Waiver Request has been consistent with that of similar projects in E.J. communities. Research at BSL-3 and BSL-4 levels will not proceed until all Federal, State and local approvals and reviews have been completed. | 19 |
| 10/14/11 | Representative Gloria L. Fox | Request for a notice of the "Supplemental Filing" to be published in the Environmental Monitor, and an additional comment period to commence. | The MEPA review was extended, and the actions were noticed in three separate editions of the Environmental Monitor. | 20 |

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|---|---|---|---|---|
| 10/19/11 | Anderson & Krieger, LLP | Concerns with BU attempt to obtain an "expedited review through rolling submissions. | See Response 20. | 21 |
| | | Request for a notice of the "Supplemental Filing" to be published in the Environmental Monitor, and an additional comment period to commence. | See Response 20. | 22 |
| 10/20/11 | Representative Byron Rushing | Concerns with BU's attempt to obtain an "expedited review through rolling submissions.<br><br>Request for a notice of the "Supplemental Filing" to be published in the Environmental Monitor, and an additional comment period to commence. | See Response 19. The MEPA review process has allowed for considerable public review as provided for in the MEPA statutes. | 23 |
| 09/20/11 | Kenneth King | General concern that BU is not open about activities and incidents at the NEIDL, citing cases of concealment of the tularameia "incidents".<br><br>[Article entitled "Germs Gone Wild was attached to Mr.King's letter.] | The "Culture of Safety" and many other measures which have been and will be implemented to ensure safe operation of the NEIDL laboratories are described in the FSRA and in the SFEIR. See Responses 02, 05, 11 and 12. | 24 |

BG

FORT POINT ASSOCIATES, INC.
33 Union Street
3rd Floor
Boston, Massachusetts 02108



August 30, 2011

RE: National Emerging Infectious Diseases Laboratories

Dear Reviewer:

You recently received a copy of a letter sent to Richard K. Sullivan, Jr., the Secretary of Energy and Environmental Affairs regarding the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University. The copy you received may not have included several graphics which were part of the appendices.

Please find attached the photo graphic entitled "Biosafety Level Operations" which is to be inserted at the end of Appendix A – Laboratory Biocontainment Safety Levels, and two maps entitled "Massachusetts BSL-3 Labs" and Boston/Cambridge BSL-3 Labs" which are to be inserted in Appendix B - BSL-3 Laboratories.

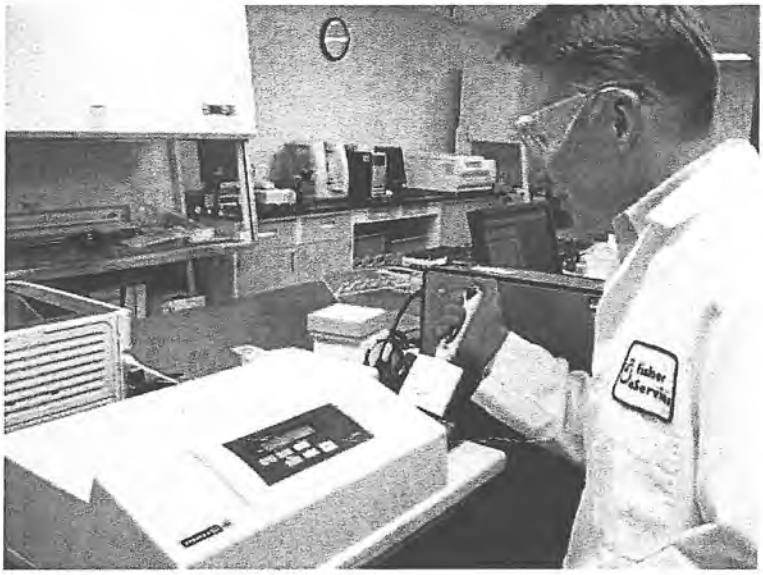
Please contact me at 617-357-7044 x204 if you have any questions regarding this document.

Regards,

Jamie M. Fay
President

# Biosafety Level Operations

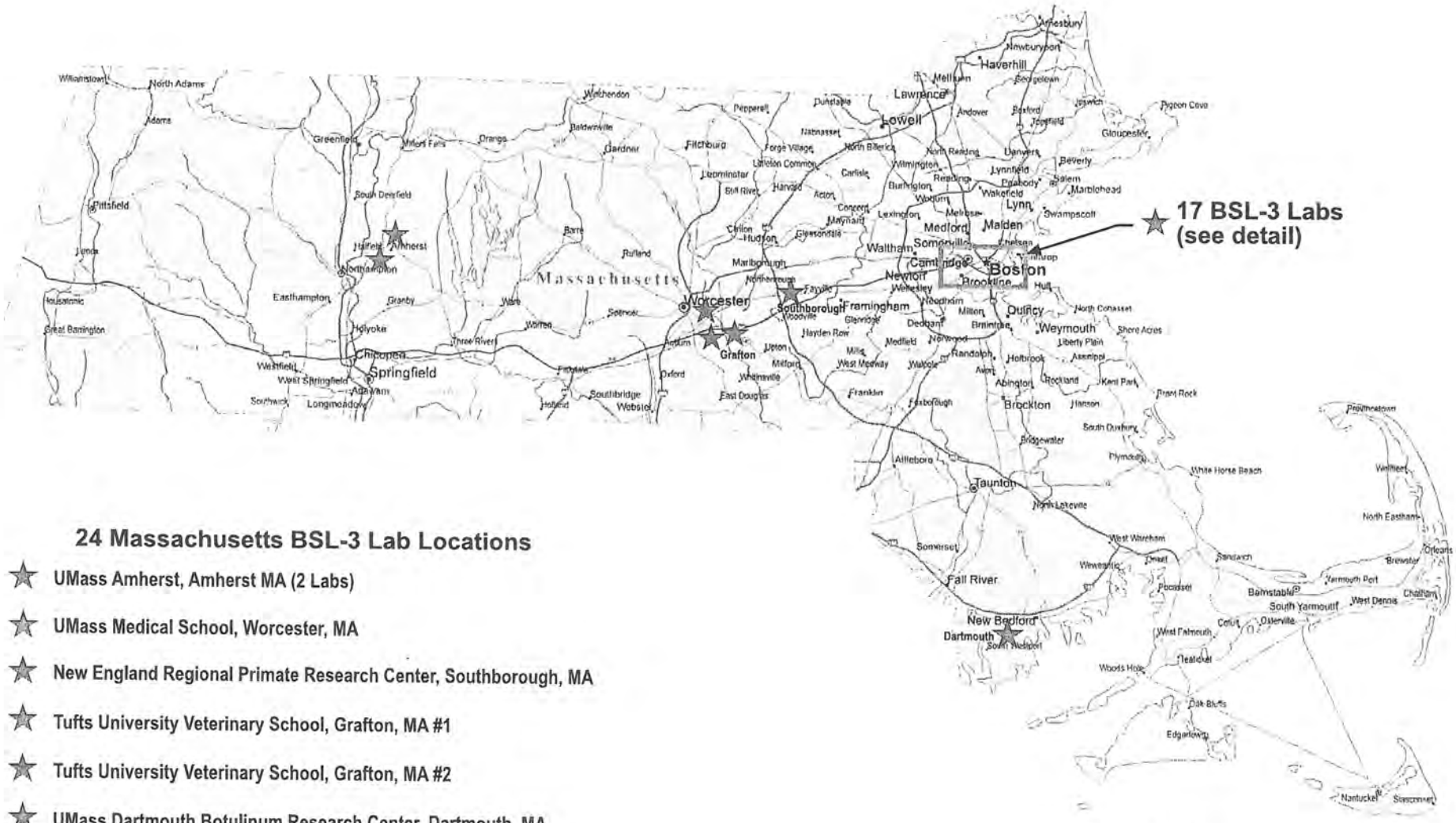
Typical BSL-2 Laboratory Operations



Typical BSL-3 Laboratory Operations

Typical BSL-4 Laboratory Operations

# Massachusetts BSL-3 Labs




## 24 Massachusetts BSL-3 Lab Locations

- UMass Amherst, Amherst MA (2 Labs)
- UMass Medical School, Worcester, MA
- New England Regional Primate Research Center, Southborough, MA
- Tufts University Veterinary School, Grafton, MA #1
- Tufts University Veterinary School, Grafton, MA #2
- UMass Dartmouth Botulinum Research Center, Dartmouth, MA
- Cambridge, MA (4 Labs- See Sheet 2)
- Boston, MA (13 Labs- See Sheet 2)

Sources: Board of Health - Amherst, Dartmouth, Grafton, Southborough, and Worcester

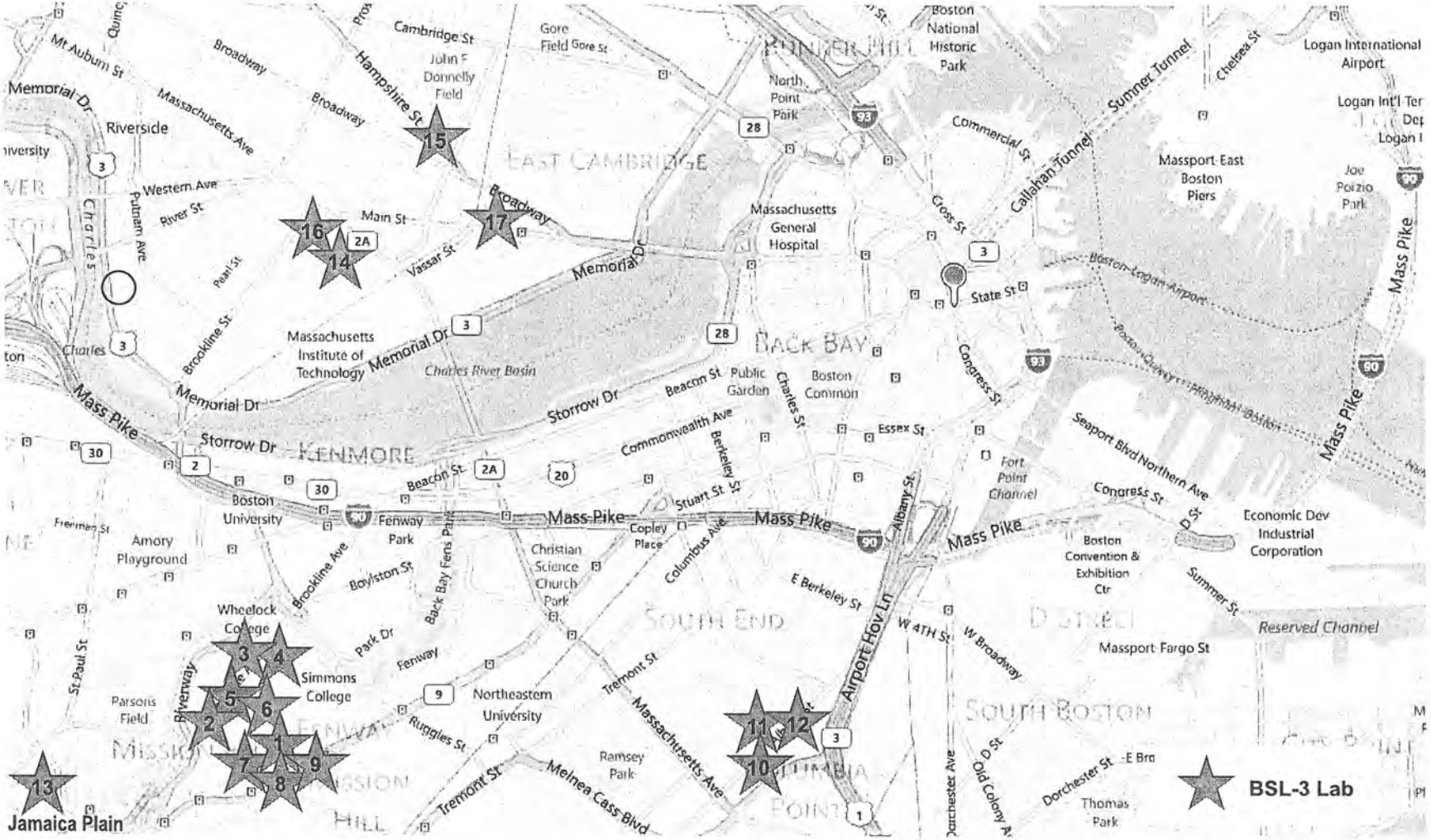
Sheet 1 of 2

August 24, 2011

BOSTON UNIVERSITY

Fort Point Associates, Inc.

# Boston/Cambridge BSL-3 Labs




## Boston

1. Immune Disease Institute
2. Brigham and Women's Hospital
3. Dana Farber Cancer Institute #1
4. Dana Farber Cancer Institute #2
5. Dana Farber Cancer Institute #3
6. Children's Hospital Medical Center
7. Harvard University Regional Center of Excellence
8. Harvard University School of Public Health #1
9. Harvard University School of Public Health #2

## Boston (con't)

10. Boston University #1
11. Boston University #2
12. Boston University #3
13. Massachusetts Department of Public Health

## Cambridge

14. Sanofi Pasteur Biologics
15. Idenix, Inc.
16. Novartis Vaccines and Diagnostics
17. Broad Institute



August 24, 2011

Sources: Boston Public Health Commission, Cambridge Public Health Commission

AICUM
Association of Independent Colleges and Universities in Massachusetts
11 Beacon Street
Suite 1224
Boston, MA 02108-3093
617.742.5147
www.aicum.org



August 30, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

The Association of Independent Colleges and Universities in Massachusetts (AICUM) represents the interests of 60 independent colleges and universities throughout Massachusetts, the 250,000 students who attend those institutions and the nearly 100,000 employees who work at those institutions. Our members include large nationally renowned research universities, smaller, highly regarded liberal arts colleges, religiously affiliated institutions, and colleges with special missions focused on business or music or allied health services.

As AICUM's president, I write to express our support for Boston University's request to permit the National Emerging Infectious Disease Laboratory (NEIDL), which is part of a national network of secure facilities that study diseases of major public health concern. Construction of the facility located on Boston University's Medical Campus was completed in 2008, so it is now time for the research to begin in this $200,000,000 research facility.

Boston University's request to open BSL-2 and BSL-3 laboratories for research is both a reasonable and responsible approach to the permitting of this research center. There are hundreds of BSL-2 labs on the Boston University campus and thousands more throughout the Commonwealth. Boston University now operates three of the twenty-three permitted BSL-3 laboratories in the state.

The City of Boston has strict operating requirements for these labs. The Boston Public Health Commission and the public safety departments in the City are extremely capable of handling the commissioning and oversight for these laboratories.

The fact that MEPA has never denied a permit in any of the twenty-three existing BSL-3 laboratories in the state speaks directly to the issue of public safety of these labs. They are safe and Boston University has the proven capability to operate these labs safely and securely.

To further delay the needed research in this state-of-the-art facility is a waste of the taxpayers' monies, delays vital research projects and has the potential to cost the Commonwealth millions of dollars in grants. For these reasons, and because the NEIDL research can save lives and invent cures for deadly infectious diseases, I support the waiver application.

Mr. Secretary, I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Richard Doherty

Richard Doherty
President
AICUM, Inc.

BOSTON PUBLIC HEALTH COMMISSION

Building a Healthy Boston

RECEIVED

AUG 31 2011

MEPA

August 30, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing to support Boston University's Phase One waiver application to open BSL-2 and BSL-3 laboratories in the NEIDL building. The NEIDL is well suited to support laboratory research that does not involve the use of the BSL-4 Laboratory and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories.

The Boston Public Health Commission has detailed protocols and permitting processes in place that regulate BSL-2 research using RDNA and all BSL-3 and BSL-4 laboratories operating in the city. Our inspectors are well-trained and our work is coordinated with other city departments, including the Fire Department and Inspectional Services. The City of Boston feels confident that our current regulations and our coordinated permitting, inspecting, and enforcement practices are sufficient to ensure the continued safety of our BSL laboratories.

We ask that the MEPA process not be used to delay the opening of the BSL-2 and BSL-3 laboratories in the NEIDL; these labs should be allowed to open once they have completed the city's permitting requirements. Our support for the waiver application acknowledges the vital research that will occur in these laboratories and the importance of initiating activity in a building that was designed to allow for safe investigations.

I am happy to review with you our existing regulations and requirements and hope that you will approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Barbara Ferrer

Barbara Ferrer, Ph.D., MPH, M.Ed
Executive Director

OFFICE OF THE EXECUTIVE DIRECTOR
1010 MASSACHUSETTS AVENUE · BOSTON, MASSACHUSETTS, 02118 · P: 617-534-5264 · F: 617-534-7165 · WWW.BPHC.ORG

## Gage, Bill (EEA)

**From:** Vallely Bartlett, Maeve (EEA)
**Sent:** Tuesday, September 06, 2011 11:13 AM
**To:** Gage, Bill (EEA)
**Subject:** FW: Boston University's request to conduct research at the NEIDL
**Attachments:** SARS in the City-Gene Watch published version.docx

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**From:** Sullivan, Rick (EEA)
**Sent:** Thursday, September 01, 2011 10:14 AM
**To:** Vallely Bartlett, Maeve (EEA)
**Subject:** Fw: Boston University's request to conduct research at the NEIDL

Let's talk

---

**From:** Lynn Klotz [mailto:lynnklotz@live.com]
**Sent:** Thursday, September 01, 2011 08:12 AM
**To:** Sullivan, Rick (EEA)
**Cc:** Hardaway, Kathleen (EEA)
**Subject:** Boston University's request to conduct research at the NEIDL

To: Secretary Richard Sullivan
Executive Office of Energy and Environmental Affairs
rick.sullivan@state.ma.us

cc: Kathleen Hardaway
kathleen.hardaway@state.ma.us

Dear Secretary Sullivan,

Under no circumstances should the Boston University National Emerging Infectious Disease Laboratory (NEIDL) be allowed to conduct BSL3 level research until a risk analysis has been approved by the courts. Personally, I doubt that the courts will approve any risk assessment along the lines of TetraTech's assessment currently underway.

I am attaching an article that I recently published on the NEIDL risk assessment attempts. In that article, I quote a National Research Council recounting of an escape from a BSL3 laboratory of the deadly and highly contagious SARS virus through an infected lab worker. The escape resulted in deaths of people outside the laboratory.

My further concern is the Boston University is trying a back-door way into conducting dangerous BSL3 research at the NEIDL by petitioning you to allow lower level BSL1/2 research, and (from what I have been told) to allow stimulant studies of accidental releases from the laboratory. A release of a non-contagious stimulant will prove nothing. For example, it cannot mimic a lab worker spreading a contagious disease outside the lab.

Sincerely yours,

## GENEWATCH

**SARS IN THE CITY**
By Lynn C. Klotz

Within a matter of weeks in early 2003, severe acute respiratory syndrome (SARS) spread from the Guangdong province of China to rapidly infect individuals in some 37 countries around the world. The brief epidemic infected more than 8,000 people and killed nearly 800, almost 10% of those infected. Fortunately, timely public-health actions, such as isolation of victims, stopped SARS before it became a world-wide epidemic. It is gone from nature, at least for now. We dodged a world-wide epidemic.

But SARS lives on, imprisoned in BSL3 and BSL4 laboratories around the world, and has already escaped more than once through infected lab workers. If we experience another SARS epidemic, many scientists feel that it will have started from a laboratory escape.

An escape of a highly contagious pathogen from a lab in a city is more likely to seed an epidemic; and this time, we may not be able to dodge it. What if a lab researcher is infected with a highly contagious deadly disease that is transmitted by casual contact, a victim's cough or from contaminated surfaces? Besides SARS, the 1918 pandemic flu also comes to mind. The Boston University National Emerging Infectious Disease Laboratory likely will research SARS and the 1918 pandemic flu.

Under the reasonable assumption that employees tend to live near where they work, the probability of an epidemic would be far greater from an infected employee living and working in or near Boston. For instance, the number of casual contacts with strangers will be sizeable for an infected researcher taking public transportation, a likely way to commute. Transmission of infection to others, called secondary infections, would be almost impossible to trace. For a laboratory located in the suburbs or rural area, most employees would drive, so their daily casual contacts with strangers would be fewer, and there is at least some chance of tracing others exposed.

Tetra Tech, a world-wide consulting firm, was hired by the National Institutes of Health to carry out yet another risk analysis for the BU NEIDL. The analysis is in progress. This is BU's third attempt at a believable risk analysis for their lab. It is worthwhile to review the history of risk assessments for the BU lab.

Attempt number one: This 2004 risk analysis considered only one accident scenario and only one pathogen, a small anthrax spill in the laboratory. A number of lawsuits brought by residents of Roxbury, the largely African-American Boston neighborhood and the site of the NEIDL, challenged the certification of the risk analysis by the Massachusetts' Executive Office of Environmental Affairs (EOEA). In 2006, a Superior Court judge deemed the certification "arbitrary and capricious" and ordered the BSL4 laboratory not to open until an acceptable risk analysis was carried out.

Attempt number two: The NIH then set out on its own risk analysis, which it unveiled in 2007. The analysis was comprised of fifteen pdf files-with dozens of photographs, drawings, graphs and statistics-that gave the impression of a precise and effort-laden risk analysis. But it takes only a quick scan of the many files to realize that the whole analysis was set up to give the answer BU wanted, namely that the inner city Roxbury location for the lab was acceptable, not only acceptable but the safest location for the laboratory.

Here is how NIH reached this suspect conclusion: As ordered by the Superior Court, they did consider alternative sites in Massachusetts besides densely populated Roxbury, namely Tyngsborough (a BU-owned suburban site) and Peterborough (a BU-owned rural site). The deadly and contagious viruses chosen for the analysis were ebola, sabia, monkeypox and Rift Valley fever. These choices addressed another criticism of the first risk analysis that no contagious pathogens were considered. (Anthrax is not contagious.) So far, all fine and good.

These are all "exotic" viruses (to use the NIH terminology) but represent no present or likely future public-health threat to the United States. The only scenario that NIH chose to analyze was a single researcher infected at work with one of the four exotic viruses, and then bringing his/her infection home. The viruses are only mildly contagious, so intimate contact is required for transmission. Symptoms appear quickly so patients can be diagnosed and precautions taken, unlike the HIV/AIDS virus that can silently infect large numbers of victims without anyone being aware.

Since the viruses would likely infect only family members, health care providers and others in intimate contact with the initial victim, the number of secondary infections would be similar no matter where the victim lives or works, so population density at the victim's home or laboratory workplace would not much matter. NIH asked only the question that would give them the answer they wanted. Location is nothing, to reverse the common real-estate mantra.

But how does urban Roxbury become the safest site? The answer lies in Rift Valley fever virus, which is transmitted by mosquitos from cattle and other farm animals to humans. Even though many of Boston's streets were laid out by cattle in colonial times, there are no cattle there now. So Rift Valley fever virus would infect more people in suburban or rural settings where farm animals live. Urban Roxbury then becomes the safest place for the NEIDL compared to suburban and urban locations.

Between the first and second risk-analysis attempts, Massachusetts changed governors from Mitt Romney to Deval Patrick and the management of EOEA changed as well. The new EOEA folks made a smart move. They realized that they did not have the background to understand the issues, so they asked the National Academy of Sciences to appoint a National Research Council (NRC) committee of experts to critique the risk analysis. The NRC committee delivered their detailed critique in late 2007, concluding that the NIH analysis was not sound and credible, that the worst case scenarios had not been adequately identified, and that the information underlying the alternative site analysis was insufficient or inappropriate. The critique also questioned the infectious agents selected.

Now back to the in-progress Tetra Tech risk analysis. Tetra Tech presented its preliminary results to local residents at the Roxbury Community College in October 2010. Among its findings was that a secondary infection of SARS to someone outside the lab from a lab researcher would occur once in 10,000 years in a worst-case scenario, and likely only once in over a million years. Tetra Tech looked at only two scenarios, a centrifuge accident and a massive earthquake that would level the laboratory. They did not look at the risk of a SARS-infected lab worker, unaware he/she was infected, transmitting the infection to someone outside the laboratory.

The NRC committee commenting on the Tetra Tech preliminary work concluded "at this point in time it cannot endorse the illustrative analyses presented as scientifically and technically sound or likely to lead to a thorough analysis of the public health concerns previously raised by the NRC." The committee also noted "Consideration of the available case studies (such as the SARS case described below) suggests the possibility that transfer of a pathogen outside the laboratory by an infected worker is an important class of risk events."

There have been at least three SARS escapes from laboratories through infected lab workers. The incident from the NRC 2010 document quoted below warns of the danger of a future SARS escape in a densely populated area:

> "In China, SARS/CoV was grown in a BSL-3 laboratory by a worker who apparently had worn inappropriate personal protective equipment (PPE) and then treated the sample to inactivate the virus before removing it to a BSL-1 laboratory for further work on the open bench. The worker failed to verify the complete inactivation of the virus and subsequently became ill and was admitted to a fever hospital. The laboratory was not notified of this development and the worker later returned to the laboratory. A second worker who handled the "inactivated" sample also became ill. A graduate student who observed the laboratory procedure later traveled by train to her home several hundred miles away. After returning to the laboratory she became ill and once again traveled to her home by train where her mother, a physician, admitted her to a hospital and treated her. The student was asked if she worked with SARS/CoV (she said no because her research involved another virus). It was not until the mother became ill and died that SARS/CoV was identified. Other laboratory workers also became ill and other hospital personnel died. This case study illustrates several important points: people make mistakes (improper PPE); not everyone follows procedures (failure to test sample for inactivity); people may die if not properly diagnosed and treated."[1]

Another message from this story is that research on deadly, highly contagious pathogens should be conducted only in BSL4 laboratories in isolated locations where extra precautions in addition to location are available, never in a populated area since SARS has also escaped from a BSL4 laboratory.

How many bites of the apple will Boston University have before they realize that a BSL4 Laboratory in densely populated Boston is a bad and dangerous idea? When will the city or state step up and say "No! No BSL4 lab in Boston," following Cambridge's lead?

***Lynn C. Klotz is co-author of*** Breeding Bio Insecurity: How U.S. Biodefense Is Exporting Fear, Globalizing Risk, and Making Us All Less Secure. *He is working with scientists and Roxbury residents to propose an alternative vision for the Boston University labs.*

BG

COBTH
CONFERENCE OF BOSTON TEACHING HOSPITALS

11 Beacon Street, Suite 710
Boston, MA 02108
Phone: 617-723-6100
Fax: 617-723-6111
www.cobth.org



September 1, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

On behalf of the Conference of Boston Teaching Hospitals (COBTH), I am writing to support Boston University's Phase One waiver application to open BSL-2 and BSL-3 laboratories in the National Emerging Infectious Disease Laboratory (NEIDL) building. The NEIDL is well suited to support laboratory research that does not involve the use of the BSL-4 Laboratory and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories.

COBTH worked closely with the Boston Public Health Commission on its BSL-2, BSL-3 and BSL-4 regulations and we are confident that those regulations and protocols, under which our hospital laboratories operate, provide the necessary safeguards and reporting procedures to ensure the safety of these laboratories. We ask that the MEPA process not be used to further delay the operation of the BSL-2 and BSL-3 laboratories in the NEIDL.

Boston is home to many medical research milestones and the top five hospital recipients of National Institutes of Health funding are COBTH-member hospitals. As centers for research, we know firsthand the impact that research has on the local and regional economy, but more importantly on patients and their families. Boston University's request for a waiver is a reasonable approach that will enable critical research to be conducted safely in this state of the art facility. It will also send a clear message to the research community that the Commonwealth is willing to take the necessary steps to support this research.

I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

John Erwin
Executive Director

## Gage, Bill (EEA)

**From:** Hardaway, Kathleen (EEA)
**Sent:** Tuesday, September 06, 2011 4:42 PM
**To:** Vallely Bartlett, Maeve (EEA); Gage, Bill (EEA)
**Subject:** FW: Boston University Waiver Request

Kathleen Hardaway
Executive Assistant to Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114
(617) 626-1015
Email: Kathleen.Hardaway@state.ma.us

---

**From:** Michele Maniscalco [mailto:checkerboardchatter@yahoo.com]
**Sent:** Friday, September 02, 2011 3:44 PM
**To:** Sullivan, Rick (EEA); Hardaway, Kathleen (EEA)
**Subject:** Boston University Waiver Request

Dear Secretary Sullivan:

I am writing today because I strongly oppose Boston University's Phase I Waiver Request to open the BSL 1 and 2 labs immediately, and to open the BSL level 3 lab without a MEPA review of the completed Supplemental Environmental Impact Report. Because of the extremely hazardous nature of the pathogens to be studied and the density of the population surrounding the lab site, which hapens to be four blocks from my home, I consider it an unacceptable risk to take any shortcuts in the environmental impact review.

Approval of Boston University's waiver request would create a dangerous precedent for developers to bypass the MEPA risk assessment process.

I urge you to deny the waiver request, and I also request that your office hold a public hearing on the Phase 1 Waiver request before issuing a draft decision. This hearing should be scheduled at a location and time of day that is convenient and accessible to working members of the public, especially those in the affected South End and Roxbury communities.

Yours truly,

Michele D. Maniscalco
100 West Concord Street, #4
Boston, MA 02118
checkerboardchatter@yahoo.com

BG

RECEIVED

SEP 19 2011

MEPA

September 14, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am writing to provide my support for the BU NEIDL petition to grant a waiver that would allow the NEIDL to operate and conduct BSL-2 and BSL-3 research.

I am currently a Professor in the Department of Medicine, Section of Infectious Diseases and in the Department of Microbiology at Boston University School of Medicine. I am also the Director of Research in the Section of Infectious Diseases. I am also the principal investigator on several NIH funded research projects focused specifically in the area of infectious diseases and the host immune response to these organisms. My academic accomplishments are also exemplified by my service on numerous varied and diverse study sections through the Center for Scientific Review at the NIH. I have also served as the Chair of the study section reviewing the Center of Biomedical Research Excellence (COBRE) grants. The COBRE grants support thematic multidisciplinary centers that augment and strengthen institutional biomedical research. I have also served on numerous special emphasis study sections at the Institute level. I have also reviewed grant applications for diverse national and international private foundations in the area of infectious diseases.

During my tenure at Boston University I have also served as a member of the Instuitional Biosafety Committee (7 years) and as Chair of the IBC for 3 years. In this capacity I interfaced with numerous safety committees at BU and BMC, principal investigators, scientists, as well as members of the Boston Public Health Commission. Thus I feel I am well qualified to provide my strong support for this waver.

Boston University is a major research institute that safely operates 350 BSL-2 and three BSL-3 laboratories on its campus. There is nothing unique or inherently dangerous about BSL-2 or BSL-3 laboratories and BU has the expertise to operate these laboratories.

There are stringent regulations in place for the operation for BSL-2 and BSL-3 laboratories. In the case of the BSL-3 labs, the City of Boston and the federal government both require exhaustive reviews before a laboratory can be commissioned.

Boston University has a record of safely operating its BSL-2 and BSL-3 laboratories. Boston Public Health Commission's Executive Director Barbara Ferrer recently wrote a letter of support for the waiver to the EOEEA saying, "The NEIDL is well suited to support laboratory research...and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories."

The NEIDL is a state-of-the-art facility that cost $200,000,000, and it is a waste of taxpayers' money not to have this facility operating.

A refusal of the waiver essentially establishes new levels of review that have not been applied to existing labs in the Commonwealth. Currently, there are thousands of BSL-3 labs across the country. A new review standard would essentially place the Commonwealth at competitive disadvantage against these other labs.

In closing, I would like to stress that basic biomedical research in the area of emerging infectious diseases is essential so that that new cures can be found, and ultimately lives saved.

If I can provide you with any additional information, please don't hesitate to contact me at 617- 414-5305.

Sincerely,

Caroline Attardo Genco, PhD
Research Director Section of Infectious Diseases
Professor
Department of Medicine, Section of Infectious Diseases
Department of Microbiology
Boston University School of Medicine
Boston MA, 02118
phone 617-414-5305
fax 617-414-5280
Email cgenco@bu.edu

BG

Leadership is our business

**Associated Industries of Massachusetts**
222 Berkeley Street | P.O. Box 763
Boston, MA 02117-0763

www.aimnet.org | 617.262.1180 | fax 617.536.6785



September 6, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

**RE: AIM Support of Phase One Waiver – BioSquare Phase II**

Dear Secretary Sullivan:

Associated Industries of Massachusetts (AIM) is the largest employer association in Massachusetts. AIM's mission is to promote the well being of its thousands of members and their employees and the prosperity of the Commonwealth by improving the economic climate, proactively advocating fair and equitable public policy and providing relevant reliable information and excellent services.

I am writing to express AIM's support for Boston University's request to permit the National Emerging Infectious Disease Laboratory (NEIDL) and, specifically, its application for a Phase One waiver under the provisions of 301 CMR 11.11 allowing the NEIDL building located within the BioSquare Phase II project to be used for laboratory research that does not involve the use of the BSL-4 Laboratory.

Boston University's request to open BSL-2 and BSL-3 laboratories for research is both a reasonable and responsible approach to the permitting of this research center. The City of Boston has strict operating requirements for these labs and the Boston Public Health Commission and the public safety departments in the City are extremely capable of handling the commissioning and oversight of these laboratories. In addition, Boston University is well equipped to operate these labs - there are hundreds of BSL-2 labs on the Boston University campus and Boston University now operates three of the twenty-four permitted BSL-3 laboratories in the state.

Many of our members operate in biotech, pharmaceutical, life sciences and similar areas. They chose Massachusetts because we are one of the leading areas in the world for research and innovation and we are home to world renowned institutions of higher learning, including Boston University. The Biosafety Lab will be an important component in this area, complimenting and expanding upon all of the work that BU and other universities do on a daily basis.

Further delay of the needed research in this state-of-the-art facility is a waste of the taxpayers-monies, hinders vital research projects and has the potential to cost the Commonwealth millions of dollars in grants. The MEPA process should not be used to delay the opening of the BSL-2 and BSL-3 laboratories in the NEIDL; these labs should be allowed to open once they have completed the city's permitting requirements. If BSL-3 laboratories are subject to review under MEPA, with the attendant delay and uncertainty, Boston could lose further opportunities to attract world class companies interested in adding jobs in Boston.

For these reasons AIM supports Boston University's waiver application.

Please do not hesitate to contact me if you have any questions.

Sincerely yours,

Richard C Lord

Richard C. Lord
President and
Chief Executive Officer

GREATER BOSTON CHAMBER

265 FRANKLIN STREET, BOSTON, MA 02110-3113

617.227.4500 FAX 617.227.7505 bostonchamber.com

BG

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SEP 9 2011

MEPA

Greater Boston Chamber
The Hub of Business

September 7, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

On behalf of the Greater Boston Chamber of Commerce, I am writing to support Boston University's Phase One waiver application to open BSL-2 and BSL-3 laboratories in the National Emerging Infectious Disease Laboratory (NEIDL) building.

The Chamber has supported Boston University's efforts to launch the NEIDL facility since the time of its initial application to the National Institutes of Health, and continues to advocate for the commencement of research activities at this facility for the following reasons:

Facility Safety: The NEIDL is a state-of-the-art facility and its laboratories have undergone extensive design and review processes in order to allow for safe investigations on infectious disease. In addition, Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories.

Strong Regulation: The Boston Public Health Commission has detailed protocols and permitting processes in place that regulate BSL-2 research using RDNA and all BSL-3 and BSL-4 laboratories operating in the city. It is the Chamber's understanding that these stringent regulations coupled with coordinated permitting, inspecting, and enforcement practices are sufficient to ensure the continued safety of the city's BSL laboratories.

Vital Research: Enabling infectious disease research to commence at the NEIDL will hasten the development of potentially life-saving therapies and treatments, while helping to solidify Greater Boston's reputation as a global center of cutting-edge research and development.

Job Creation – Research activities at the NEIDL will help to support hundreds of local jobs ranging including environmental services, lab technicians, scientists and administrative staff, at a time of sluggish job growth both locally and nationally.

The Chamber has long supported and worked for a regulatory climate that promotes research and innovation while ensuring public safety and awareness. Maintaining such a balance is critical to advancing the region's ability to compete for new life science jobs, public and private investment, and partnership opportunities – and to preserving the leadership of Massachusetts' world-renowned life science cluster. As such, the Chamber believes that the BSL-2 and BSL-3 laboratories in the NEIDL should be allowed to open once they have completed the city's permitting requirements, rather than subjecting them to a MEPA review process.

I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Paul Guzzi

Paul Guzzi
President & CEO

BG

MAUREEN E. FEENEY
BOSTON CITY COUNCIL



September 8, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am writing to express my strong support for Boston University's waiver request to open the National Emerging Infectious Diseases Laboratories (NEIDL).

Boston University's request to open the NEIDL for BSL-2 and BSL-3 research is both reasonable and responsible. Hundreds of laboratories currently operate BSL-2 research across the Commonwealth. Boston University not only operates BSL-2 laboratories on its campus, but also hosts three of the 24 permitted BSL-3 laboratories in Massachusetts. These laboratories are safe and BU has proven itself capable of operating these labs safely and securely.

To this day, MEPA has never required such a review of any of the existing BSL-3 laboratories in the state. This is a testament to the public safety and security of these labs, which is a priority for me as a Boston City Councillor. In fact, the City Council passed new legislation in 2006 which requires that every research facility registers its laboratories with the City of Boston, and documents its hazardous materials and chemicals so that first responders are prepared. With the City of Boston's strict operating requirements and under the supervision of the Boston Public Health Commission and our public safety departments, I am confident that research in the NEIDL can be conducted in a safe and secure manner.

DISTRICT 3
BOSTON CITY HALL, ONE CITY HALL SQUARE, BOSTON, MASSACHUSETTS, 02201
617-635-3455 FAX: 617-635-3734 Maureen.Feeney@cityofboston.gov

I would like to see this state-of-the-art $200,000,000 facility put to good use. The research that would be conducted in the NEIDL can lead to cures that can save lives. In addition, this facility has the potential to bring in millions of dollars in research grants to Boston. I do not want to see these ends jeopardized, which is why I urge you to approve the waiver request.

Thank you.

Sincerely,

Maureen Feeney

Maureen E. Feeney
Boston City Councillor

DISTRICT 3
BOSTON CITY HALL, ONE CITY HALL SQUARE, BOSTON, MASSACHUSETTS, 02201
617-635-3455 FAX: 617-635-3734 Maureen.Feeney@cityofboston.gov

## Gage, Bill (EEA)

**From:** Vallely Bartlett, Maeve (EEA)
**Sent:** Tuesday, October 11, 2011 12:33 PM
**To:** Gage, Bill (EEA)
**Subject:** FW: voice from the past

Late-but we should add to our list.

-----Original Message-----
From: Elizabeth R. Simons [mailto:esimons@bu.edu]
Sent: Saturday, October 08, 2011 2:41 PM
To: Vallely Bartlett, Maeve (EEA)
Subject: Fwd: voice from the past

Sorry - typo in your e mail address.

----- Forwarded message from esimons@bu.edu -----
Date: Sat, 08 Oct 2011 14:38:31 -0400
From: "Elizabeth R. Simons" <esimons@bu.edu>
Reply-To: "Elizabeth R. Simons" <esimons@bu.edu>
Subject: voice from the past
To: Maeve.Vallely.Bertlett@state.ma.us

Hi, Maeve,
In getting ready to write re BU's request to carry our BSL-2 and BSL-3 research in the NEIDL, imagine my surprise at finding you as the suggested addressee. Many years ago you lived across Chestnut Street from us and were a friend and classmate of my daughter Lee. I'm still living at 117 Chestnut St. and still on the faculty at BUSM. Lee lives outside Chicago, has a 17yr old daughter and a 15yr old son, is changing careers from hi-powered MBA Health Care Administration to MA in consulting.
As to the NEIDL, my research is on tuberculosis, handling of which requires BSL-3, and has been completely frustrated by the inability to carry it out. The NEIDL has the instrument I need (and specified), a lab where the work could be done if it only were permitted to work there. The potential of our studies, in view of the world-wide increased threat of TB, especially multi-drug resistant variants, is huge. I'd like to get them under way while I am still able to do so, hence this plea.
Best regards
Elizabeth R. Simons

Elizabeth R. Simons, Ph.D.
Professor of Biochemistry
Boston University School of Medicine
72 E. Concord Street, K407
Boston, MA 02118
617-638-4332 phone
617-638-5339 FAX
esimons@bu.edu
ersimons@earthlink.net

----- End forwarded message -----

Elizabeth R. Simons, Ph.D.
Professor of Biochemistry

Boston University School of Medicine
72 E. Concord Street, K407
Boston, MA 02118
617-638-4332 phone
617-638-5339 FAX
esimons@bu.edu
ersimons@earthlink.net

LEHIGH UNIVERSITY

Alan J. Snyder
*Vice President and Associate Provost*
*for Research and Graduate Studies*

305 Sinclair Laboratory
7 Asa Drive
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610-758-6120 Fax: (610) 758-5810
e-mail: ajs410@lehigh.edu
*www.lehigh.edu/~inresrch/index.html*

BG

September 9, 2011

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SEP 13 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing as a member of the scientific community to express my support for prompt commencement of the very important work of the National Emerging Infectious Disease Laboratory (NEIDL). I am presently Vice President and Associate Provost for Research and Graduate Studies at Lehigh University. I was previously Interim Vice Dean for Research and Graduate Studies at the Penn State College of Medicine.

Specifically, I am writing in favor of Boston University's application for a Phase One waiver under the provisions of 301 CMR 11.11 allowing the NEIDL building located within the BioSquare Phase II project to be used for laboratory research that does not involve the use of the BSL-4 Laboratory. At a time in which we seek to use every research dollar as wisely as possible, and in which emerging infectious disease is among the major threats to human life, well being and productivity, it is time for the work to begin in this $200,000,000 research facility.

There are 24 BSL-3 laboratories in the Commonwealth of Massachusetts, seventeen of which are in the City of Boston and three of which are at Boston University. There are, as you know, hundreds of BSL-2 laboratories at BU alone. It is eminently reasonable and responsible to begin permit operation of the BSL-2 and BSL-3 laboratories within a university, city and commonwealth with such deep experience in, and capacity for, their safe and productive operation. I understand that MEPA has previously determined that none of the twenty-four existing BSL-3 laboratories in the state posed the kind of risk that would warrant MEPA review. Thus, MEPA's own assessment supports the view that Boston University has the proven capability to operate these labs safely and securely.

As a national biomedical and pharmaceutical innovation hub, it makes sense that the Boston area would have the concentration of BSL laboratories that it does. In this regard, delays and uncertainties are concerning. We depend upon technology hubs as a source of the innovations that employ people in productive, societally beneficial work, and we all depend upon the products of such work. In this regard, uncertainty as to how or whether eminently qualified scientists and administrators can obtain permission to operate an important laboratory is distressing.

Mr. Secretary, I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Dr. Alan J. Snyder

BG

DANA-FARBER CANCER INSTITUTE | BRIGHAM AND WOMEN'S HOSPITAL

Judy E. Garber, M.D., M.P.H
Director, Center for Cancer Genetics & Prevention
Department of Medical Oncology
Professor of Medicine
Harvard Medical School

Dana-Farber Cancer Institute
450 Brookline Avenue
Boston, Massachusetts 02215-5450
617.632.2282 tel
617.632.2649 fax
judy_garber@dfci.harvard.edu
www.dana-farber.org

RECEIVED
SEP 9 2011
MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am a breast oncologist and clinical cancer geneticist at the Dana Farber Cancer Institute and Professor of Medicine at Harvard Medical School. This year, I am president of the American Association for Cancer Research, the largest organization of cancer researchers in the world.

I understand that Boston University is asking the Commonwealth of Massachusetts to grant a waiver to allow the National Emerging Infectious Disease Laboratories (NEIDL) to conduct BioSafety Level (BSL)-2 and 3 research.

Hundreds of BSL-2 and BSL-3 labs currently operate safely in the state. A refusal of the waiver essentially establishes new levels of review that have not been applied to existing labs in the Commonwealth. Currently, thousands of BSL-3 labs exist across the country in universities and in industry. A new review standard would essentially place the Commonwealth at competitive disadvantage against these other labs.

Boston University is a major research institute that currently operates 350 BSL-2 and three BSL-3 labs on its campus. BU has the expertise to operate these labs which are neither unique nor inherently dangerous. Stringent regulations govern the operation for BSL-2 and BSL-3 labs. City and the federal government both require extensive reviews before a BSL-3 lab can be commission. I understand that Boston Public Health Commission's Executive Director Barbara Ferrer recently wrote a letter of support for the waiver to the EOEEA, based on BU's exemplary record of managing these laboratories.

The NEIDL is a state-of-the-art facility that cost $200,000,000, and not to have this facility operating is a waste of taxpayers' money. Furthermore, research on emerging infectious diseases could lead to effective diagnostics and therapeutics and saving lives.

I fully support a waiver for BU to allow the NIDL to conduct this important research, and appreciate your consideration of their application.

Sincerely,

Judy E. Garber, MD MPH

BG

HARVARD UNIVERSITY
Office of the Provost

Massachusetts Hall
Cambridge, Massachusetts 02138

t.617.496.5100
f.617.495.8550

September 9, 2011

RECEIVED
SEP 21 2011
MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: National Emerging Infectious Disease Laboratories BioSquare Phase II, Boston, MA (EOEEA # 12021)

Dear Secretary Sullivan:

We are writing in connection with Boston University's proposed National Emerging Infectious Disease Laboratory (NEIDL) and, specifically, its application for a Phase One waiver under the provisions of 301 CMR 11.11 allowing the NEIDL building located within the BioSquare Phase II project to be used for laboratory research that does not involve the use of the BSL-4 Laboratory. As the regulatory process continues regarding the proposed full scale program of the NEIDL facility, we support the commencement of the more limited but important research this waiver application seeks to allow.

The Boston metropolitan area is populated with the highest density of biomedical research laboratories in the country. Therapies that are being administered to patients around the world have emerged from the inventive culture created by our unmatched life science cluster here in Massachusetts and in Boston specifically. Across Boston, the kind of experimentation BU seeks to embark upon with this waiver is being pursued and adding to our basic understanding of disease in ways that will improve the lives of citizens around the world for years to come. This biomedical research cluster also is a critical economic engine for the greater Boston area and the Commonwealth. We fully support adding to this rich research ecosystem the important work Boston University is planning for this facility.

BG

**ALBANY LLC**
P.O. Box 157
Wayland, MA 01778

RECEIVED

SEP 15 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

September 10, 2011

RE: Support for Waiver Request - "NEIDL"
Boston University Biological Research Laboratory, Albany Street, Boston, Massachusetts

Dear Secretary Sullivan,

We are writing in support of the application for a waiver by Boston University to be permitted to commence using the biological research laboratory they have built on Albany Street in Boston. Our property is located across the street from the laboratory, at 535 Albany Street in Boston. We have owned our property for decades and for over a decade served on the community review committee for the development of the "Biosquare" project. We support the development of the NEIDL building as a part of the Biosquare development and would like to see it actively in use by scientists and technicians as soon as possible.

As long-term, active, members of the business community, we were pleased when Boston University obtained critical federal funding and community support from all of the research and teaching institutions in the Boston and Cambridge area to locate this state of the art facility in our neighborhood.

We view it as a plus that highly trained scientists will be working on treatments for various diseases in a controlled and regulated environment designed for that purpose before those pathogens can cause serious epidemics. Boston is one of the few areas in the country where the skills, facilities, and education level of scientists are available to do this. This is necessary work and our hard-earned tax dollars have been invested in the infrastructure to make this work successful. Time is of the essence. Further delays are a waste of our resources and could delay finding treatments for serious health challenges.

We understand that the design of the building includes several levels of laboratories and fully support Boston University's proposal to phase in activities in the building so that the bio-safety laboratories at levels 2 and 3 begin operations soon while the bio-safety level 4 laboratory completes the process of review and approval by the National Institutes of Health Blue Ribbon Panel, the Boston Public Health Commission and the Centers for Disease Control and resolves any remaining legal issues.

Please feel free to call us at 508-358-4654 if you have any questions. Thank you for your consideration.

Bonnie L. Gossels

Elaine F. Gossels

BG

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114
12 de septiembre, 2011



Querido Señor Sullivan,

Le pido su apoyo en darle los documentos necesarios a la universidad para abrir el laboratorio que no está abierto. Confió en que la universidad tiene la capacidad de manejar las investigaciones y los estudios efectivamente y con caución.

Es una pérdida de capital y una pérdida de recursos no poder usar ese laboratorio considerando cuanto tiempo tiene que se construyó.

Por favor permítale a Boston University abrir finalmente el laboratorio para estudiar y para investigar casos de menos niveles.

Gracias,

Francisco Tapia

27 Hereford Street
Boston, MA 02115

September 13, 2011

**Re: Boston University laboratory permits**

Richard Sullivan, Secretary
Executive Office of Energy and Environmental Affairs
Via email: rick.sullivan@state.ma.us

Dear Secretary Sullivan:

I live in Boston, and my professional training is in both urban design (Master of Landscape Architecture, University of Pennsylvania) and public health (Master of Public Health, UCLA). I have long been involved in the BU lab issue and continue to be alarmed at BU's efforts to operate the NEIDL laboratories.

BU has demonstrated repeatedly that it is not to be trusted to prioritize the public welfare in conducting its bio-scientific research. The tularemia outbreak of 2004, for example, was due to negligence in safety procedures, as reported by the Boston Public Health Commission (see report, attached). Far more alarming, the University's concealment of this very serious incident, in violation of legal reporting requirements, indicates that its self-interest outweighs its obligations to the public interest.

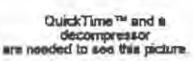
BU has a long record of lab safety violations, and a long history of misrepresentation to the community about this project, facts of which you are probably aware. (If you are not, the Roxbury Safety Net group can provide this information.) The government would be egregiously imprudent to entrust the community's welfare to an institution that has long shown its flagrant disregard for public safety.

Therefore, I am wring to ask you to reject BU's Phase I Waiver request to open the Level 1 and 2 labs immediately, and to open the BSL3 without a MEPA review of the completed Supplemental Environmental Impact Report. It is not surprising that BU wants to evade regulatory review; if it were a responsible institution, it would welcome all public oversight to maximize protection. Instead, it has been trying for years to foist a potentially hazardous laboratory on a densely populated urban area, with the least amount of regulation and oversight.

Further, your approval of BU's waiver request would create a dangerous precedent, encouraging other developers to skirt the MEPA risk assessment process.

Before you issue your draft decision on the Phase I Waiver request, I urge that you convene a public hearing, to be sure that you hear the comments of the many residents and scientific experts who have studied this issue for years. Please schedule the hearing at a time and place that allows community people to attend.

Sincerely,




Shirley Kressel

cc: Kathleen Hardaway
kathleen.hardaway@state.ma.us

# Report of Pneumonic Tularemia in Three Boston University Researchers

November 2004 – March 2005

**M. Anita Barry, MD, MPH**
Director, Communicable Disease Control
Boston Public Health Commission

March 28, 2005

## Forward

By John Auerbach, Executive Director
Boston Public Health Commission

This report gives a comprehensive overview of the 2004 tularemia outbreak at Boston University. The issues contained in this report highlight the need for additional City-wide safety measures to prevent the recurrence of such an event. The growth in the number of laboratories in the City working with potentially hazardous organisms and substances, including the increase in the amount of research involving Select Agents, requires new and expanded governmental oversight at multiple levels.

Discussion about how best to achieve the proper level of monitoring and oversight must involve officials at the local, state and federal level. However, even while such discussions are proceeding, BPHC believes that positive action steps should be undertaken at a local level to insure the health and safety of microbiology research laboratory workers and the greater Boston community. In the coming weeks and months the Commission will do the following:

1. Develop and implement new mandatory guidelines on the monitoring and reporting of occupationally acquired infectious disease illness among microbiology research laboratory workers.
2. Develop and implement mandatory procedures for the public health response to reported occupationally acquired infectious diseases.
3. Identify a public health worker to monitor practices in microbiology research laboratories, particularly those working with the most dangerous organisms and toxins.
4. Develop and offer a mandatory educational training for Institutional Biosafety Committees, Human Resources, and Occupation Health personnel responsible for ID research laboratories
5. Solicit the input of laboratory science and infectious disease experts to consider specific policy and regulatory changes regarding laboratory operations, including but not limited to the criteria for specimen acceptance, periodic verification of the organism's virulence, storage, chain of custody, and sharing of specimens with other research labs.
6. Closely monitor the internal progress made at BU to strengthen infection control practices in its laboratories.

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## Summary

In November 2004, three cases of tularemia (1 confirmed, 2 probable) were reported to the Boston Public Health Commission (BPHC). All three cases occurred in laboratory researchers who believed they were working with the Live Vaccine Strain (LVS) of *Francisella tularensis*, the organism that causes tularemia. The LVS strain of *F. tularensis* is an attenuated form of the bacterium not previously associated with human illness. The first two cases became ill in May; the third in September, 2004. Laboratory testing by the Centers for Disease Control and Prevention (CDC) in late November, 2004 showed that the LVS stock used by the BU researchers was contaminated with Type A tularemia, a wild-type, virulent form of the organism. Because of their potential for use as bioterrorism agents, Type A and B tularemia are classified as Category A agents by the CDC, and their use is restricted to CDC - approved select agent programs. These programs must have facilities with appropriate safeguards and security in place. An investigation was conducted by the BPHC, the Massachusetts Department of Public Health (MDPH), and the CDC. Review of the BSL2 laboratory where research was conducted and interviews with research personnel revealed inconsistencies in laboratory safety practices, but the source of the Type A tularemia has not been identified to date. Outside Boston, the investigation into the source of the wild type tularemia is ongoing, and results of additional CDC tests and investigations are pending.

# I. Introduction

Tularemia is a zoonotic bacterial disease, caused by the bacterium *Francisella tularensis*, a small, gram-negative coccobacillus. Tularemia can have various clinical manifestations depending on the route of introduction and the virulence of the organism. Primary pneumonic tularemia results from inhalational exposure and though uncommon, is considered the most severe form of disease with mortality rates as high as 30-60% if untreated. Disease onset is abrupt, characterized by fever, chills, malaise, low back pain, myalgias, and pleuritic chest pain. The incubation period is 1-14 days, averaging 3-5 days. Human to human transmission has not been documented.[1]

There are two types of *F. tularensis*: Type A and Type B, distinguished by virulence and other biochemical properties. Type A is more virulent than Type B. The live vaccine strain (LVS) of *F. tularensis* is a Type B, further attenuated strain of *F. tularensis* not previously associated with human disease. Type A and B *F. tularensis* are classified as select agents by the CDC, which regulates the possession of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The exception to that is the LVS strain of *F. tularensis* which is not a select agent. Recommendations differ regarding the level of laboratory safety practices required when working with cultures of LVS. However, biosafety guidelines mandate that any laboratory work involving manipulation of Type A or Type B tularemia be performed using BSL3 level precautions.

On November 10, 2004 the Boston Public Health Commission was notified that three Boston University researchers working with tularemia had been ill in 2004, with symptoms consistent with pneumonic tularemia. Two became ill in May, and the third in September. All three had worked with what they believed to be the live vaccine strain (LVS) of tularemia in conjunction with vaccine development research. Subsequent serologic testing by the Massachusetts State Laboratory Institute (SLI) confirmed the presence of antibodies to tularemia in the three cases, a key step in diagnosis. BPHC investigated the implicated laboratory, interviewed laboratory personnel, and reviewed research documents and practices related to *F. tularensis* at the Boston University laboratory to determine the source of illness and introduce appropriate control measures.

# II. Initial Plan for Investigation and Control

A collaborative investigation was conducted by the Boston Public Health Commission (BPHC), Massachusetts Department of Public Health (MDPH) and the Bacterial Zoonoses Branch of the Division of Vector-borne Infectious Diseases, Centers for Disease Control and Prevention (CDC). On November 12, a conference call with representatives from Boston University (BU), BPHC, MDPH, the CDC, and the Boston

[1] Tularemia as a Biological Weapon: Medical and Public Health Management. JAMA 2001 285: 2763-2773

field office of the Federal Bureau of Investigation (FBI) agreed on initial response measures, including the following:

(1) immediate stoppage of all work conducted using tularemia;
(2) review of research protocols and safety measures in place at the BU laboratory where the workers had become ill;
(3) tularemia specimen submission to CDC for further testing and analysis;
(4) survey of all available personnel working in the vicinity of the implicated tularemia laboratory regarding laboratory practices, illness, and other risk factors for tularemia; and
(5) voluntary serologic testing among laboratory personnel for evidence of tularemia infection.

## III. Case Investigation and Surveillance for Other Cases

### *Methods*

A BPHC public health nurse interviewed the three reported tularemia cases. Medical records for the three cases were obtained and reviewed for clinical information. Information collected included presentation of illness, duration of illness, treatment, and outcomes.

To identify any other potential cases among laboratory workers, BPHC requested that BU provide records of absenteeism among workers in the implicated infectious disease laboratory. In addition, the Boston University Occupational Health Center monitored laboratory workers for any subsequent reports of illness.

In this investigation, a case was defined according to CDC guidelines:

- a case is *probable* if the case is clinically compatible with laboratory results indicative of presumptive infection

- a case is *confirmed* if it is a clinically compatible case with confirmatory laboratory results

### *Results*

All three cases reported working directly with tularemia. Clinical information describing disease progression was obtained from health providers, and symptomology was similar among cases. All three were treated with antibiotics and recovered. Tularemia infection was not diagnosed by any of the treating physicians, none of whom were associated with the BU Occupational Health Center. Since tularemia is not transmitted person-to-person, secondary cases in laboratory or non-laboratory contacts of the cases were not expected and were not found.

# IV. Epidemiologic Survey

## *Methods*

From November 23 to December 9, 2004, all available laboratory researchers and personnel working in the vicinity of the 6th floor laboratory where tularemia research was conducted were interviewed by the BPHC using a standardized survey. The survey included questions on health history, including previous pneumonia and symptom history during the time period when tularemia was being manipulated in the laboratory. Specifically, personnel were asked if they had developed symptoms consistent with tularemia infection for a period of 72 hours or greater between May 1st and November 15th, 2004. Respondents were also asked about possible environmental exposures, travel history, including visits to Martha's Vineyard and other areas known to have endemic tularemia. Information was also collected on laboratory practices and safety procedures when working with *F. tularensis*, and general laboratory safety measures for all laboratory activities.

## *Results*

The Infectious Disease Laboratory on the 6th floor of the Evans Biomedical Research Building is a site for research conducted by Boston University students, employees, and Boston Medical Center clinicians. At the time of the investigation, BU reported that a total of 77 people worked on the floor in some capacity. BPHC interviewed 62 researchers and administrative staff, including all seven of the researchers directly involved in the tularemia research. Of the 62 people, 57 voluntarily provided serum for tularemia antibody testing. Five individuals declined testing, citing for "no exposure" or "personal" reasons.

None of the seven tularemia researchers had traveled to endemic areas between May and November 2004, compared to 17% of those who did not work with tularemia. Four researchers working directly with tularemia reported symptoms. Fever and fatigue/ malaise were the most common symptoms. Of the four researchers reporting these symptoms, three had pneumonic tularemia. The other researcher had a febrile illness with serology negative for tularemia.

Researchers reported performing laboratory activities with a wide range of frequencies. Centrifuging was performed more than 16 times per month by 42.6% of the researchers. In contrast, 80.9% never lyophilized.

Survey participants performed various laboratory procedures. Hand tightening or loosening screw caps (n=42), centrifuging (n=41) and vortexing (n=40) were the most commonly reported activities by the 47 people who worked in the laboratory. The objectives of various research projects and the experience of the researcher determined specific laboratory activities. There was wide variability in the use of protective

equipment and infection control measures. Of the 25 researchers who reported counting bacterial colonies, only eight (32%) reported always using a biosafety cabinet to do so.

The tularemia researchers reported a wide variety of laboratory activities. Eight laboratory procedures were performed by all the cases. Due to the small numbers involved, illness could not be statistically associated with a specific laboratory procedure. However, activities that may have resulted in aerosolization of bacteria were identified and performance of these activities prior to onset of illness was reviewed. All three cases performed multiple laboratory activities during the course of routine research that may have resulted in exposure, including preparation of cultures in broth and on agar, counting bacterial colonies on open agar plates, capsule preparation, centrifugation, and lyophilization. Chamberlain's media, believed to enhance the virulence of tularemia in culture, was used on several occasions. The first two cases became ill in late May, and at that time worked with large quantities of *F. tularensis* in liquid broth. Both cases reported numerous laboratory activities using infectious material at that time, but did not recall any specific laboratory accident or spill. The third case, with illness onset in late September, reported performing similar activities. This case also reported the use of a colony counter examining open plates of *F. tularensis* cultures outside a biosafety cabinet or fume hood.

# V. Serologic Survey

## *Methods*

Survey participants were asked to voluntarily provide a blood specimen to assess whether they had been infected with tularemia. Blood specimens were collected at the time of the surveys and were submitted to the Massachusetts SLI to test for antibody against *F. tularensis*.

Laboratory criteria for interpreting test results followed CDC guidelines, as follows:

- Results are *presumptive positive* if an elevated serum antibody titer(s) (≥1:128) to *F. tularensis* antigen (without documented fourfold or greater change) is observed in a patient with no history of tularemia vaccination OR detection of *F. tularensis* in a clinical specimen by fluorescent assay.

- Results are *confirmatory* when there is isolation of *F. tularensis* in a clinical specimen OR a fourfold or greater change in serum antibody titer to *F. tularensis* antigen is observed

### *Results*

Two laboratory workers were identified as probable cases; both had paired convalescent serum titers >1:128 and symptomology consistent with pneumonic tularemia. No blood samples were available prior to illness for these two cases. One laboratory worker was identified as a confirmed case; this individual had blood drawn prior to onset of illness, and paired serum showed a four-fold increase in antibody titer, with subsequent samples showing titer levels >1:128.

Fifty-one non-cases were presumptive negative based on a single serum sample, drawn at least two weeks after all tularemia related work in the laboratory was stopped. Two additional individuals became ill during the course of the investigation; blood specimens for both were negative for tularemia antibody.

Finally, two researchers in a separate laboratory on another floor in the same building were tested because they were identified as having low levels of antibodies to LVS *F. tularensis* using a research assay conducted in August, 2004. This research assay was not an approved diagnostic test. Both tested negative for tularemia antibodies at the SLI, and reported no exposure, having only briefly visited the implicated laboratory to have blood drawn. Neither researcher had ever worked with *F. tularensis*.

## VI. Environmental/Laboratory Inspection

### *Methods*

All laboratory space where work with *F. tularensis* was conducted was inspected by BPHC and MDPH officials. On November 19, 2004, health officials inspected the laboratory and reviewed physical facilities to assess exposure risks. BPHC requested the results of all testing of ventilation, biosafety cabinets, and laboratory equipment. Interviews of laboratory staff were used to assess physical facilities, laboratory activities, and other environmental or procedural areas of concern. Finally, all records related to shipping, handling, and access to tularemia, as well as all research protocols and actions taken by laboratory staff were reviewed. Shipping and handling documents were verified when possible through the shipper or receiver, and access to tularemia reagents was confirmed using laboratory notebooks and a select agent logbook.

### *Results*

Laboratory Overview

The 6$^{th}$ floor of the Evans Biomedical Research Building is a quadrant set-up, with a total of four BSL2 laboratories. Separate tissue culture, bacterial culture, and instrument rooms, as well as biosafety cabinets, were shared among the four laboratories. Tularemia research using animals was conducted on a separate floor in a BSL3 suite. Researchers and BU Environmental Health and Safety personnel reported that animals in that laboratory were not removed from the BSL3 room prior to euthanizing, and all necropsies

and tissue sampling was performed in the BSL3 room. All information regarding locations where tularemia research was conducted was verified through interviews with researchers and an internal BU investigative committee.

Ventilation and Biosafety Cabinets
BU reported no operating problems with the HVAC system, and submitted reports from an outside engineering contractor that measured air flow throughout the laboratory, verified air flow at each duct and fume hood, and assessed function of intake and exhaust systems. No problems were reported. The laboratory used a 100% fresh air supply, and had exhaust venting through the roof and an air exchange rate above recommended levels. In addition, BPHC Office of Environmental Health confirmed that air flow was adequate.

Environmental Risk
According to CDC, the LVS strain of *F. tularensis* presents only low-grade environmental risk for transmission. The bacterium is unlikely to survive for a long period in a laboratory outside of culture or stock. Despite the fact that the laboratory space was not thought to be contaminated or a source of ongoing exposure, BU reported that all equipment in the laboratory had been decontaminated by BU's Office of Environmental Health and Safety (OEHS) by November 19, 2004.

Facilities and Equipment
The appropriateness of facilities and equipment for laboratory activities being performed were reviewed. No specific failures of equipment were identified. However, availability of fume hoods and biosafety cabinets was very limited. Investigation of procedures that may have resulted in exposure was limited by a lack of specific research protocols detailing methodology.

# VII. CDC Testing and Investigation

## *Methods*

The *F. tularensis* materials used in research by BU were sent to the CDC for virulence testing and additional characterization. Initial testing was conducted during the week of November 15 to 19, 2004 on two vials of *F. tularensis* used by BU in research during the time period from April-November 2004. These included a sub-cultured stock vial grown from *F. tularensis* received from the University of Nebraska on April 15, 2004, and the original vial of *F. tularensis* received from the University of Iowa on June 3, 2004. Both LVS strains had the same American Type Culture Collection (ATCC) number. After initial results of testing by the CDC became available, the original vial received from Nebraska was sent to CDC from BU in late December 2004 and tested as well.

Between November 22, 2004 and January 6, 2005, BU sent and CDC tested all vials in BU's possession containing *F. tularensis* from either the University of Nebraska or the University of Iowa. Initial testing was done to assess whether the strain was Type A or

Type B, and if Type B, whether the strain was LVS. Mouse inoculation tests were performed to determine virulence, and additional testing was done to help further characterize the strains. Because many different strains of tularemia exist, CDC investigators employed pulse field gel electrophoresis (PFGE) and genomic sequencing to attempt to identify specific tularemia strains by comparing them with other known isolates. The tularemia strains isolated from BU samples were compared to known isolates from the East Coast and Midwest United States, an isolate from an outbreak in Martha's Vineyard in 2000, the SCHU-4 isolate, and several others. It should be noted that PFGE testing of *F. tularensis* is in early stages of use, mandating that results be interpreted with caution.

### *Results*

On November 22, 2004, CDC informed BPHC and MDPH their testing had revealed that the original vial from Iowa contained the pure LVS (Type B strain), but that the sub-cultured vial from Nebraska contained both Type A (virulent) and a small amount of Type B (LVS) tularemia. On December 3, 2004 CDC reported that the original vial BU received from Nebraska also contained both strains, though the amount of Type A present was less than in the sub-cultured vial that was initially tested by CDC.

By January 6, 2005, CDC testing had shown that all materials submitted by BU received from the University of Nebraska – including the original vial and the sub-cultured vials – contained a Type A strain of unknown origin. All specimens that BU had obtained from the University of Iowa contained pure Type B LVS.

The Type A strain contaminating the LVS sent from Nebraska was further characterized by PFGE. On December 8, 2004 CDC reported results of PFGE against other known Type A isolates, including the SCHU-4 strain, a clinical isolate from an outbreak in Martha's Vineyard in 2000 (MV2000), and several known Midwestern and East Coast strains (around 20 Type A strains total). Tests showed that the unknown strain from BU was distinct from the MV2000 isolate, as well as from all other East Coast isolates tested. The unknown strain was indistinguishable from the SCHU-4 isolate and some Midwestern strains. Testing by CDC also revealed that a Type A strain present at BU prior to receipt of the LVS from the University of Nebraska (ATCC 6223), was distinct from the unknown Type A strain (See below). To date, additional testing at CDC has been unable to further characterize the contaminating Type A strain found in the LVS stock BU received from Nebraska. However, results of additional CDC testing are still pending.

## VIII. Review of Laboratory Isolates at Boston University

## Methods

To identify possible sources of virulent *F. tularensis,* BPHC requested that BU provide dates of receipt for all shipments of *F. tularensis*. In addition to the two LVS strains, health authorities requested a description of all other tularemia strains at BU.

## Results

The Type A strains identified at BU were:

- SCHU-4, a Midwestern strain, was received by BU from CDC in late August 2004
- Two Type A strains were sent from the University of Iowa in September 2004 and received by BU in October 2004.

  *All three of the above Type A strains (SCHU-4 and two strains from Iowa) were handled in accordance with select agent guidelines, including dual-signatory receipt and shipment, secured storage, and video surveillance. BU reported that there was no evidence from logbooks or other sources that anyone had access to any of these strains since their receipt.*

- Seven vials containing an avirulent Type A strain (ATCC 6223) from research conducted in 1990 were discovered during an inventory of the BU laboratory in 2003. Once identified these vials were reported to the CDC Select Agent program and moved into a separate secured freezer.

No isolates from cases of tularemia cared for at Boston Medical Center were stored or worked on in the research laboratory, including isolates from a Martha's Vineyard case that had received care at Boston Medical Center. BU reported that the isolate from Martha's Vineyard was destroyed in 2000 and never entered a research laboratory.

CDC investigated possible sources of contamination outside of the BU laboratory, including materials at the University of Nebraska laboratory that shipped the LVS tularemia to BU. No source has been identified in the investigation to date, and a report of CDC findings in Nebraska has not been released.

A timeline of receipt of all tularemia strains at BU follows.

| Date | Type/Strain | From | To | Notes |
|---|---|---|---|---|
| 2000 | Type A, clinical isolate | Martha's Vineyard | Clinical laboratory | Isolated and destroyed in 2000 |
| March 12, 2003 | Type A, ATCC 6223 | 6th floor ID laboratory, BU | Select Agent freezer at BU | Discovered during inventory; declared to CDC Select Agent and moved to secured area |
| April 15, 2004 | LVS, Type B (contaminated) | University of Nebraska | BU | Used in research, 6th floor ID laboratory |
| June 4, 2004 | LVS, Type B | University of | BU | Used in research, 6th floor |

| | | | | |
|---|---|---|---|---|
| | | Iowa | | ID laboratory |
| August 31, 2004 | SCHU-4, Type A | CDC | BU | Logged in according to select agent protocols, transferred to secure area, unopened |
| October 14, 2004 | 2 Type A strains | University of Iowa | BU | Logged in according to Select Agent protocols, transferred to secure area, unopened |

# IX. Review of Research Related Documents

## *Methods*

BPHC obtained documents detailing the research with *F. tularensis*, including the NIH grant under which all work was conducted, the BU research protocols for work with *F. tularensis*, laboratory notebooks, a chronologic accounting of research, shipping and receiving documents for *F. tularensis*, and other supporting documentation. Documents were reviewed for completeness as well as insights as to how infection of laboratory workers and contamination of the *F. tularensis* may have occurred. Due to the implications of work with select agents, documents were also reviewed for any indications of protocol and procedural errors.

The following documents related to research with *F. tularensis* were submitted by BU and reviewed by the BPHC:

- NIH grant
- Correspondence between NIH and BU Re: tularemia grant application
- Institutional Biosafety Committee (IBC) records and approvals
- IRB consent forms for research related phlebotomy and antibody testing
- Laboratory notebooks of the three researchers who were tularemia cases
- Research protocols and methodologies as described by the tularemia cases for the periods surrounding their illness
- Shipping and receiving documents
- Invoice for clinical agglutination kit purchased 4/2004
- Research abstracts presented by the tularemia researchers
- Chronological account of all research performed with *F. tularensis*

## *Results*

There was no evidence to suggest intentional infection or contamination based on these records. Grant-related materials provided investigators with an overview of the research performed and the plans for future experiments. Research protocols describing manipulations performed by the tularemia cases in the time period surrounding illness

were prepared subsequent to illness based on laboratory notebooks and interviews of researchers, the principle investigator, and the internal BU investigative committee. These protocols revealed laboratory activities during which exposure may have occurred, however, no laboratory accidents were identified.

# X. Review of Biosafety Laboratory Procedures

## *Methods*

BPHC reviewed all biosafety laboratory procedures, safety training, accident logs, and occupational health guidelines for laboratory exposures submitted by BU. Two areas of biosafety were reviewed:

(1) General BSL2 practice
(2) Select agent handling and practices

BPHC requested training records for all researchers in the tularemia laboratory and reviewed responses related to laboratory activities obtained through the epidemiological survey. BPHC also assessed occupational health practices and policies for evaluation of potential laboratory exposures and acquired infections, and reporting of communicable diseases to BPHC as required by state and city laws and regulations. Select agent storage and handling procedures were reviewed as well. Next steps were identified for tularemia research to resume.

## *Results*

General BSL2 Practice

If followed, generally accepted BSL2 practices should lessen the risk of acquiring illness during the handling of virulent tularemia (Type A). However, researchers cited routine failure to comply with safety protocols. For example, researchers noted the lack use of personal protective equipment when counting colonies on an open bench.

All employees had completed BSL2 level training. Of the seven tularemia researchers, five had completed BSL3 level training. However, survey responses to questions about safety measures actually used in the laboratory varied widely.

The BU Occupational Health Center policies regarding illness in laboratory personnel were reviewed, and requirements for notification of public health agencies were emphasized. A delay in reporting illness was in part attributable to the fact that contamination of the LVS strains with wild type tularemia was unknown, and the belief that LVS did not cause disease. In addition, cases sought medical care at three different health care sites without initial involvement of the BU Occupational Health Center.

Select Agent Handling and Practices

Select agent protocols regarding the receipt and storage of Type A *F. tularensis* were reviewed for the three strains BU knowingly received. Select agents were stored in a

separate locked freezer with video monitoring. Receipt required at least two signatures, and there was no evidence of any use of these materials after they were received. The Type A *F. tularensis* was being stored in storage in anticipation of aerosol challenge experiments to be conducted at a later date. Despite stringent guidelines on receipt and storage of Select Agents, the BU laboratory did not have a system of laboratory testing in place to verify that the organisms being used in research were those that had been requested.

The Boston Public Health Commission identified the following steps to be completed before tularemia research resumes at BU:

1. Retraining
   - BSL3 training for all tularemia researchers, provided by the State Laboratory Institute
   - Refresher training on laboratory safety for all other laboratory personnel on the 6th floor
   - Retraining on Select Agent requirements for appropriate personnel regarding protocols and handling
   - Consultation with BU Occupational Health Center for all workers regarding risks, illness reporting requirements, obtaining baseline serum, and vaccination as appropriate

2. Communication
   - IBC and IRC protocols provided to all workers by Principal Investigators – to be read and signed as understood

3. Standard Operating Procedures (SOP) and Infrastructure
   - Modification and strengthening of SOPs by any Principal Investigator who conducts work using a BSL2 and/or a BSL3 laboratory, in conjunction with an outside expert
   - Updating of SOPs by Principal Investigators for any laboratory activities that may cause aerosolization
   - Review of all laboratory equipment by the BPHC Office of Environmental Health and Safety, along with Principal Investigators

## XI. Conclusions

Several conclusions have resulted from this investigation.

1. **At this time, the source of Type A *F. tularensis* in the BU laboratory remains unknown.** However, this highly virulent strain of bacteria likely caused the illness in all three researchers. Laboratory practices and safety measures used in the BSL2 laboratory were inadequate to prevent exposure, and the pathogenicity of the Type A strain of *F. tularensis* increased the risk of disease.

2. **The extensive investigation to date has found no evidence to indicate that either the contamination of the LVS stock or the infections of the BU researchers were intentional.** Based on discussions with all parties involved and review of the laboratory and research records, it is unlikely that BU researchers were aware that the LVS stock was contaminated until DNA tests performed in October as part of the research showed differences between stocks of bacteria that should have been identical.

   Testing at CDC continues in the effort to determine the time and place of contamination of the original vial. CDC is currently focusing its investigation on potential sources of the Type A tularemia outside Boston. The local investigation may need to be reopened pending the outcome of further CDC investigation or the availability of additional information.

3. **The tularemia outbreak at BU was limited to three BU employees and never posed a risk to the public at large.** Since tularemia is not transmitted person-to-person, secondary cases in laboratory or non-laboratory contacts of the cases were not expected and were not found. Furthermore, epidemiological and serological survey of employees working at the lab showed that no other lab workers were infected.

4. **The failure to identify work-related illness in laboratory staff is a major concern for health officials.** BU should have had stronger procedures in place to monitor its laboratory personnel. Had such procedures been in place, the cluster of suspicious illness in the tularemia lab would likely have been detected earlier and the third case may have been prevented.

5. **The failure to immediately report suspicious work-related illness to local and state health departments is a major concern.** BU should have reported the suspect cases of tularemia as soon as they were identified. BU needs to ensure that in the future there is a vigilant approach to regular monitoring the health of lab workers and to immediately reporting suspicious illnesses among laboratory workers to the appropriate governmental authorities.

6. **Appropriate infection control practices in laboratories must be clearly documented for all workers and enforced.** The BU tularemia laboratory failed to consistently utilize adequate precautions when handling and manipulating laboratory specimens. A systematic approach to retraining laboratory personnel is essential to insure that the required knowledge and skill levels are met and maintained. Special attention needs to be paid to the training and monitoring of laboratory personnel working with Select Agents.

7. **The BU Institutional Biosafety Committee was not able to ensure compliance with appropriate laboratory protocols and procedures.** BU should review staffing, resources and designated authority of this critically important body to insure it has the means to guarantee maximal safety in the future.

We respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Alan M. Garber
Provost
Harvard University

Jeffrey S. Flier
Dean of the Faculty of Medicine
Harvard Medical School

BG

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

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SEP 13 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am writing in my capacity as President of Brigham and Women's/Faulkner Hospital to offer my full support of the petition to the Commonwealth of Massachusetts. I understand that Boston University is asking the Commonwealth of Massachusetts to grant a waiver to allow the National Emerging Infectious Disease Laboratories (NEIDL) to conduct BioSafety Level (BSL)-2 and 3 research.

Hundreds of BSL-2 and BSL-3 labs currently operate safely in the state. A refusal of the waiver essentially establishes new levels of review that have not been applied to existing labs in the Commonwealth. Currently, thousands of BSL-3 labs exist across the country in universities and in industry. A new review standard would essentially place the Commonwealth at competitive disadvantage against these other labs.

Boston University is a major research institute that currently operates 350 BSL-2 and three BSL-3 labs on its campus. BU has the expertise to operate these labs which are neither unique or inherently dangerous. Stringent regulations govern the operation for BSL-2 and BSL-3 labs. City and the federal government both require extensive reviews before a BSL-3 lab can be commission. Boston Public Health Commission's Executive Director Barbara Ferrer recently wrote a letter of support for the waiver to the EOEEA saying, "The NEIDL is well suited to support laboratory research...and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories."

The NEIDL is a state-of-the-art facility that cost $200,000,000, and not to have this facility operating is a waste of taxpayers' money. Furthermore, research on emerging infectious diseases could lead to effective diagnostics and therapeutics and saving lives.

Sincerely,

Elizabeth Nabel

Elizabeth G. Nabel, MD

PARTNERS HEALTHCARE

BG

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SEP 15 2011

MEPA

13 September, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing this letter in strong support for the waiver requested by Boston University to permit them to conduct research in the National Emerging Infectious Diseases Laboratories Institute (the NEIDL) at BSL-2 and BSL-3. As a long time researcher in the biomedical sciences, I understand the need for expanded infrastructure and facilities to carry out research on infectious diseases. The significant delay in the risk assessment to permit full opening of the NEIDL has hampered the ability to carry out this important research.

I am fully confident in Boston University's ability to ensure that the work is carried out in a safe and secure manner. BU is a major research institute that already safely carries out research in hundreds of BSL-2 and three BSL-3 laboratories, proving its ability to ensure safety in NEIDL operation. There is nothing inherently dangerous to the public about the work that has been proposed to be carried out and, importantly, the NEIDL is a state-of-the-art facility whose design surpasses that of existing laboratories in the city. Needless to say, it is a waste not to have this facility open and operating.

I am particularly concerned about calls to refuse the waiver, based on the need to review operations in BSL-2 and/or BSL-3 laboratories. The Commonwealth of Massachusetts and other states do not review such laboratories. A denial of the waiver would set a dangerous precedent and chill academic, biotech and pharmaceutical expansion in the state. Such a denial would also be counter to the states experience of many years of safe operations of BSL-2 and BSL-3 laboratories, including those at Boston University.

I urge you to grant the waiver.

Yours sincerely,

Ronald B. Corley
19 Nash Lane
Weston, MA 02493

BG


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Dorchester, MA 02122
phone: (617) 265-4380
fax: (617) 822-2132




September 13, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attention: MEPA Office
Maeve Vallely-Bartlett, EEA #12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am Nancy Bucken the Executive Director of the Neponset Health Center. I am writing in support of Boston University's request for permission to begin doing BSL-2 and BSL-3 research in the National Emerging Infectious Disease Laboratories (NEIDL). Boston University already conducts research at this level in many other laboratories on their campus, they have a strong track record of safe lab operations, and the same regulatory oversight that control BSL-2 and BSL-3 research everywhere else in the city would also be in place to oversee research in the NEIDL. The building has already been built. Rather than see taxpayer dollars wasted while a state-of-the-art facility sits idle, we think that allowing Boston University to begin doing research at these lower biosafety levels is in everyone's best interest.

Sincerely,

Nancy Bucken

Nancy Bucken, Executive Director
Neponset Health Center
398 Neponset Ave
Dorchester, MA 02122
617-282-3200

BG

To: Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Valley-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114
Date: September 8, 2011
Re: Waiver for Opening of BSL-2 and BSL-3 at Boston University NEIDL



Dear Mr. Sullivan,

I am the Training Manager for the Boston University National Emerging Infectious Diseases Laboratories (NEIDL), and I am writing to you to ask you to approve research at Biosafety Level Two (BSL-2) and BSL-3 at NEIDL. To give you a brief background, my role at the NEIDL is to design, implement, manage, and provide training for all NEIDL employees who work in or around our Biosafety Level Four (BSL-4) facility. I also oversee the comprehensive training received by our BSL-2 and BSL-3 researchers and support staff, and work closely with our research safety team to ensure the labs are safe and the personnel are safely conducting research in our existing non-NEIDL labs around the campus. My experience includes time at many BSL-2, BSL-3, and BSL-4 laboratories around the United States, and I chose to come to NEIDL two years ago because I believed in 1) the mission of the NEIDL, which is to research infectious diseases, find cures, and save lives, 2) the capabilities of the personnel working here, and 3) the need for a facility like this in a metropolitan area, where there is a sophisticated infrastructure and expertise in place to support this level of research. I also chose to work here because I believed that the BSL-2s and BSL-3s would be open and become operational within a short amount of time, given that there are so many others like it within the city limits, including those already at Boston University.

Boston University is a major research institute that safely operates 350 BSL-2 and three BSL-3 labs on its campus. There is nothing unique or inherently dangerous about BSL-2 or BSL-3 labs and BU has the expertise to operate these labs. As you know, there are stringent regulations in place for the operation for BSL-2 and BSL-3 labs. In the case of the BSL-3 labs, the City and the federal government both require exhaustive reviews before a lab can be commissioned. Boston University has a record of safely operating its BSL-2 and BSL-3 labs. Boston Public Health Commission's (BPHC) Executive Director Barbara Ferrer recently wrote a letter of support for the waiver to the EOEE saying, "The NEIDL is well suited to support laboratory research...and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories." A refusal of the waiver, which is already supported by our local regulatory authority (BPHC) essentially establishes new levels of review that have not been applied to existing labs in the Commonwealth. Currently, there are thousands of BSL-3 labs across the country. A new review standard would essentially place the Commonwealth at competitive disadvantage against these other labs.

Beyond the statistics and facts regarding the stringent regulatory environment and safety record of our university, there are other key considerations that are arguably more important when considering

whether to begin active research at BSL-2 and BSL-3 at NEIDL. The NEIDL is a state-of-the-art facility that cost $200,000,000. Beyond the cost of the structure, the building is costing us in other ways. Hundreds of thousands of dollars are expended daily, in salaries, supplies, and energy consumption. First and foremost, this expenditure is a waste of taxpayers' money every day that the facility remains inactive. Further, for every day this facility is dormant, the talented staff we have here consider leaving NEIDL, Boston University, and the Massachusetts area to go work at other labs that are actively performing research. In the two years that I have been here, we – NEIDL and Massachusetts - have lost approximately 10 personnel, (and their families who were working or going to school in Massachusetts) for this reason alone. On an individual and universal level, this loss and the knowledge that we may not open for an unknown amount of time affects productivity, morale, and impacts the progress we can make toward opening all levels of our lab. Therefore, there is a significant added cost in retraining, recruitment, loss of knowledge, and the loss of the contributions that these individuals were hired to provide in the first place. This loss of personnel and unknown opening date also affects the ability to recruit, as our colleagues across the country and world watch what is happening here at NEIDL, unwilling to apply and move here, due to the perceived lack of stability and lack of community support. We cannot hire the best because the best essentially want to come and work in an active lab, where there are guaranteed funding and grant opportunities, and a future.

If the lab does not open soon, it is deeply saddening to think about what may happen to the people who have come here to make this building open; the expense it has cost these people, the community, the government, and the taxpayers; and to the people whose lives are affected or cut short every day by diseases that we can fight if given the chance. Therefore, on behalf of those mentioned above, and as a representative of NEIDL, I appeal to your office to please approve the waiver, which will allow this building to operate at BSL-2 and BSL-3 as soon as possible.

Sincerely,

Alexis Brubaker

## Gage, Bill (EEA)

**From:** Hardaway, Kathleen (EEA)
**Sent:** Wednesday, September 14, 2011 3:41 PM
**To:** Vallely Bartlett, Maeve (EEA); Gage, Bill (EEA)
**Subject:** FW: The BU Lab

Kathleen Hardaway
Executive Assistant to Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs 100 Cambridge Street, Suite 900 Boston, MA 02114
(617) 626-1015
Email: Kathleen.Hardaway@state.ma.us

-----Original Message-----
From: Dot Walsh [mailto:dwalsh@peaceabbey.org]
Sent: Wednesday, September 14, 2011 11:01 AM
To: Sullivan, Rick (EEA)
Subject: The BU Lab

Dear Mr. Sullivan,

I am writing about the proposed lab in the South End. I would ask that you find out the origins of Lyme disease (there is a book published)and then make your decision about the lab. The People of Massachusetts do not deserve this facility.

Thank You for your consideration and attention.

Dot Walsh

Dot Walsh
The Peace Abbey
2 N. Main Street
Sherborn, MA. 01770-0216
www.peaceabbey.org
508-655-2143

BG

September 14, 2011

RECEIVED

SEP 15 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing in support of Boston University's request for a waiver that would allow the National Emerging Infectious Diseases Laboratory (NEIDL) to begin its work and conduct research at the Biosafety Levels 2 and 3 (BSL2 and BSL3).

I am an Associate Professor at the Boston University School of Medicine (BUSM) and my laboratory is actively involved in developing novel therapeutics to prevent the transmission of HIV. I have over 25 years of experience carrying out BSL3 level research and did so at Harvard University, the University of Massachusetts Medical School, and BUSM. I have also been the director of a BSL3 laboratory at BUSM for the past 15 years. In addition to my BSL3 research experience, I have extensive experience in biosafety. I was the Chair of Boston University's Institutional Biosafety Committee for over 4 years. I also served as a member of the Boston Public Health Commission Working Group on Biosafety in Laboratories and as an *ad hoc* member of the Oversight Framework Development Roundtable for the National Science Advisory Board for Biosecurity (NSABB). I am currently the Chair of a committee at BU that has been charged with developing plans and policies for the university to be in compliance with pending regulations that are being developed by the NSABB for the oversight of research with dual use potential.

Given my background and my knowledge of the laboratory and biosafety procedures in place at BU, I am confident that research in the NEIDL at BSL2 and BSL3 can be carried out safely. As you know, local and federal guidelines and regulations govern research at the BSL2 and BSL3 levels and Boston city regulations require that BSL3 laboratories be extensively reviewed before they can be commissioned. Consequently, the NEIDL laboratories will be fully vetted before research can begin.

Given the importance of the research to public health and emerging infectious diseases that will take place at the NEIDL, I strongly urge you to approve Boston University's request for a waiver to begin work at BSL2 and BSL3.

Sincerely,

Gregory A. Viglianti, PhD
68 Claybrook Road
Dover, MA 02030

**Boston University** Henry M. Goldman
School of Dental Medicine
Office of the Dean

Medical Campus
100 East Newton Street, Suite 317
Boston, Massachusetts 02118-2308
T 617-638-4780 F 617-638-4490
jhutter@bu.edu

Jeffrey W. Hutter, DMD, MEd
Dean
Spencer N. Frankl Professor in Dental Medicine

BG

BOSTON UNIVERSITY

RECEIVED

SEP 20 2011

MEPA

September 15, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am the Dean and Spencer N. Frankl Professor in Dental Medicine at the Boston University Henry M. Goldman School of Dental Medicine which is located on the Boston University Medical Campus.

I received a D.M.D. degree from the University of Pennsylvania School of Dental Medicine; a Certificate in Endodontics from the Naval Dental School, National Naval Medicine Center, Bethesda, Maryland; and an M.A. in Education and Human Development from The George Washington University. I am a Diplomate of the American Board of Endodontics, a past Director of both the American Board of Endodontics and the Board of Directors of the American Association of Endodontists, a Past-President of the American Association of Endodontists, and Past-Chair of both the American Dental Association Council on Scientific Affairs and Commission on Dental Accreditation.

I share my scientific credentials with you because I wish to convey my support of the granting of waiver that would allow the Boston University National Emerging Infectious Disease Laboratories (NEIDL) to operate and conduct BSL-2 and BSL-3 research. As an Endodontist and an academic dean, I cannot overstate the importance of the research that will be conducted in this facility when the requested waiver is granted.

As you know, thousands of BSL-2 and BSL-3 labs operate safely in the United States on a daily basis. Boston University alone safely operates 350 BSL-2 and three BSL-3 labs on its campus. Boston University is a major research institute that has demonstrated the ability and expertise to operate these labs over many years. Should the requested waiver be refused it would indicate to the scientific community that a new and unannounced level of review had been established for BSL-2 and BSL-3 labs in the Commonwealth of Massachusetts. This undefined level of review would most certainly be a competitive disadvantage for the Commonwealth and ultimately, stall the research currently being conducted on emerging infectious diseases and impact finding cures and saving lives.

As you are well aware, there are stringent regulations in place for the operation of BSL-2 and

BSL-3 labs and as such, you can and should be confident that Boston University will operate these labs in the same expert and safe manner with which it operates all of its other BSL-2 and BSL-3 labs. Indeed, the Executive Director of the Boston Public Health Commission Barbara Ferrer has stated her support for this waiver noting Boston University's excellent record operating BSL-2 and BSL-3 labs.

As a scientist, I encourage you to allow Boston University to use the NEIDL as requested so that important and lifesaving research can be conducted. As a taxpayer, I encourage you to allow this facility to be utilized so that this $200,000,000 state-of-the-art facility does not continue to sit empty and idle.

Thank you for your consideration.

Sincerely,

Jeffrey W. Hutter, DMD, MEd
Dean
Spencer N. Frankl Professor in Dental Medicine

BG

9/15/11

RECEIVED

SEP 19 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I recently completed my clinical training in Neurology at Massachusetts General Hospital and Brigham and Women's Hospital. I have now started a fellowship at Boston University researching emerging causes of viral encephalitis. The prime motivating factor that drove me to pursue this non-traditional fellowship was the unique and extraordinary talent of the people recruited to work at the NEIDL as well as the amazing resources for doing cutting edge research there. Despite having a young family to support, I passed up jobs that paid 3-4 times what I currently make because I feel that the research I can do at NEIDL will make a real difference in the lives of the patients to whom I have chosen to dedicate my career, people who suffer from the devastating neurologic complications of infectious diseases. In order to do this work, I ask that you grant a waiver for NEIDL to conduct BSL-2 and BSL-3 research.

Temporarily, I am working in a BSL-2 facility literally across the street from NEIDL and can't imagine why an entire facility that is as secure and state-of-the-art as the NEIDL should lie fallow while permissions regarding BSL-4 work are sorted out. I have a family with 2 children under the age of two, and I would never pursue work that would endanger their health. I truly believe that the practices employed in the facility where I currently work at Boston University are safe and thoughtful. I have no reason to believe that this culture of safety won't be employed in the NEIDL. Please allow for the lifesaving work that NEIDL promises to promote to move forward.

Best regards,

Michael Wilson, MD

Michael Wilson, MD

BG

Sandra Silver, Ph.D.
200 Lake Street #11
Burlington, VT 05401
ssilverstark@gmail.com



September 15, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am writing to support Boston University's petition for a waiver that would allow the National Emerging Infectious Disease Laboratories (NEIDL) to operate and conduct Biosafety Level (BSL)-2 and BSL-3 research.

I am a virologist and have worked in the biotechnology industry in the Boston/Cambridge area for over twenty years. My experience includes working with infectious agents in BSL-2 and BSL-3 laboratories. I resided in Boston's South End Neighborhood from 1997 until June of this year, when I moved to Vermont. While in Boston, I served on the Community Liaison Committee (CLC) for the NEIDL from June 2006 through May 2011 and served as Chair of the Committee for the past two years.

As a scientist and member of the CLC, I am familiar with the types of agents, nature of the research, facility requirements and safety regulations for each of the Biosafety levels. While serving on the CLC, I had several opportunities to tour the NEIDL from top to bottom and, in my opinion, it is a "state-of-the-art" facility in terms laboratory design, safety and security. Controversy and litigation surrounding the BSL-4 laboratories have prevented Boston University from conducting ANY research in the NEIDL regardless of BSL designation; therefore the NEIDL has remained empty since construction was completed in 2008. This seems unnecessary and unfair not only to Boston University, but to the taxpayers who paid for the facility and the research community. If there were no BSL-4 laboratories in the NEIDL, the facility would be fully operational at this time. There is no logical reason why the BSL-2 and BSL-3 laboratories should be held to a higher standard of review than the thousands of other BSL-2 and BSL-3 laboratories throughout Boston, Cambridge and the US. In fact, Boston University currently operates several hundred of these laboratories on its campus and has been in full compliance with the stringent regulations and oversight procedures that have been established by the local and federal authorities.

I urge you to allow Boston University to open the NEIDL, allowing BSL-2 and BSL-3 research to be conducted. Please don't hold the NEIDL hostage while waiting for resolution on the BSL-4 laboratories.

Thank you.

Sincerely,

Sandra Silver, Ph.D.

#12021



BG

Dear Mr. Sullivan,

Recently, Boston University submitted a waiver that would allow the National Emerging Infectious Diseases Laboratories to operate and conduct BSL 2 and BSL 3 research. The Public Safety Department at the NEIDL would like to express our overwhelming support for this endeavor. All members of the Public Safety Department employed at the NEIDL are graduates of the Massachusetts Special State Police Academy and as such, we can assure you that the safe operation of our facility is a top priority for every member of the NEIDL community. Public Safety has been on the premises since the ground breaking of the facility, and staffs the building 24 hours. We have witnessed firsthand the progression of the security measures that have evolved since the NEIDL's inception. This growth has been both safe and effective.

Boston University currently manages 350 BSL 2 and three BSL 3 laboratories and the majority of the Public Safety Department has extensive experience in maintaining access control for those labs. Not only is the NEIDL's state of the art equipment better suited for BSL 2 and BSL 3 research than most facilities in New England but the security measures we have in place far out weigh those for most research facilities in the entire country. From a Public Safety standpoint, we feel confident that access control and other site security concerns associated with beginning research would be completely unfounded. In addition to those measures already in place, by screening those entering the NEIDL perimeter we are able to monitor personnel and communicate with them to obtain their feedback so as to continually improve our security policies. As a result, Boston University has the experience, means and expertise to safely operate the proposed laboratories within the NEIDL.

Our role as Public Safety within the NEIDL coincides with that of the dedicated and talented staff that would be working within the research laboratories. If the proposal is granted, these individuals will be working to benefit a majority of the public by their research in the development of vaccines and cures within BSL 2 and BSL 3 labs. We recognize our joint commitment to the mission that Boston University has implemented to maintain a safe and secure environment for research, and look forward to the opportunity of utilizing our skills and training to accomplish this goal.

Respectfully submitted,

Boston University Public Safety Officers (N.E.I.D.L)

Rae Annese

Joseph Maldonis

Jeffrey Barros

Justin Phelps

Christopher Barros

David Quartuccio

Dustin Botelho

Jason Rogers

Kathryn Connaughton

Nancy Santana

John Gallivan

Michael Tupe

David Granados

Paul Wynne

Al Lacerda

Ryan MacRoberts

Robert Tino

MARK COFFEY (PS SYSTEMS)

BG

September 16, 2011

RECEIVED

SEP 19 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, Ma. 02114

Dear Secretary Sullivan,

I am writing to voice our support to the Commonwealth of Massachusetts for granting a waiver to Boston University Medical Center (BUMC) and the National Emerging Infectious Disease Laboratory (NEIDL) to conduct "Biosafety - Level 2 and Level 3" (BSL-2 and BSL-3) research at their newly constructed laboratories located on XXX Albany St. on the BUMC campus in the South End of Boston.

Our company, along with our partners, has invested over 80 Million dollars in different real estate endeavors within a block of the NEIDL without a single concern for the facility or BUMC'S ability to safely operate the same. In fact, we have always viewed it's presence as positive to our location and to our marketing efforts. The increase of management level positions and support staff will only enhance our entire neighborhood.

My understanding is that BUMC currently operates BSL-2 and BSL-3 at other locations on campus, and therefore have proven their ability to the same at a more modern, sate of the art; ( NEDL-5 ) level facility.

For the last 9 years, BUMC has always been upfront and straight forward with their communication as to their plans and permitting. This facility has received scrutiny, both locally as well as nationally, and continues to answer the "what if" question time and time again. We feel it is time, at the very least; to permit BSL-2 research to commence and reserve committing to BSL-3 until NIH has conducted a full supplemental risk assessment.

Thank you in advance for your consideration of this request.

Yours very truly,

Robert E. Kenney
President

KENNEY DEVELOPMENT COMPANY INC. 120 FULTON STREET, BOSTON, MA 02109-1426 TEL. 617-742-6640 FAX 617-742-0318

# BOSTON CITY COUNCIL

www.cityofboston.gov/citycouncil
city.council@cityofboston.gov

One City Hall Square ◊ 5th Floor ◊ Boston, MA 02201 ◊ Phone: (617) 635-3040 ◊ Fax: (617) 635-4203


September 19, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: National Emerging Infectious Diseases Laboratories, Boston University MEPA Waiver Request, EOEEA #12021**

Dear Secretary Sullivan:

We represent Boston City Council Districts 4, 7 and voters citywide. We are writing to urge you to deny Boston University's ("BU's") request for a Phase One waiver from applicable MEPA regulations in connection with its proposed operation of the National Emerging Infectious Diseases Laboratories (the "NEIDL") at Boston University Medical Center. The requested waiver would allow BU to open BSL-1 and BSL-2 laboratories immediately. It would allow BU to open BSL-3 laboratories and conduct research on highly contagious pathogens in the NEIDL, all without further MEPA review. The waiver would circumvent judicially-mandated environmental reviews put in place in order to ensure that the surrounding communities of Roxbury and the South End are not subjected to unnecessary risks associated with conducting research on potentially lethal pathogens in densely-populated urban neighborhoods.

Although BU argues that it would only conduct lower-level research pursuant to this waiver, it has always proposed the NEIDL as an integrated laboratory facility with BSL-1 through BSL-4 lab spaces. Therefore, work done in the non-BSL-4 lab spaces could easily involve much more high-risk material than would be the case at other lower-security labs. BU has not provided any specific information in its waiver request about which pathogens would be studied at the NEIDL and what work would be done by the various labs that it contains.

BU's waiver request stipulates that no research would proceed at the BSL-3 level until the NIH's risk assessment is complete. However, the University has twice failed to meet its obligation to prepare an adequate and scientifically credible assessment of the risks associated

with research on contagious pathogens in the NEIDL. Until we are fully aware of and have confidence in the precaution and mitigation measures taken by the university, operations should not commence at the NEIDL.

For these reasons, I ask that you deny the waiver request and retain full jurisdiction to review the risk assessment for *all* labs located in the NEIDL. Such a denial would allow the project to receive full MEPA review as has been anticipated by both community members and the courts. At the very least, I ask that, should you deem the waiver request to have any merit, you hold a public hearing beforehand.. That hearing should be held at a location and time that is convenient and accessible to the public, particularly the affected South End and Roxbury communities.

Thank you for your time and consideration.

Sincerely,

#12021 BG

RECEIVED

SEP 19 2011

MEPA

Dr. Kath Hardcastle
700 Albany Street
Boston
MA 02118
Tel. 617-438-1938

8th September 2011

Dear Secretary Sullivan

Letter of support for the Commonwealth of Massachusetts to grant a waiver that would allow the opening of the BSL2 and BSL3 laboratories at the NEIDL

I am the Clinical Veterinarian for the National Emerging Infectious Disease Laboratories (NEIDL) at Boston University. I relocated here from the United Kingdom to take up this exciting and prestigious position in June of 2010. Previously I had worked as a Laboratory Animal Veterinarian in Containment Level 3 and 4 laboratories in the UK and saw a great opportunity both to bring past experience and knowledge to a unique project as well as building significantly upon them. As Boston University already operates both ABSL2 and ABSL3 labs throughout both its campuses and had been selected by the NIH to support a National Bio-containment Laboratory; I felt assured that it was well placed to launch the NEIDL as a new facility. The regulatory requirements surrounding research involving animals are exhaustive but particularly so at higher containment levels; thus any large establishment of BU's stature able to safely operate such laboratories, with an AAALAC accredited animal care and use program and an assured select agent program, has proven organizational capacity to establish the NEIDL.

As a foreign professional I have had much to learn regarding the regulations and oversight of animal research and laboratories in this country at a local, state and national level. It is not at all clear to me however why the NIH risk assessment and legal issues surrounding the opening of a BSL4 laboratory continues to impact the use of some 60% of the NEIDL building which houses BSL2 and BSL3 laboratories and vivaria. It has been important for me to establish contacts with other professionals within my field since arriving in the US and I have many colleagues working in containment laboratories in Massachusetts and further afield who are similarly puzzled by the current situation and those within Massachusetts state that their facilities were not subject to risk assessments by NIH Blue Ribbon Panels prior to commissioning. There appears to be a notable discrepancy in the way that BU is being overseen. The NEIDL, by its very nature, is already on the world stage and in many ways this sustained delay could be seen as embarrassing to BU and indeed the City of Boston that we are unable to bring this facility into the light of day due, in the main to bureaucracy.

The NEIDL is a globally unique building boasting quite remarkable engineering detail, as well as state of the art equipment much of which has highly specialized adaptations for use within containment. The capital investment of around $200 million now continues to require millions of dollars annually in maintenance alone. Meanwhile some 50 uniquely accomplished members of staff from areas of scientific expertise to safety not only attempt to maintain their departments but are also still trying to

prepare themselves to provide the required resources to operate the building as soon as it opens to avoid confounding the delay.

The enormous ongoing expenditure is an obvious concern as is the increasing lag time before a return on this true investment is seen. In the current economic climate, areas of growth are more important than ever and it is important to note that while the mission of the NEIDL is to better understand, treat, and prevent emerging and re-emerging infectious diseases there is also a huge financial benefit to many organizations in having another functional resource in that endeavor. Fiscal markets may ebb and flow, many industries may be affected by them, but pathogenic micro-organisms are not. They will continue to cause infectious disease which will affect human and animal health. The need to expand on our capabilities to address infectious disease is not in any kind of downturn and allowing Boston University to begin work in this building will very quickly have a positive impact on advances in human medicine and economic growth in this sector.

For approximately 3 months of this year Boston University encouraged members of staff from any department or campus to take part in guided tours of the NEIDL. The uptake was phenomenal and as a tour guide, I experienced firsthand the wonder and awe that rapidly turned to gratitude in our visitors. Many individuals expressed a sense of comfort that facilities do exist to be able to combat pathogens that may be crossing from animals to humans for the first time, manifesting as a strong desire to see the NEIDL open and performing its duties. Feedback from our guests strongly indicated that scientists, their research and its support is held in extremely high regard, recognizing the work that is undertaken on behalf of potentially millions of people.

Finally, I have seen several fine and highly trained members of staff leave Boston University solely due to the delays in opening of the building. Exceptional recruits have been made to the NEIDL because of the unique and specialized field that it services but people with vision and dedication have become disenchanted and chosen to hone their skills or pursue their life saving research at other establishments. There is a great acceptance that the time to going live at BSL4 from first opening the BSL2 laboratories may be significant but until this process begins I am certain that we will continue to lose human resources from all departments which will always be the greatest attribute that any establishment can have.

In summary, I write to support and indeed petition for the Commonwealth of Massachusetts to grant a waiver that would allow NEIDL staff to begin BSL2 and BSL3 operations, to launch the journey towards a return on this magnificent investment in the future health of human populations all over the world.

Yours Sincerely

Kath Hardcastle

Dr. Kath Hardcastle

#12021 BG

Dear Mr. Sullivan,

My name is Karsten Olejnik and I am writing to encourage you to grant a waiver for Boston University to allow BSL-2 research to be performed at the National Emerging Infectious Diseases Laboratories (NEIDL). As a way of introduction, I am a German native who moved to Boston to do research on lipid-like molecules in the Langer group at the Koch Institute for Integrated Cancer Research at MIT.

As a member of the Boston research community and as a BSL-2 researcher myself, I can feel frustration of my fellow researchers about the inability to conduct scientific research at Boston University. Researchers are currently deprived of the state-of-the-art facilities and equipment present at the NEIDL that could aid them in the study and development of treatments for important emerging infectious diseases. Unfortunately the BSL-2 research facility is tied directly to the deservedly stringent regulations and risk assessment associated with getting clearance for BSL-4 research.

I believe that it is a shame that the NEIDL as a state-of-the-art facility that cost $200,000,000, is not operational. Thousands of taxpayer dollars are wasted every day because of expiring warranties and service contracts for equipment that is neither in use nor even accessible for research. I do think that in these times, where every dollar spent in research is a precious good, you have to allow BU to operate this facility.

The Commonwealth of Massachusetts is one of the prime areas for biomedical and biotechnological research. All multinational pharmaceutical companies have at least branch offices in this area. Novartis has major research facilities in Cambridge; Sanofi-Aventis has 8000 employees in Massachusetts after they acquired Genzyme. Hundreds of start-up companies that are doing biomedical research are producing millions of dollars in taxes and employing ten thousands of people. A refusal of the waiver essentially establishes new levels of review that have not been applied to existing labs in the Commonwealth. Currently, there are thousands of BSL-2 and BSL-3 labs across the country. A new review standard would essentially place the Commonwealth at competitive disadvantage against these other areas. New start-up companies might not settle here because of the fear of not being able to get their labs approved in a reasonable timeframe and companies might not expand their research facilities and hire people. This will have a fundamental influence on the tax revenue and the already tight budget.

Therefore I believe that the ability to conduct BSL-2 experiments at the NEIDL should be considered on its own merits against the current standards of safety for such research facilities. Following the rigorous metrics already in place for BSL-2 facilities there is no reason why such research should not be allowed to be conducted at the NEIDL. In the Boston area there are thousands of BSL-2 laboratories and Boston University themselves currently operates hundreds of BSL-2 labs with a strong history of safety. In light of these facts I hope that you will grant the waiver to allow BSL-2 work to occur at the NEIDL.

Sincerely,

K. Olejnik

Karsten Olejnik

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.
The primary teaching affiliate of the Boston University School of Medicine.

BU Boston University School of Medicine

DANIEL G. REMICK, M.D.
Chair and Professor of Pathology
*Boston University School of Medicine and Boston Medical Center*
Department of Pathology and Laboratory Medicine, Medical Campus
670 Albany Street, 4th Floor
Boston, MA 02118-2653
T 617-414-7043, F 617-414-7073

September 19, 2011

Sec. Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA no. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: BSL-2 research at the National Emerging Infectious Disease Laboratories**

Dear Sec. Sullivan,

I am writing to urge you to allow a waiver to conduct biosafety level 2 (BSL-2) research at the National Emerging Infectious Disease Laboratories (NEIDL) at Boston University. BSL-2 research has a very low level of danger. For example, all of the material that pathologists receive from patients at the Boston Medical Center are considered BSL-2 specimens. Indeed, all specimens sent to pathology laboratories across the United States are is considered to be BSL-2 level material. I recognize the need for additional scrutiny in order to conduct the BSL-3 and BSL-4 research and understand that additional approvals will be required before this research may begin.

However, granting a waiver that will permit BSL-2 to proceed would be highly appropriate use of resources at the NEIDL. This superb facility should be opened to help create jobs in a safe manner. I have toured the laboratory, both the BSL-2 and the BSL-4. As an active investigator I can only describe the BSL-2 facility as state of the art.

Please grant the waiver to allow BSL-2 work to begin. These outstanding labs should be put to use immediately, to further science and maintain Massachusetts's lead as a pioneer in biomedical research.

Sincerely,

Daniel Remick

Digitally signed by Daniel Remick
DN: cn=Daniel Remick, o=Boston University, ou=Pathology, emailAddress=remickd@bu.edu, c=US
Date: 2011.09.18 16:51:19 -04'00'

Daniel G. Remick, M.D.

## Gage, Bill (EEA)

**From:** Hardaway, Kathleen (EEA)
**Sent:** Tuesday, September 20, 2011 12:26 PM
**To:** Vallely Bartlett, Maeve (EEA); Gage, Bill (EEA)
**Subject:** FW: Comments on BU waiver request

Kathleen Hardaway
Executive Assistant to Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114
(617) 626-1015
Email: Kathleen.Hardaway@state.ma.us

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**From:** Kenneth King [mailto:kennethelw@yahoo.com]
**Sent:** Tuesday, September 20, 2011 12:23 PM
**To:** Sullivan, Rick (EEA)
**Cc:** Hardaway, Kathleen (EEA)
**Subject:** Comments on BU waiver request

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Comments on National Emerging Infectious Diseases Laboratories, Boston University MEPA Waiver Request, EOEEA #12021**

Dear Secretary Sullivan:

I write to urge you to deny Boston University's request for a Phase One waiver from MEPA regulations in connection with its proposed operation of the National Emerging Infectious Diseases Laboratories at the BU Medical Center.

I am the author of *Germs Gone Wild: How the Unchecked Development of Domestic Biodefense Threatens America* (New York: Pegasus, 2001), a book focused on the dangers posed by the vast proliferation of high-containment (high-risk) germ labs since 2001, and the discrepancies between the safety propaganda of lab promoters and the actual history of such facilities.

I devote an entire chapter of the book to the BU project, a history which illustrates the book's concerns in rather obvious ways. While BU was concealing the tularemia infections of researchers in a BSL-2 lab—an incident which Dr. Richard Ebright, Director of the Waksman Institute at Rutgers University said "would be impossible for any competently-run microbiology laboratory"—BU promoters were hyping their proposed new facilities with slogans like a "submarine in a bank vault."

That the university deliberately concealed the tularemia incidents while seeking regulatory approvals from your office and the city of Boston is inexcusable. That BU and the NIH approached the risk assessment process as a mere formality is likewise inexcusable.

Your Office acted astutely in 2007, when it commissioned the National Research Council to evaluate the adequacy of the NIH's latest Environmental Impact Statement. Interestingly, the panel which concluded that the assessment's science "was not sound or credible" was significantly composed of scientific insiders—people whose institutional affiliations would discourage them from exaggerating the risks of any proposed research facility.

BU's inability or unwillingness to accurately recognize or acknowledge the full panoply of risks makes it unlikely that the risks will be adequately mitigated—as occurred, for instance, when the infected BU researchers didn't suspect tularemia for months because they "believed" they were working with a nonvirulent strain.

Circumventing the current ongoing reevaluations of the BU project will surely not inspire the confidence of local residents (or those of us who watch such matters from afar). Starting research at this time will look like a back door into the broad but vague BSL-4 mission which has been contemplated for the BU facility from the beginning.
Starting BSL-3 research at this time seems particularly questionable. BSL-3 research focuses on pathogens which may cause serious or lethal disease after inhalation. BSL-3 diseases may differ from BSL-4 diseases only to the extent that some possibility of effective treatment exists—**if the diseases are promptly recognized and accurately diagnosed.**

The Centers for Disease Control have allowed one particularly dangerous sort of research to be conducted at something it calls "BSL-3 enhanced." In an incident described in the Epilogue to *Germs Gone Wild*, researchers in a BSL-3 lab in the University of Wisconsin-Madison (following a path blazed earlier by the CDC's own researchers) crossed H5N1 bird flu and H3N2 human flu to create multiple mutated viruses which are both deadlier than ordinary bird flu (with a 50% mortality rate) and directly transmissible between humans. The tularemia which infected BU researchers in 2004—and was not diagnosed for several months—was not easily transmissible between humans. I hope I do not need to explain the consequences had that incident involved one of the new lab-created hybrid flu monsters.

A 2007 report by the Government Accountability Office highlighted the risks posed by the staggering proliferation of BSL-3 and BSL-4 facilities and the inadequacies of current regulatory schemes. (The proliferation wasn't even being tracked, much less adequately regulated.) Of particular concern were the difficulties of training the expected horde of 15,000 new researchers. Those difficulties—along with the problems of basic facility maintenance—can only be exacerbated by the budget constraints such facilities will likely face long into the future.

I am forwarding by separate E-mail an attachment listing accidents which have occurred at mostly BSL-3 facilities during the last several years. These include the 2009 death of a University of Chicago researcher from the "weakened" plague he was studying, a 2009 Detrick tularemia infection reminiscent of the Boston episode, and the SARS exposures and death caused by multiple accidental releases from Asian "high-containment" labs in 2003-2004.

The citizens of Boston deserve for the risks posed by such facilities to be fully considered. The ongoing reevaluation is necessary because, earlier, the risks weren't adequately examined. BU should not be allowed to short-circuit that reevaluation now.

Sincerely,

Kenneth King
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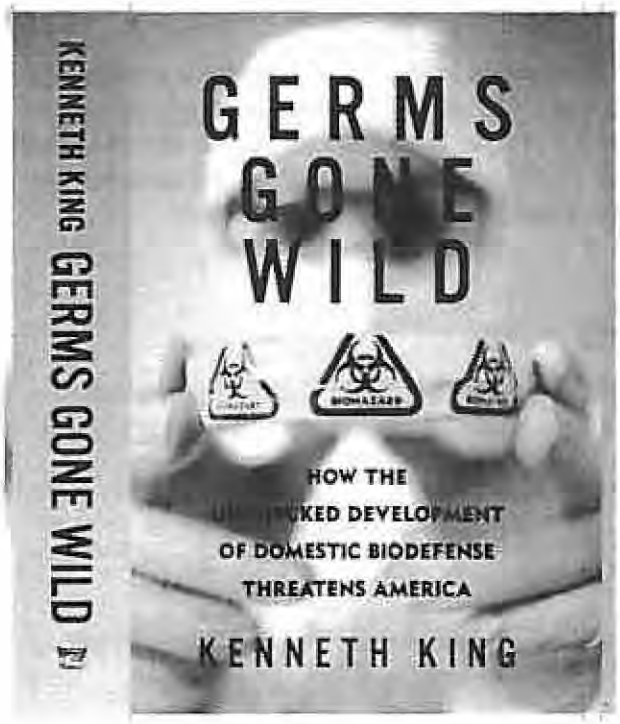
www.germsgonewild.com




"A superb guided tour of the demented world of twenty-first century bioweapons research in America"–**Ed Hammond, The Sunshine Project**

*"A chronicle of the development of America's largely unseen biodefense infrastructure . . . intriguing . . . the author combines meticulous research, an often flippant style, and unshakable faith."–**Publisher's Weekly***

## *GERMS GONE WILD* SPECIAL: GERM LAB INCIDENTS FROM AROUND THE COUNTRY, BY STATE

The first column indicates the state impacted or implicated, the second column the page number on which the incident is discussed in GERMS GONE WILD. Incidents cited only in the 2007 Associated Press review of CDC accident reports leaked to the AP are referenced as "AP." A link to the AP tabulation is provided at the GERMS GONE WILD website at www.germsgonewild.com, under "Resources."

The details of many incidents discussed in GERMS GONE WILD were originally derived from the AP and the archives of the Sunshine Project at www.sunshine-project.org. Most of these incidents would be unknown to the public if not for the work of these two organizations. Given the secrecy prevalent in biodefense research, they likely represent only "the tip of the iceberg."

This secrecy is exacerbated by the failure of the National Institutes of Health to enforce its Institutional Biosafety Committee (IBC) guidelines—supposedly an important part of the government's minimal regulatory schemes. (See Chapters Ten and Fifteen of GERMS GONE WILD.) The date given for most such IBC incidents is 2004—because that's the year The Sunshine Project identified the problems in its thorough survey of IBCs: *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research*, available at www.sunshine-project.org/biodefense/tspibc.pdf. I list here only the incidents discussed in GERMS GONE WILD. We can assume that most of the IBC problems identified in 2004 continue to exist.

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| AL (+CA, NC, MD) | 126 | Live anthrax mailed by Southern Research Institute to Oakland Children Hospital's Research Institute. (2004) |
| AZ | AP | Flagstaff: Missing vial anthrax. (2005) |
| CA | 34 | Berkeley: RM spotted fever mistakenly handled as though less harmful pathogen. (2005) |
| | 99 | Court rules Lawrence Livermore environmental review inadequate. (2006) |
| | 126 | Oakland Children's Hospital experiments with live anthrax, believing it to be deadened. (2004) |
| | 141 | San Diego: Power outage during valley fever necropsy. (2004) |
| | 211 | U Cal Davis conceals research monkey escape. (2004) |
| | 216-217 | Allergan (botulinum mfg.) no Institutional Biosafety Committee (IBC). (2004) |
| | 220 | Institute for Genomic Research: No functional IBC. (2004) |
| | AP | Cypress: Missing brucella. (2005) |
| CO | 140 | CDC at Fort Collins: Safety violation with Russian spring-summer virus. (2004) |
| | AP | Fort Collins: Worker drops plate of plague. (2006) |
| | AP | Fort Collins: Venezuelan equine encephalitis exposure. |
| CT | 447-450 | Groton--Safety problems at Pfizer. (1995-2004) |
| | AP | New Haven, Yale: Missing Q fever. (2004) |
| DE | 223 | Univ. of Delaware: IBC problems. (2004) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| FL | 217 | Midwest Research Institute--no IBC. (2004) |
| GA | 37-39 | Total power loss in new CDC labs; denial of info to public and *Atlanta Journal-Constitution*. (2007) |
| | 66-69 | Georgia State BSL-4 faulted by GAO for inadequate perimeter security. (2008) |
| | 147 | Univ. of GA BSL-3 lab: mechanical failures cause leakage of thousands of gallons of animal waste; facility tries to conceal from university authorities and the public. (2008) |
| | 163-164 | CDC experiments combining bird flu with human flu, creating forms of bird flu directly transmissible between humans. (2004-?) |
| | 165-169, 221 | Athens: The Southwestern Poultry Research Center, a BSL-3 facility, helps recreate the extinct 1918 flu. (2002?-2005?) |
| | 220-221 | Atlanta—Emory University: Nonfunctional IBC. (2004) |
| | 226 | CDC denies info requests of Sunshine Project. (2005-present) |
| | 228 | Univ. of GA: Nonfunctional IBC. (2004) |
| | 138 | CDC: Missing Q fever. (2005) |
| | AP | Atlanta: Lab worker infected with brucella. (2004) |
| HI | 138-139 | Major problems with records and inventory of germ samples. (2007) |
| IA | 34 | Univ. of Iowa: Unauthorized experiments to create antibiotic-resistant forms of tularemia. (2005) |
| | 141 | Ames, National Animal Disease Center: Wastewater pipe leaks. (2006) |
| | AP | Ames: Brucella exposures. (2006 & 2007) |
| IL | 34 | Chicago: Univ. Illinois at Chicago BSL-3 lab props open doors (the hell with "containment"—germs need fresh air too.) (2004) |

| STATE | GGW pp. | INCIDENT. |
|---|---|---|
| IL, cont. | 150 | Univ. of Chicago researcher dies from weakened version of the plague. (2009) |
| | 211 | Southern Research Institute (which shipped live anthrax to Oakland Children's Hospital) managing Argonne National Laboratory. (2004- ) |
| IN | 223 | Indiana University: Denial of public access to IBC minutes. (2004) |
| KS | Throughout. (2006-present) | Little or no actual select agent experience, but a co-conspirator with the Department of Homeland Security in creating a fairy-tale lab, "The NBAF in Wonderland," or "We're Off to See the Wizards." Propaganda still in full flourish; actual accidents must await actual lab operations. |
| KY | AP | Univ. of KY: Plague exposure. (2006) |
| LA | 225 | Tulane IBC problems. (2004) |
| | AP | Univ. LA: Brucella exposure. (2006) |
| MA | 375 | Boston University conceals tularemia infections of three researchers. (2004-2005) |
| | 383 | National Research Council slams NIH environmental impact statement for Boston Univ. BSL-4 lab. (2007) |
| | AP | Grafton, Tufts--Probable botulinum exposure. (2006) |
| | AP | Lexington: Missing anthrax. (2004) |
| | AP | Jamaica Plain: Glanders bacteria missing. (2003) |
| MD, DC | 34 | NIH-Bethesda: Failure of steam valve in biological waste treatment tanks. (2004) |
| | 6 | Multiple headlines about contaminations, releases, and other safety failures at USAMRIID, Fort Detrick. (2000-2006) |
| | 94 | CIA experiments slipping LSD into drinks of American bioweapons researchers. (1953) |
| | 126 | Detrick exhaust fan left off. (2005) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| **MD, DC,** cont. | 220 | Rockville, Institute for Genomic Research: Nonfunctional IBC. (2004) |
| | 336 | Detrick—glanders infection; anthrax releases; chemical dump. (2000, 2002, 1991-2004) |
| | 337 | Over 100 vials of live bacteria found in Detrick dump. (2003) |
| | 337-340 | Detrick--security and inventory problems, including discovery of 9,000 uninventoried germ samples. (1992-2009) |
| | 354-355 | Tularemia infection of Detrick researcher goes undiagnosed for over two weeks. (2009) |
| | 452-453 | Maryland State Police's surveillance (aided by DHS) of Barry Kissin, a Frederick, MD atty. and prominent critic of USAMRIID biodefense facility. (2005-2008) |
| | AP | Detrick--Ebola exposure? (2004) |
| | AP | Frederick, Southern Research Institute: Anthrax exposure. (2004) |
| | AP | Walter Reed: Improper disposition tularemia germs. (2004) |
| | AP | Walter Reed: Shipping discrepancy tularemia. (2005) |
| | AP | Walter Reed: Possible plague exposure. (2005) |
| | AP | Walter Reed: Plague exposure. (2005) |
| | AP | Walter Reed: Water supply leak in plague lab. (2006) |
| | AP | Rockville: Bird flu exposure. (2007) |
| **MI** | AP | Royal Oak: Valley fever, brucella exposures. (2006) |
| | AP | Troy, BioPort: Possible anthrax exposures. (2006) |
| **MO** | 127 | Kansas City, Midwest Research Institute: Leaking anthrax. (2005) |
| | 140 | St. Louis, Washington Univ.: Employees enter plague lab with no protective garb. (2004) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| MO, cont. | 177-178 | Univ. St. Louis: Researcher Mark Buller deliberately breeds mousepox (close relative of smallpox) which defeats existing vaccines and antibiotics. (2003) |
| | 217 | Kansas City, Midwest Research Institute--no IBC. (2004) |
| | AP | Kansas City--Missing anthrax. (2004) |
| | AP | Kansas City, Midwest Research Institute: Missing tularemia. (2004) |
| MS | 126 | U Miss: Grad student breaks anthrax flask. (2007) |
| | AP | Hamilton: Q fever centrifuge leaking. (2005) |
| NC | 34 | Chapel Hill: Exhaust fan fails in BSL-3 lab. (2005) |
| | 225 | NC State--IBC problems. (2004) |
| | 227 | Alpha Vax--IBC problems. (2004) |
| | 228 | East Carolina--IBC problems. (2004) |
| | 228 | UNC--IBC problems. (2004) |
| | | Lenoir, Greer Labs: Missing plague. (2004) |
| | AP | Probable exposure VEE virus (2004) |
| NJ | 136 | Newark, Public Health Research Institute: Plague-infested dead mice go missing. (2005) |
| | 138 | Live plague-infested mice go missing. (2008) |
| | AP | Trenton: Anthrax inventory discrepancy. (2006) |
| | AP | Newark: Missing glanders. (2006) |
| | AP | Newark: Missing anthrax. (2006) |
| NM | 127 | Los Alamos: Unauthorized shipment of anthrax from Northern Arizona Univ. (2001) |
| | 140 | Notebook (presumably contaminated) removed from monkeypox lab. (2006) |
| | 217 | Albuquerque, Lovelace Respiratory Institute: No IBC until 2008. (1970s-2008) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| **NM**, cont. | AP | Albuquerque: Lab workers bitten by plague monkeys. (2006, 2007) |
| | AP | Albuquerque: Staphylococcus missing. (2003) |
| **NY** | 4, 15-26 | Review of major problems at Plum Island. (1954-present) |
| | 34 | Albert Einstein College of Medicine: TB exposure involving Madison Aerosol Chamber. (2005) |
| | 220 | Plum Island: No IBC meetings after DHS takeover. (2004) |
| | 220 | Rockefeller University: No functional IBC. (2004) |
| | 165-169, 221. | Mt. Sinai School of Medicine: 1918 flu recreation. (2002?-2005?) |
| | 223 | NY State Dept. Health: Inactive IBC. (2004) |
| | 451-453 | Buffalo: Prosecution of art professor and genetic modification critic Steven Kurtz as a "bioterrorist." (2004-2008) |
| **OH** | 139 | Columbus: Explosion of package containing West Nile virus at FedEx facility. (2003) |
| | 173-175 | Meridian Bioscience accidentally ships 1957 flu to over 6000 labs in 18 countries. (2004-2005) |
| | 220 | Columbus, Battelle: No IBC minutes. (2004) |
| | AP | Columbus, Battelle--Inventory discrepancy staphylococcus. (2004) |
| | AP | Toledo: Researcher infected by valley fever. (2004) |
| | AP | Columbus, Battelle: Missing botulinum. (2005) |
| | AP | Columbus, Battelle: Bird flu exposure. (2007) |
| **OK** | 138 | Stillwater: Tularemia-infected mouse goes missing. (2006) |
| **PA** | AP | Scranton: Brucella inventory discrepancies. (2003) |
| **SC** | 227 | Univ. SC—University operating sham IBC. (2004) |
| | AP | Irmo, Univ. SC: Missing anthrax. (2006) |
| **TN** | 127, 218-220 | Oak Ridge: Unauthorized anthrax work; multiple safety violations in conducting the research. (1998-2004) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| TX | 28-37 | Texas A&M: Discovery of unreported researcher infections and exposures by the Sunshine Project leads to CDC investigation, discovery of biosafety train wreck, and shutdown of select agent research. (2006-2007) |
| | 66-69 | San Antonio: GAO faults perimeter security at Southwest Foundation, "private" BSL-4 lab. (2008) |
| | 222 | San Antonio, Southwest Foundation: IBC problems. (2004) |
| | 231 | Southwest Foundation--Sunshine Project files complaint for failure to comply with NIH public access provisions. (2004) |
| | 231-232 | U Texas-Austin: Bird flu centrifuge accident. (2006) |
| | 233 | U Texas San Antonio--IBC problems. (2004) |
| | 394-395 | Galveston: UTMB secrecy and info denials. (2003-present) |
| | 396-402 | Galveston hurricanes and effect on BSL-4 labs. (2008) |
| | 402-408 | UTMB-Galveston sponsors secret bill in effort to exempt their biodefense activities from the Texas Public Information Act. (2009) |
| UT | 128 | Dugway advertises for anthrax fermenters. (2005) |
| | 290-311 | Multiple contamination and safety problems at Dugway, with associated concealments and deceptions. (1950s-present) |
| VA | AP | Manassas: Plague shipping discrepancy. (2004) |
| | AP | Manassas: Brucella shipping discrepancy. (2005) |
| | AP | Anthrax shipping discrepancy. (2005) |
| | AP | VEE shipping discrepancy. (2005) |
| | AP | Richmond: Anthrax shipping discrepancy. (2005) |
| | AP | Charlottesville: Possible tularemia release. (2006) |
| WA | 30 | Seattle: Problems with Madison Aerosol Chamber cause TB exposures. (2003) |

| STATE | GGW pp. | INCIDENT |
|---|---|---|
| **WA**, cont. | 221-222 | Univ. Wash: IBC problems; planning dangerous experiments with 1918 flu. (2002-2004?) |
| **WI** | 439-440 | Univ. Wisconsin: Researcher suspended from lab work for conducting unauthorized experiments breeding antibiotic resistance into brucella. (2010) |
| | 445-446 | Univ. Wisconsin: Yoshihiro Kawaoka's dangerous experiments crossing bird flu and human flu, entitled "At Long Last, The Pandemic Flu Monster We've All Been Waiting For." (2010) |
| | AP | Madison, Univ. WI: Botulinum shipping discrepancy. (2005) |
| | AP | U Wis.: Brucella exposure. (2006) |
| **WY** | 223-224 | IBC problems. (2004) |
| **ASIA** | 137-138, 146 | Three escapes of SARS from high-containment labs, one infecting members of the public and killing a researcher's mother. (2003-2004) |
| **EUROPE** | 169-173 | The Austrian facility of US pharmaceutical company Baxter ships human flu virus samples "contaminated" with bird flu to several European facilities. (2009) |
| **United Kingdom** | 39-42 | FMD release from "world class" research facility causes significant outbreak, with an estimated economic loss of 147 million pounds. (2007) |
| | 179 | The last recorded smallpox death in the world results from a lab release in 1978. |
| **USSR** | 122-125 | An accidental release of anthrax spores from a Soviet research facility kills at least 64 people in Sverdlovsk (now Yekaterinburg). Soviet authorities conceal the cause of the deaths until 1992. (1979) |

## Gage, Bill (EEA)

**From:** Vallely Bartlett, Maeve (EEA)
**Sent:** Thursday, September 22, 2011 1:32 PM
**To:** Gage, Bill (EEA)
**Subject:** FW: BioDefense Laboratory

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**From:** Crowley, James (EEA) **On Behalf Of** internet, env (ENV)
**Sent:** Thursday, September 22, 2011 9:38 AM
**To:** Vallely Bartlett, Maeve (EEA)
**Subject:** FW: BioDefense Laboratory

Comments on the Bio lab

**Jim Crowley**
External Relations Coordinator
Tort Claims Coordinator
Executive Office of Energy and Environmental Affairs

---

**From:** Samuel Bauer [mailto:samuel.bauer@gmail.com]
**Sent:** Wednesday, September 21, 2011 1:36 AM
**To:** internet, env (ENV)
**Subject:** BioDefense Laboratory

Dear Secretary Sullivan,

I am writing to you concerning the BioDefense Laboratory at Boston University Medical Center. It is my understanding that there is a Phase 1 Waiver request to open the BSL1 and 2 labs immediately and to open the BSL 3 without a MEPA review of the completed Supplemental Environmental Impact Report.

While these waiver requests may seem trivial in light of the larger controversy surrounding the BioDefense Laboratory, they are immensely important. Your approval of these waiver requests would create a precedent for developers to bypass the MEPA risk assessment process. This would implicitly place developers above the law while simultaneously placing the communities affected by these developers in potentially unhealthy and unsafe living conditions.

I ask that you convene a public hearing before you issue your draft decision on the Phase 1 Waiver request. A public hearing would provide a place for you to hear the concerns of the many residents and scientific experts who have studied the issue. The hearing should be at a location and time that is convenient for the public, particularly the affected South End and Roxbury communities. Thank you for your consideration of this case.

Sincerely,

Samuel M. Bauer

70 Chiswick Rd, Apt 4
Brighton, MA 02135

samuel.bauer@gmail.com

BG

CRG Council for Responsible Genetics

COUNCIL FOR RESPONSIBLE GENETICS
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Telephone: 617-868-0870 Fax: 617-491-5344
email: crg@gene-watch.org web: www.councilforresponsiblegenetics.org

September 23, 2011



Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: National Emerging Infectious Diseases Laboratories, Boston University MEPA Waiver Request, EOEEA #12021**

Dear Secretary Sullivan:

I represent the Council for Responsible Genetics (CRG), a non-profit organization that has served the public interest for over 25 years in addressing the social and ethical implications of emerging issues in biotechnology. CRG was one of the early proponents for Federal guidelines to address safety issues related to recombinant DNA research and worked for many years promoting Massachusetts guidelines on biosafety. We are currently working with Assistant Secretary of Labor for Safety and Health David Michaels to revise OSHA guidelines on biolab safety.

We are writing to urge you to deny Boston University's ("BU's") request for a Phase One waiver from applicable MEPA regulations in connection with its proposed operation of the National Emerging Infectious Diseases Laboratories (the "NEIDL") at Boston University Medical Center. The requested waiver would allow BU to open BSL-1 and BSL-2 laboratories immediately. It would allow BU to open BSL-3 laboratories and conduct research on highly contagious pathogens in the NEIDL, all without further MEPA review. The waiver would circumvent judicially-mandated environmental reviews put in place in order to ensure that the surrounding communities are not subjected to unnecessary risks associated with conducting research on potentially lethal pathogens in densely-populated urban neighborhoods.

The University uses the proliferation of BSL-2 labs as a reason justifying a waiver of review. We believe it merits quite the opposite. BSL-2 labs handle biological materials that pose significant risks to health, safety and the environment. BSL-2 labs employ the largest number of researchers of any type of biolab, they conduct research on the largest variety of organisms and pathogens, including genetically modified organisms and yet they employ the least stringent training programs of any kind of biolab. Furthermore, working practices in these laboratories are not standardized nor are they well documented. This fact is highlighted by the large numbers of infections documented in BSL-2 laboratories as a result of non-compliance with guidelines and regulations. Indeed, the three Boston University laboratory workers that became infected with tularemia (rabbit fever) a few years ago were working with it in a BSL-2 lab. Due to its high virulence, the strain of pathogen in question is considered a category A agent by the Centers for Disease Control and a viable bioweapons agent; it has been included in the biological warfare programs of the USA, Russia and Japan at various times and clearly should have merited enhanced protections including being located in a higher level biocontainment facility. Yet, an investigation by the Boston Public Health

Commission found that "the BU Institutional Biosafety Committee was not able to ensure compliance with appropriate laboratory protocols and procedures." Moreover they found that the University's "failure to identify...and immediately report suspicious work-related illness in staff is a major concern for health officials."

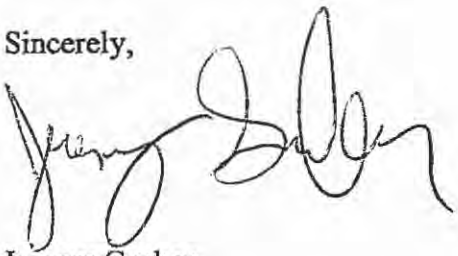
Finally BSL-2 laboratories "seed" higher containment facilities. A lax approach to biosafety and security at BSL-2 laboratories therefore has implications for higher containment facilities, particularly where those facilities are both located in the same complex and integrated with higher biosafety level facilities as proposed by Boston University. Indeed, under certain modified circumstances, research normally confined to BSL-3 labs may be conducted in BSL-2 labs. There have been no assurances from the University that such won't take place.

It is even more egregious that Boston University should seek a waiver for a proposed BSL-3 facility. By definition, BSL-3 labs include work done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Pathogens such as M. tuberculosis, St. Louis encephalitis virus and Coxiella burnetii are regularly studied in such facilities. Significant safety practices and procedures as well as oversight are required.

Since proposing the NEIDL in 2003, BU has repeatedly provided vague and incorrect information regarding the project. Most important, it has failed on multiple occasions to meet its obligation to prepare an adequate and scientifically credible assessment of the risks associated with research in the NEIDL.

For these reasons, we ask that you deny the waiver request and retain full jurisdiction to review the risk assessment for *all* labs located in the NEIDL. Such a denial would allow the project to receive full MEPA review as has been anticipated by both community members and the courts and ensure that public health and safety remain primary considerations.

Sincerely,



Jeremy Gruber
President
Council for Responsible Genetics

BG

September 23, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy + Environmental Affairs
Attn: MEPA Office
Maeve Vallely – Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114



Re: Request for The Commonwealth of Massachusetts to Grant a Waiver for NEIDL to Operate and Conduct BSL-2 + BSL-3 Research

Dear Secretary Sullivan:

I am a volunteer member of the NEIDL Community Liaison Committee, representing South Boston, and write to ask that The Commonwealth of Massachusetts grant a waiver that will allow the NEIDL to operate and conduct BSL-2 and BSL-3 research.

As you know, BSL-2 and BSL-3 laboratories operate safety in the Commonwealth of Massachusetts on a daily basis, and Boston University has the expertise and an impressive track record of successfully operating 350 BSL-2 and three BSL-3 labs in a safe and secure manner on its campus.

Since NEIDL has not been operational since construction completion 3 years ago, it would be good for NEIDL to finally become operational, especially since the building was constructed at a cost of $200 million of taxpayers' money. A waiver would enable much needed research on tuberculosis in the BSL-2 labs as early as this November.

Obviously, the City and Federal Government rightfully have stringent regulations in place for the operation of BSL-2 and BSL-3 labs, and once the NIH, Boston Public Health Commission and the Centers for Disease Control grant their final approvals for BSL-4, then more much needed research can commence as well.

As a result, this translates into the need to hire researchers and other technical personnel, a boost to job creation in the greater Boston economy. Moreover, the research will fast-forward the development of vaccines and cures, resulting in lives saved.

I understand that a refusal of the waiver will in effect establish new levels of review that have not been applied to existing labs in the Commonwealth of Massachusetts. A new review standard would place the Commonwealth of Massachusetts at a distinct competitive disadvantage against other national laboratories.

Thank you for this opportunity to express my support.

Sincerely,

Linda K. Lukas
15 Sleeper Street, #502
Boston, MA 02210

/lkl

BG

Stephen P. Burgay
1592 Commonwealth Avenue
West Newton MA 02456
September 24, 2011

September 23, 2011

RECEIVED
SEP 27 2011
MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy & Environmental Affairs
Att: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114-9827

Dear Mr. Secretary:

I am writing to express my support for Boston University's (BU) request for a Phase One Waiver which would enable it to conduct lower biosafety level research in newly constructed space in its National Emerging Infectious Disease Laboratory (NEIDL) located on the BU medical campus in Boston.

Every day, Biosafety Level (BSL) 2 and 3 research is done safely at thousands of locations in the state, including many at BU laboratories located across the street from the NEIDL. At the same time, the Boston Public Health Commission is a recognized national leader in regulating BSL-3 labs and closely monitors all of the work done at BU as well as other research institutes across the city. With this expertise, track record and independent supervision in place, it makes no sense to leave empty the thousands of square feet of state-of-the-art BSL-2 & BSL-3 labs located in the NEIDL. Instead we should put that space to use, expand the research and jobs that go with it, and find ways to prevent and cure diseases, such as tuberculosis, which endanger public health.

BU's request enjoys widespread support in the local and scientific community. Its scientists are world-class, and the institution conducts hundreds of millions of dollars in sponsored research every year. And the city of Boston is a recognized center of life science activity. BSL 2 & 3 research has been part of this activity for many years, and it is time to put those parts of the NEIDL to work. I hope you will look favorably upon the university's waiver request.

Sincerely,

Stephen P. Burgay

Stephen P. Burgay

# MASSACHUSETTS WATER RESOURCES AUTHORITY

Charlestown Navy Yard
100 First Avenue, Building 39
Boston, MA 02129

Frederick A. Laskey
Executive Director

Telephone: (617) 242-6000
Fax: (617) 788-4899
TTY: (617) 788-4971


BG

September 26, 2011

Mr. Richard Sullivan, Secretary
Executive Office of Energy and Environmental Affairs
100 Cambridge St, Suite 900
Attn: MEPA Office, William Gage
Boston, MA 02114

RECEIVED
SEP 26 2011
MEPA

Subject: Notice of Project Change, EOEEA #12021
BioSquare Phase 2, Boston

Dear Secretary Sullivan:

The Massachusetts Water Resources Authority (MWRA) appreciates the opportunity to comment on the Notice of Project Change for the BioSquare Phase 2 Project. Boston University's National Emerging Infectious Diseases Laboratories (NEIDL) building, located within the BioSquare Phase 2 project area was completed three year ago. Boston University now proposes to commence Biosafety Level Operations (BSL)-2 research activities in the fall 2011, and seeks additional City and State regulatory approvals necessary for the proposed BSL-3 level operations. BSL-3 operations will begin once the risk assessment currently being prepared by the National Institutes of Health (NIH) is completed and considered and other approvals necessary for BSL-3 research have been obtained from the City of Boston Public Health Commission and the Centers for Disease Control Prevention.

MWRA comments focus specifically on issues related to the permitting required within our Toxic Reduction and Control (TRAC) Group.

Discharge Permitting

Pursuant to 360 CMR 10.023(18), MWRA prohibits the discharge of any substance containing pathogenic organisms in such quantities as determined by local state and/or federal law as hazardous to the public health or environment, including but not limited to any "Infectious or Physically Dangerous Medical or Biological Waste" as defined and identified by the Massachusetts Department of Public Health in its regulations entitled " Storage and Disposal of Infectious or Physically dangerous Medical or Biological Waste, State Sanitary Code Chapter VIII," at 105 CMR 480.010, and whose disposal via the municipal Sewerage System is

prohibited by 105 CMR 480.200. MWRA's Sewer Use Regulations found at 360 CMR 10.000 include other applicable prohibitions and standards.

Once Boston University has received all the necessary reviews and approvals for operations at its NEIDL building, the University should contact Mr. Stephen Buczko, Industrial Coordinator within MWRA's TRAC Group at (617) 305-5619 for assistance in obtaining a Sewer Use Discharge Permit. Boston University must have a Sewer Use Discharge Permit for the NEIDL building prior to discharging any wastewater from the clinical, medical, research laboratories, and animal facilities found on site into the MWRA sanitary sewer system.

Should you have any questions or require further information on these comments, please contact me at (617) 788-1165.

Very truly yours,

Marianne Connolly

Marianne Connolly
Sr. Program Manager, Regulatory Compliance

cc: Stephen Buczko, MWRA, Toxic Reduction and Control (TRAC)

C:MEPA/12021BioSquareNPCBoston

BG

BICL BOSTON
IMAGING CORE LAB

580 Harrison Avenue, 4th Floor
Boston, MA 02118, USA

**Ali Guermazi, MD**
President
EMAIL: Ali.Guermazi@bicl.org
TEL: + 1 (617) 584 6851

RECEIVED
SEP 26 2011
MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan,

I am writing in favor of Boston University's request to permit the National Emerging Infectious Disease Laboratories (NEIDL) and, specifically, its application for a Phase One waiver request. It is time for e research to begin in this $200,000,000 research facility.

Boston University's request to open BSL-2 and BSL-3 laboratories for research is both a reasonable and responsible approach to the permitting of this research center. There are hundreds of BSL-2 labs on the Boston University campus and thousands of BSL-2 labs in the Commonwealth. Boston University now safely operates three of the twenty-four permitted BSL-3 laboratories in the state.

The City of Boston has strict operating requirements for these labs. The Boston Public Health Commission and the public safety departments in the City are extremely capable of handling the oversight for these laboratories.

The fact that MEPA has previously determined that none of the twenty-four existing BSL-3 laboratories in the state posed the kind of risk that would warrant a MEPA review speaks directly to the issue of public safety of these labs. They are safe and Boston University has the proven capability to operate these labs safely and securely.

To further delay needed research in this state-of-the-art facility is a waste of taxpayer dollars, delays vital research projects and has the potential to cost the Commonwealth millions of dollars in grants. For these reasons, and because the NEIDL research can save lives and invent cures for deadly infectious diseases, I support BU's waiver application.

As a business located directly across the street from the NEIDL at 601 Albany Street, Boston Imaging Core Lab is supportive of the waiver and looks forward to the day when the NEIDL is active and the research that the building was designed for is started.

Mr. Secretary, I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Sincerely,

Ali Guermazi, MD

B6

SOUTH BOSTON COMMUNITY HEALTH CENTER

William J. Halpin, Jr.
*Chief Executive Officer*

Nisha Thakrar, M.D.
*Medical Director*

September 26, 2011

RECEIVED
SEP 27 2011
MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attention: MEPA Office
Maeve Vallely-Bartlett, EEA #12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

On behalf of South Boston Community Health Center I am writing in support of Boston University's request for permission to begin doing BSL-2 and BSL-3 research in the National Emerging Infectious Disease Laboratories (NEIDL). Boston University already conducts research at this level in many other laboratories on their campus, they have a strong track record of safe lab operations, and the same regulatory oversight that control BSL-2 and BSL-3 research everywhere else in the city would also be in place to oversee research in the NEIDL. The building has already been built. Rather than see taxpayer dollars wasted while a state-of-the-art facility sits idle, we think that allowing Boston University to begin doing research at these lower biosafety levels is in everyone's best interest.

Sincerely,

William J. Halpin, Jr.
Chief Executive Officer

BG

September 26, 2011

801 Massachusetts Avenue
Suite 470
Boston, MA 02118

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114



Dear Richard K. Sullivan, Jr.;

I am writing this letter to express my support for opening the Boston University NEIDL for BSL-2 and BSL-3 research.

As a clinician and practicing health provider at Boston Medical Center and Boston University School of Medicine my research in the past 35 years has focused on addressing the social determinants of health which influence the receipt of health care services, in turn leading to disparities in mortality. My research has addressed breast, cervical, and colon cancer, cardiovascular disease, diabetes, exercise, depression, eating disorders, and domestic violence. My current focus is on systems interventions to reduce health disparities. Our team represents one of 9 funded sites on the NCI Center to Reduce Cancer Health Disparities Patient Navigation Research Program (U01 CA116892). This is the largest controlled trial of the benefits of care coordination and patient navigation for women and men with cancer or abnormal cancer screening tests.

Boston University is a major research institute that safely operates 350 BSL-2 and three BSL-3 labs on its campus. There is nothing unique or inherently dangerous about BSL-2 or BSL-3 labs and Boston University has the expertise to follow the stringent regulations in place for their operation. In the case of the BSL-3 labs, the City and the federal government both require exhaustive reviews before a lab can be commissioned.

Boston University's record of safely operating its BSL-2 and BSL-3 labs was recently affirmed by Barbara Ferrer, the Boston Public Health Commission's Executive Director, who wrote a letter of support for the waiver to the EOEEA saying, "The NEIDL is well suited to support laboratory research...and Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories."

In my opinion it is a waste of taxpayers' money not to have this facility operating after spending more then $200,000,000 to build it. Therefore, I believe the NEIDL should be opened for BSL-2 and BSL-3 research immediately.

Sincerely,

Karen Freund MD MPH
Chief, Women's Health Unit
Director, Boston University Center of Excellence in Women's Health
Director, Boston University
Women's Health Interdisciplinary Research Center

clf
conservation law foundation

For a thriving New England

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www.clf.org

September 27, 2011

**BY EMAIL**
Secretary Richard K. Sullivan, Jr.
Attn: William Gage, MEPA
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: National Emerging Infectious Diseases Laboratories**
**Boston University's MEPA Waiver Request**
**EOEEA #12021**

Dear Secretary Sullivan:

This letter provides comment from the Conservation Law Foundation (CLF) on Boston University's (BU) request for a Phase One Waiver for its proposed National Emerging Infectious Diseases Laboratories (NEIDL). CLF is a plaintiff in federal litigation regarding the proposed NEIDL. See *Allen et al.* v. *National Institutes of Health et al.*, Civil Action No. 06-10877-PBS (D. Mass.). CLF is a nonprofit, member-supported, public interest advocacy organization that works to solve the environmental problems that threaten the people, natural resources and communities of New England. CLF urges you to deny BU's waiver request.

BU's requested waiver would relieve the requirement for MEPA review of BSL-1, BSL-2, and BSL-3 research facilities at the NEIDL. Though BU does not plan to operate BSL-3 laboratories until its "risk assessment" (BU's term for its DSFEIR/S) is complete, BU would not obtain MEPA review or certification prior to operating those labs. BSL-1-3 labs constitute 86% of the area of the NEIDL building. BU's characterization of this area as "Phase One" of the project is euphemistically inaccurate. 310 CMR 11.11(4) provides that Phase One waiver approval may be appropriate for "partial waivers," but BU's request to waive MEPA review for 86% of the project looks like an attempt to evade MEPA review. As you well know, this is a highly contentious project that has been in litigation for some time. Allowing BU to avoid comprehensive MEPA review for the large majority of the project would be improper given the serious nature of the risks involved.

## I. BU has Failed to Meet the Regulatory Requirements for Issuance of a Phase One Waiver.

MEPA regulations provide that a waiver is appropriate only where strict compliance with regulatory requirements (a) would result in an undue hardship for the Proponent, unless based on delay in compliance by the Proponent, and (b) would not serve to avoid or minimize Damage to the Environment. 301 CMR 11.11(1). BU has not, and cannot, show that either of these standards has been met.

### A. Denial of BU's Waiver Request will not Cause Undue Hardship

The basis for BU's claim that it will suffer undue hardship if its waiver request is not granted is that the university has invested nearly $200 million in the NEIDL (including federal grant money) only to have the facility sit unused because compliance with MEPA and NEPA has "taken longer than anticipated." BU has conveniently left out two essential pieces of information.

First, BU's own failure to prepare an adequate EIR during either of its first two attempts is the primary reason the MEPA process has taken "longer than anticipated." BU's first attempt to prepare an FEIR was found insufficient by the Massachusetts Supreme Judicial Court (SJC), which held that BU:

> "inadequately addressed the consequences of a release of contagious pathogens from the Biolab, potentially denying State agencies the opportunity for meaningful review of the environmental impact of such a release and consideration of the measures that would be necessary to mitigate environmental damage...[and] never addressed [reasonable alternatives] ... even insofar as to explain that location outside the South End would not, for whatever reasons be feasible."

*Allen* v. *Boston Redevelopment Authority*, 450 Mass. 242, 257, 259 (2007). The Court also noted that "[t]he release of a highly virulent and contagious pathogen from the Biolab would present numerous and unique challenges for State agencies, which those agencies likely would not confront if the release involved a noncontagious pathogen." *Id.* at 257.

BU's DSFEIR (second attempt) was reviewed by a National Research Council (NRC) committee of the National Academy of Sciences at your office's request. The NRC determined that the DSFEIR was not sound and credible, had not adequately identified and thoroughly developed worst case scenarios, and did not contain the appropriate level of information to compare the risks associated with alternative locations.[1]

The NRC was again engaged, this time by the National Institutes of Health (NIH), to review their third attempt to prepare an adequate EIR. The NRC determined last November that it could not "endorse the illustrative analyses presented as scientifically and technically sound or likely to lead to a thorough analysis of the public health concerns previously raised by the NRC."[2] This analysis, which has been significantly delayed because of the many problems NIH confronted during its development, is still underway.

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[1] National Research Council, *Technical Input on the National Institute of Health's Draft Supplementary Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Disease Laboratory, Boston University, A Letter Report* at 2 (2007).

[2] National Research Council, *Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 2* at 8 (2010).

It was precisely the likelihood that your office might be denied the opportunity to review a full calculation of the risks associated with this project that motivated the SJC to make the statement above. BU's waiver request seeks to again deny your office of essential information regarding the NEIDL – this time by getting permission to skip the process rather than merely omitting critical information as before. Any hardship BU experiences from this regulatory process is due only to its own inability to draft a complete and scientifically sound analysis in its prior attempts to complete the EIR. BU should not be permitted to rely on its own history of poor performance as justification for the issuance of a waiver.

Second, despite sound precedent that MEPA and NEPA analyses are to be completed prior to significant investment in a particular project and location, BU took for granted that it would receive final approval from your office and proceeded to construct the NEIDL building ahead of completing the permitting process at **its own risk**. BU cannot now claim that it will suffer "undue hardship" because it decided moving ahead with construction was a risk it was willing to take. BU's view that justifying its project to MEPA after the fact is merely an unnecessary source of delay should not affect the integrity of your office's review of this complex project.

### B. Full MEPA Review is Required to Avoid and Minimize Damage to the Environment

CLF joins in the comments of its co-counsel, Anderson & Kreiger (dated September 27, 2011) that BU's waiver request does not meet the criteria at 301 CMR 11.11(4), and offers additional comment on 301 CMR 11.11(4)(a) (a finding that strict compliance with MEPA would not serve to avoid or minimize damage to the environment must be based on evidence that the potential environmental impacts of phase one, taken alone, are insignificant).

The Superior Court and SJC, having reviewed BU's first FEIR, unequivocally determined that this project carried the risk of extreme environmental impacts. Judge Gants, at the time in the Superior Court, stated that the pathogens that could be researched at the NEIDL could "commence a deadly epidemic if any leave the laboratory" and that:

> "[t]he potential of catastrophic environmental harm arising from a project… affect[s] the amount of information that a court reasonably may expect to be contained in the Final EIR for the Secretary rationally to conclude that the EIR has adequately and properly accomplished the objectives the Secretary herself set forth—to 'ensure that a project proponent… fully discloses environmental impacts of a proposed project…'"

*Ten Residents of Boston* v. *Boston Redevelopment Authority et al.*, 21 Mass. L. Rptr. 324, 2006 WL 2440043 (Mass. Super., Aug. 2, 2006). Because BU's first FEIR did not adequately provide such information, Judge Gants vacated the Secretary's Certification. Affirming Judge Gants' decision, the SJC made quite clear that the release of a contagious pathogen from the NEIDL would result in "damage to the environment." The Court stated that:

> "[t]he final EIR failed to analyze **the likely damage to the environment** caused by the release of a *contagious* pathogen, whether through laboratory accident, escape of an infected research animal, theft, terrorism, or transportation mishap, which is a critical consideration in a densely populated urban area... The absence of any information in the final EIR about such a contingency, **one likely to cause damage to the environment**, was a substantial oversight."

*Allen*, 450 Mass. at 256-257 (emphasis added) (internal citations omitted). The Court's focus was clearly on the danger posed by a potential release of contagious pathogens from the NEIDL into the surrounding densely populated urban environment. This concern relates to all of the labs in the NEIDL, and not just BSL-4 facilities. BU acknowledges that BSL-3 areas include pathogens "that may have serious or lethal consequences" and therefore that these areas are "restricted to only those that have proper training and security access." Waiver Request at A-3.

Both the Superior Court and the SJC found that this project could cause significant damage to the environment – a finding that does not allow the issuance of a MEPA waiver. BU's struggles since the SJC decision to quantify the environmental risk posed by the NEIDL only highlight the importance of full MEPA review for this project. Further, BU's waiver request, which was only six pages despite the complexity of the proposed project, failed to provide any detailed analysis regarding environmental impacts of the BSL-1, 2, and 3 labs for which it seeks a waiver. This waiver request hardly provides you with the evidence necessary to support a finding that strict compliance with MEPA would not serve to avoid or minimize damage to the environment. In light of the courts' decisions and the inadequacy of BU's waiver request, your office has no reason to believe that a Phase One waiver is appropriate for this project.

## II. The Issuance of a Waiver to for this Project Contravenes EOEEA's Environmental Justice Policy.

The issuance of a Phase One waiver to BU would violate paragraphs 14 and 15 of EOEEA's Environmental Justice Policy. The NEIDL is located in the Roxbury/South End area, a recognized EJ community.[3] The siting of the NEIDL, a project that exceeds thresholds for wastewater,[4] in an EJ community triggers the following additional MEPA requirements pursuant to the EJ Policy.

Paragraph 14 of the EJ Policy requires enhanced public participation during MEPA review of the NEIDL. CLF understands that your office denied requests from many members of the public for a formal comment period and a public hearing prior to the issuance of your draft decision. The absence of opportunity for sufficient public comment during the waiver decision-making process is a strong reason why BU's waiver request should be denied. In contrast to the waiver review process, the MEPA regulations provide a number of opportunities for public comment during the

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[3] See MassGIS Environmental Justice Viewer.

[4] See FEIR Certificate re Biosquare Phase II (Nov. 15, 2004).

regular EIR review process. For example, pursuant to 310 CMR 11.08(3), your office "may hold public hearings, informal workshops, or public meetings at appropriate times prior to and during preparation of an EIR." Ms. Vallely Bartlett asserted in her September 16, 2011 letter, which was sent in response to public requests for additional comment opportunities during this waiver review process, that "the MEPA Office does not hold public hearings as that term is commonly used." However, the regulations clearly provide that your office may hold public hearings during the EIR process. Further, the comment period for EIRs is 30 days, with the possibility of extension (310 CMR 11.08(4)), whereas, the comment period for waivers is much shorter - only 14 days - with no explicit provision for extensions (310 CMR 11.11(6)). More problematic is the fact that, according to the regulations, the comment period for waiver applications occurs only **after** a draft decision has been issued by your office. In contrast, the comment period for EIRs occurs as soon as the EIR is received and posted by your office and **before** you engage in your formal review of the EIR. This sequence is far preferable, as the comments you receive can then inform your analysis from the start, prior to issuing a decision.

Certainly paragraph 14 of the EJ Policy provides you with a sufficient basis to expand the public comment opportunities for a waiver request; however, according to Ms. Vallely Bartlett's letter, your office is unwilling to take that step. CLF believes that your office's refusal to enhance public participation opportunities during the waiver request review process contravenes the EJ Policy. As you have heard often, BU's conduct over the past eight years has engendered significant community distrust regarding this project. Your refusal to allow meaningful opportunity for public comment – in the form of both written and oral comments **before** a draft decision is issued - contributes to the community's perception that their voices are not heard on this issue. This deficiency in public process is precisely what the EJ Policy strives to correct. Going forward, in order to comply with the EJ Policy's requirement for enhanced public participation, the waiver request must be denied in order to allow your office to engage in the enhanced public comment and hearing opportunities provided for EIRs in the MEPA regulations.

Additionally, Paragraph 15 of the EJ Policy requires enhanced analysis of environmental impacts and mitigation for the NEIDL. According to the Policy, enhanced analysis could include analysis of site planning and operational alternatives, and data on baseline public health conditions within the affected EJ Population, among others. Siting in a dense urban EJ community is a primary concern with this project. Pursuant to the EJ Policy, your office should engage in an enhanced analysis of health data and siting alternatives in order to make careful findings on this subject. Granting a waiver for 86% of the NEIDL does precisely the opposite; it denies you the ability to perform an adequate review pursuant to the MEPA regulations and an enhanced review as required by the EJ Policy.

**Conclusion**

BU has misrepresented to you that the only risks associated with this project lie in the research that will be performed in BSL-4 laboratories. As the SJC noted, the threat posed by this project is research on extremely contagious biological agents that pose the risk of serious environmental harm to an already compromised environmental justice community. These concerns are not limited to BSL-4 laboratories.

These are complex scientific issues that make analysis of risk particularly challenging. In our view, this is the type of development project and community for which the protections of the EOEEA EJ Policy were intended, making regulatory shortcuts particularly inappropriate. As such, CLF respectfully requests that you deny BU's Phase One waiver request and allow the MEPA process to proceed unabridged.

If you have any questions, we can be reached at 617-350-0990. Thank you for the opportunity to submit comments and for your consideration.

Sincerely,

Peter Shelley
Senior Counsel

Jennifer Rushlow
Staff Attorney

Cc: Gary Davis, Esq., EOEEA
Maeve Vallely Bartlett, Esq., EOEEA
Arthur Kreiger, Esq., Anderson & Kreiger LLP
Laura Maslow-Armand, Esq., Lawyers Committee for Civil Rights
Klare Allen, The Safety Net

BG

# SPILLANE & SPILLANE LLP
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JOHN W. SPILLANE
1932-2007



September 27, 2011

Secretary Richard K. Sullivan, Jr.,
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street - Suite 900
Boston, MA 02114

Re: Boston University's Phase One Waiver Application

Dear Secretary Sullivan,

I am Legislative Counsel for the Massachusetts Association of Non-Profit Schools and Colleges (**MANS&C**). This organization has 100 member institutions consisting of private independent schools, colleges and universities located in all parts of the Commonwealth of Massachusetts.

I write to you to express MANS&C's support of our member school, Boston University as it relates to its request to permit the National Emerging Infectious Disease Laboratory (NEIDL) and specifically its Phase One Waiver Application to open BSL-2 and BSL-3 laboratories within the BioSquare Phase II project to be used for laboratory research.

There are hundreds of BSL-2 labs on the Boston University campus and thousands of the labs in the Commonwealth of Massachusetts. Furthermore, there are more than 1,000 BSL-3 labs nationwide.

Boston University safely operates three of the twenty-four permitted BSL-3 laboratories in the Commonwealth of Massachusetts. The fact that MEPA has previously determined that none of the twenty-four existing BSL-3 labs in the Commonwealth pose any kind of risk that would warrant MEPA review speaks directly to the issue of public safety of these twenty-four labs. Furthermore, the City of Boston through the Boston Public Health Commission has well established and detailed procedures for regulating BSL-2 research

and all BSL-3 laboratories operating within the City. All current regulations, permitting and enforcement practices confirm the highest standards of safety.

Any further delay in the permitting of this needed research facility of our member institution, Boston University, will come at the risk of losing vital grants for research in the Commonwealth of Massachusetts, which is certainly a driver for our economy.

Mr. Secretary, on behalf of MANS&C I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Very truly yours,

John J. Spillane,
Legislative Counsel

cc: Julaine McInnis, President
William J. Conley, Jr., Vice President
Bruce T. Amsbary, Treasurer

## Gage, Bill (EEA)

**From:** Pillsbury, Martin [MPillsbury@MAPC.ORG]
**Sent:** Monday, September 26, 2011 6:27 PM
**To:** Gage, Bill (EEA)
**Subject:** MAPC comment letter on MEPA 12021 Biosquare Phase II - NPC
**Attachments:** 12021 BioSquare Phase II NPC-Phase 1 Waiver.pdf

Hi Bill,

Attached please find MAPC's comment letter on the Notice of Project Change for BioSquare Phase II. The original letter will be mailed on Tuesday.

Regards,
Martin

**Martin Pillsbury**
Manager of Environmental Planning
Metropolitan Area Planning Council
60 Temple Place, Boston, MA 02111
617-451-2770, EXT. 2012
mpillsbury@mapc.org
www.mapc.org

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MAPC
METROPOLITAN AREA PLANNING COUNCIL

*Smart Growth & Regional Collaboration*

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SEP 28 2011
MEPA

September 27, 2011

Richard K. Sullivan, Secretary
Executive Office of Energy & Environmental Affairs
Attention: MEPA Office
100 Cambridge Street, Suite 900
Boston, MA 02114

RE: BioSquare Phase II, Notice of Project Change/Phase 1 Waiver, MEPA #12021

Dear Secretary Sullivan:

The Metropolitan Area Planning Council (MAPC) regularly reviews proposals deemed to have regional impacts. The Council reviews projects for consistency with *MetroFuture*, the regional policy plan for the Boston metropolitan area; MAPC's Smart Growth Principles; the Commonwealth's Sustainable Development Principles; as well as impacts upon the environment. MAPC has reviewed the above referenced BioSquare II, Phase One Waiver and offers the following comments.

The proponent Boston University is requesting a Phase 1 Waiver to allow the start of administrative and laboratory operations at Biocontainment Safety Level (BSL) 2 and 3, in advance of the completion of the Supplemental FEIR that was scoped in the 2006 MEPA Certificate. Filing of that SFEIR with MEPA is contingent on the completion of a risk assessment by the National Institutes of Health, which is said to be at least a year from now. BSL-4 operations clearly need to wait until the completion of the risk assessment and the SFEIR, but the NPC proposes that BSL-2 operations commence this fall, and BSL-3 operations begin when the risk assessment is completed and additional state and city regulatory approvals granted.

MAPC concurs with the proponent's request to commence administrative and BSL-2 operations under a Phase 1 Waiver, but given the significantly higher standards for BSL-3 facilities, we do not concur that BSL-3 operations should begin prior to the completion of the MEPA review process for the SFEIR. The NPC's proposal for BSL-3 operations to begin "immediately following the completion of the risk assessment," but before the FSEIR has been reviewed by the public and approved by the Secretary, would short circuit the full public review process for a project that has raised serious public health concerns and which has also been the subject of litigation. The MEPA office should retain full review authority over both BSL-3 and BSL-4 operations through the completion of the SFEIR, as envisioned in the Certificate.

Additionally, MAPC is concerned with how hazardous materials will be transported to and from the project site. This concern was raised in MAPC's letter dated November 4, 2004 which commented on the project's Final Environmental Impact Report (FEIR). MAPC has included this comment letter as an attachment, as this issue was not addressed in the previous MEPA review.

Thank you for the opportunity to comment on this important project.

Sincerely,

Marc D. Draisen
Executive Director

cc: Kairos Shen, Boston Redevelopment Authority
Attachment

60 Temple Place, Boston, MA 02111 • 617-451-2770 • Fax 617-482-7185 • www.mapc.org

BG

*Commonwealth of Massachusetts*

HOUSE OF REPRESENTATIVES
STATE HOUSE, BOSTON, MA 02133-1054

**REPRESENTATIVE**
**CHARLES A. MURPHY**
21ST MIDDLESEX DISTRICT
BEDFORD, BURLINGTON,
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MAJORITY WHIP

September 28, 2011

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MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing in favor of Boston University's request to permit the National Emerging Infectious Disease Laboratory (NEIDL). Boston University's request to open BSL-2 and BSL-3 laboratories for research is both a reasonable and responsible approach to the permitting of this research center. There are hundreds of BSL-2 labs on the Boston University campus and thousands of labs in the Commonwealth. Boston University now operates three of the twenty-three permitted BSL-3 laboratories in the state.

MEPA has never denied a permit in any of the twenty-three existing BSL-3 laboratories in the state, which speaks directly to the issue of public safety of these labs. Boston University has the proven capability to operate these labs safely and securely.

The NEIDL lab will have to adhere to the strict requirements that the City of Boston has for operating this type of lab. The Boston Public Health Commission and the public safety departments in the City have proven capability of handling the commissioning and oversight for these laboratories.

Delaying this permit will be a waste of taxpayer money and potentially cost the Commonwealth millions of dollars in grants. I believe that the NEIDL research can save lives and invent cures for deadly infectious diseases, I support the waiver application. This critical research will benefit the Commonwealth financially but also by being a leader in research facilities across the country.

I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research. If you have any questions please do not hesitate to contact me.

Kindest regards,

CHARLES A. MURPHY
*Majority Whip*

The Commonwealth of Massachusetts
House of Representatives
State House, Boston 02133-1054

BG

THOMAS A. GOLDEN, JR.
16TH MIDDLESEX DISTRICT
STATE HOUSE, ROOM 527A
TEL: (617) 722-2020

RECEIVED
SEP 30 2011
MEPA

Vice-Chair
Committee on Ethics

Committee Member
Ways and Means
Telecommunication, Utilities & Energy

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900

Dear Secretary Sullivan:

I am writing in favor of Boston University's request to permit the National Emerging Infectious Disease Laboratory (NEIDL). It is time for the research to begin in this $200,000,000 research facility.

Boston University's request to open BSL-2 and BSL-3 laboratories for research is both a reasonable and responsible approach to the permitting of this research center. There are hundreds of BSL-2 labs on the Boston University campus and thousands of the labs in the Commonwealth. Boston University now operates three of the twenty-three permitted BSL-3 laboratories in the state.

The City of Boston has strict operating requirements for these labs. The Boston Public Health Commission and the public safety departments in the City are extremely capable of handling the commissioning and oversight for these laboratories.
The fact that MEPA has never denied a permit in any of the twenty-three existing BSL-3 laboratories in the state speaks directly to the issue of public safety of these labs. They are safe and Boston University has the proven capability to operate these labs safely and securely.

To further delay the needed research in this state-of-the-art facility is a waste of the taxpayers' monies, delays vital research projects and has the potential to cost the Commonwealth millions of dollars in grants. For these reasons, and because the NEIDL research can save lives and invent cures for deadly infectious diseases, I support the waiver application.

Mr. Secretary, I respectfully urge you to approve the waiver to allow Boston University to open the NEIDL for BSL-2 and BSL-3 research.

Please feel free to contact me at my office at 617-722-2020, if any additional information is needed.

Sincerely,

**THOMAS A. GOLDEN, JR.**
*State Representative*
*16th Middlesex District*

BG

# The Commonwealth of Massachusetts
## House of Representatives
## State House, Boston 02133-1054

HAROLD P. NAUGHTON, JR.
12TH WORCESTER DISTRICT
200 HIGH STREET
CLINTON, MA 01510
TEL: (978) 365-1955

Chairman
Joint Committee on
Public Safety and Homeland Security

ROOM 167, STATE HOUSE
TEL. (617) 722-2230
FAX (617) 722-2846
Harold.Naughton@MAhouse.gov

September 30, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Barlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

RECEIVED
SEP 30 2011
MEPA

Dear Secretary Sullivan:

It is a pleasure to write this letter of strong support of Boston University's request to permit the National Emerging Infectious Disease Laboratory (NEIDL). This request for approval to commence BSL-2 and BSL-3 laboratories is important for this research center. It is time for the research to begin this $200,000,000 research facility.

There are hundreds of BSL-2 labs on the Boston University campus and thousands of the labs in the Commonwealth. Boston University now operates three of the twenty-three permitted BSL-3 laboratories in the state.

The City of Boston has strict operating requirements for these labs. The Boston Public Health Commission and the public safety departments in the City are extremely capable of handling the commissioning and oversight for these laboratories.

The fact that MEPA has never denied a permit in any of the twenty-three existing BSL-3 laboratories in the state speaks directly to the issue of public safety of these labs. They are safe and Boston University has the proven capability to operate these labs safely and securely.

To further delay the needed research in this state-of-the-art facility is a waste of the taxpayers' monies, delays vital research projects and has the potential to cost the Commonwealth millions of dollars in grants. For these reasons, and because the NEIDL research can save lives and invent cures for deadly infectious diseases, I support the waiver application. Please contact my

office if you have any questions regarding this letter of support. I may be reached by phone at (978) 365-1995 or (617) 722-2230.

Sincerely,

HAROLD P. NAUGHTON, JR.
State Representative, 12th Worcester District
House Chairman, *Joint Committee on Public Safety and Homeland Security*

BG

# ALLIANCE

ALLIANCE DETECTIVE & SECURITY SERVICE, INC.

RECEIVED

OCT 4 - 2011

MEPA

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing in support of Boston University's (BU) waiver application to conduct low-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

Lower level research is currently conducted on BU's campus, throughout Boston and across the Commonwealth. There are hundreds of BSL-2 and approximately 24 BSL-3 laboratories across Massachusetts. These labs operate safely and are critical to the biomedical research that benefits humankind.

The new low level laboratories in the NEIDL are state-of-the-art and are designed to maximize safety. I believe that Boston University can and will safely conduct this lower level research.

I understand that the approval process for the BSL-4 laboratories is ongoing and that the National Institutes of Health is overseeing a supplemental risk assessment process for the BSL-4 portion of the NEIDL. I believe the supplemental risk assessment process is important and should continue.

In the meantime, BU should be allowed to open the NEIDL for BSL-2 and BSL-3 research. I appreciate your consideration of their waiver application and urge you to approve it.

Thank you for your consideration,

Richard Topham
Executive Director
Alliance Detective & Security Service, Inc.
930 Broadway
Everett, MA 02149
617-387-1261 617-389-4691 fax

BG

college BOUND DORCHESTER

RECEIVED

OCT 4 - 2011

MEPA

September 19, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

College Bound Dorchester is excited to support Boston University. We are pleased to submit this letter of support for the University as they have given our program so much support for so long.

We believe that Boston University and the NEIDL, once open and operational, will benefit our community in many ways.

As a nonprofit, we are fortunate be associated with Boston University and extremely grateful for their ongoing generosity. We are proud to lend our support to their cause.

Sincerely,

Ted Lincoln

Theodore Lincoln
Lead Teacher
Middle School
College Bound Dorchester

BG

RECEIVED

OCT 4 – 2011

MEPA

Septiembre 9, 2011

**Secretary Richard K. Sullivan, Jr.**
**Executive Office of Energy and Environmental Affairs**
**Attn: MEPA Office**
**Maeve Bartlett EEA No. 12021**
**100 Cambridge Street, Suite 900**
**Boston, MA 02114**

*Distinguido Secretario Sullivan,*

*Le escribo para dar mi apoyo para el permiso que Boston University ha pedido para abrir el nivel más bajo del laboratorio para estudio contra enfermedades contagiosas.*

*La investigación científica es importante para la salud pública. No se justifica porque Boston University no ha podido abril este establecimiento científico. En este momento existen cientos de laboratorios nivel 2 en el estado de Massachusetts*

*Entiendo que el laboratorio de nivel 4 ha sido causa de controversia y conflicto. También sé que todavía está bajo evaluación por el Instituto Nacional de Salud. Por esta razón, debería su agencia permitir que Boston University utilice los laboratorios de niveles más bajos mientras las evaluaciones para el laboratorio nivel 4 terminen.*

*Le pido que le permita a Boston University abrir y utilizar los recursos de esta facilidad para el bien de la salud pública y de la ciencia.*

*Sinceramente,*

***Primitiva Tapia***

BG

MASSHOUSING

Massachusetts Housing Finance Agency
One Beacon Street, Boston, MA 02108

TEL: 617.854.1000 | FAX: 617.854.1091
VP: 866.758.1435 | www.masshousing.com



September 8, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing in support of Boston University's (BU) waiver application to conduct low-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

Lower level research is currently conducted on BU's campus, throughout Boston and across the Commonwealth. There are hundreds of BSL-2 and approximately 24 BSL-3 laboratories across Massachusetts. These labs operate safely and are critical to the biomedical research that benefits humankind.

The new low level laboratories in the NEIDL are state-of-the-art and are designed to maximize safety. I believe that Boston University can and will safely conduct this lower level research.

I understand that the approval process for the BSL-4 laboratories is ongoing and that the National Institutes of Health is overseeing a supplemental risk assessment process for the BSL-4 portion of the NEIDL. I believe the supplemental risk assessment process is important and should continue.

In the meantime, BU should be allowed to open the NEIDL for BSL-2 and BSL-3 research. I appreciate your consideration of their waiver application and urge you to approve it.

Thank you for your consideration,

Thaddeus Miles
Director of Public Safety

BG

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

September 12, 2011

RECEIVED
OCT 4 - 2011
MEPA

**Secretary Sullivan:**

I am writing to affirm my support for Boston University's request to open the National Emerging Infectious Diseases Laboratories for lower-level research.

Currently, there are at least 24 BSL-3 labs in Massachusetts, most of which are located in the Boston/Cambridge area. I believe that BU can operate the lower-level labs safely, efficiently and successfully.

I am aware that the BSL-4 portion of the laboratory has generated some controversy. The building was completed in 2008 and has remained closed. It makes sense that BU would like to use the laboratory now for lower-level research as the risk assessment process continues.

Granting the waiver request for this $200,000,000 facility, so that it may open and begin valuable research, will be a great benefit to the Commonwealth. I respectfully ask that you grant the necessary waiver so that important research may begin along with the creation of new jobs.

Sincerely,

Kimberly K Russell-Lucas, MPH, CCRP

BG



October 3, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

This letter is to show my support for Boston University's request of a waiver.

Lower level research is currently conducted on BU's campus, throughout Boston and across the Commonwealth. There are hundreds of BSL-2 and approximately 24 BSL-3 laboratories across Massachusetts. These labs operate safely and are critical to the biomedical research that benefits humankind.

I politely ask that you grant the necessary waivers for BU to move forward with their plans.

Thank you,

Pat Augustine
Camden St
Roxbury, MA 02119

BG

RECEIVED
OCT 5 2011
MEPA

Boston University
School of Medicine &
Metropolitan College
Biomedical Laboratory and
Clinical Sciences
CityLab Academy
801 Albany Street, S-4
Boston, Massachusetts 02119

BOSTON UNIVERSITY

September 7, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

Dear Secretary Sullivan:

I am writing to support Boston University's (BU) waiver application to conduct low-level biosafety research in our National Emerging Infectious Diseases Laboratories (NEIDL). As director of two biotechnology education programs, I know the importance of research conducted in these labs. We train undergraduate students year-round in Level-2 labs.

Lower level research is currently conducted on BU's campus, throughout Boston and across the Commonwealth. There are hundreds of BSL-2 and approximately 24 BSL-3 laboratories across Massachusetts. These labs operate safely and are critical to the biomedical research that benefits humankind.

The new low level laboratories in the NEIDL are state-of-the-art and are designed to maximize safety. I believe that Boston University can and will safely conduct this lower level research.

I understand that the approval process for the BSL-4 laboratories is ongoing and that the National Institutes of Health is overseeing a supplemental risk assessment process for the BSL-4 portion of the NEIDL. I believe the supplemental risk assessment process is important and should continue.

In the meantime, BU should be allowed to open the NEIDL for BSL-2 and BSL-3 research. I appreciate your consideration of their waiver application and urge you to approve it.

Thank you for your consideration,

Sincerely,

*Constance Phillips*

Constance Phillips, M.A., M.P.H.
Research Assistant Professor of Biochemistry
Boston University School of Medicine/
Metropolitan College
BLCS & CLA Program Director

BG

September 13, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114



Dear Secretary Sullivan:

I am writing in support of Boston University's (BU) waiver application to conduct low-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The new low level laboratories in the NEIDL are state-of-the-art and are designed to maximize safety. I believe that Boston University can and will safely conduct this lower level research.

I thank you for your consideration of BU's waiver request and urge you to approve it.

Sincerely,

Jian Huan Wu

BG

SENATOR
SONIA CHANG-DÍAZ
SECOND SUFFOLK DISTRICT

COMMONWEALTH OF MASSACHUSETTS
MASSACHUSETTS SENATE
STATE HOUSE, BOSTON, MA 02133-1053

ROOM 413C
TEL. (617) 722-1673
SONIA.CHANG-DIAZ@MASENATE.GOV
WWW.MASENATE.GOV

COMMITTEES:
EDUCATION, CHAIR
BONDING, CAPITAL EXPENDITURES AND STATE ASSETS
CHILDREN, FAMILIES AND PERSONS WITH DISABILITIES
MUNICIPALITIES AND REGIONAL GOVERNMENT
TOURISM, ARTS AND CULTURAL DEVELOPMENT



October 4, 2011



Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: National Emerging Infectious Diseases Laboratories, Boston University MEPA Waiver Request, EOEEA #12021**

Dear Secretary Sullivan:

I represent residents in Boston City Council Districts 4 and 7, and voters citywide. I am writing to urge you to deny Boston University's ("BU's") request for a Phase One waiver from applicable MEPA regulations in connection with its proposed operation of the National Emerging Infectious Diseases Laboratories (the "NEIDL") at Boston University Medical Center. The requested waiver would allow BU to open BSL-1 and BSL-2 laboratories immediately. It would allow BU to open BSL-3 laboratories and conduct research on highly contagious pathogens in the NEIDL, all without further MEPA review. The waiver would circumvent judicially-mandated environmental reviews put in place in order to ensure that the surrounding communities of Roxbury and the South End are not subjected to unnecessary risks associated with conducting research on potentially lethal pathogens in densely-populated urban neighborhoods.

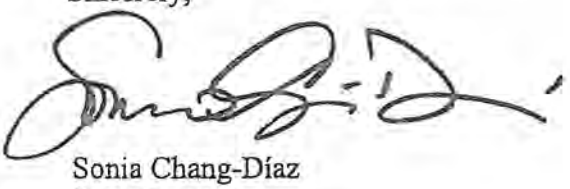
Although BU argues that it would only conduct lower-level research pursuant to this waiver, it has always proposed the NEIDL as an integrated laboratory facility with BSL-1 through BSL-4 lab spaces. Therefore, work done in the non-BSL-4 lab spaces could easily involve much more high-risk material than would be the case at other lower-security labs. BU has not provided any specific information in its waiver request about which pathogens would be studied at the NEIDL and what work would be done by the various labs that it contains.

BU's waiver request stipulates that no research would proceed at the BSL-3 level until the NIH's risk assessment is complete. However, the University has twice failed to meet its obligation to prepare an adequate and scientifically credible assessment of the risks associated with research on contagious pathogens in the NEIDL. Until I am fully aware of and have confidence in the precaution and mitigation measures taken by the university, I urge that operations should not commence at the NEIDL.

For these reasons, I ask that you deny the waiver request and retain full jurisdiction to review the risk assessment for *all* labs located in the NEIDL. Such a denial would allow the project to receive full MEPA review as has been anticipated by both community members and the courts. At the very least, I ask that, should you deem the waiver request to have any merit, you hold a public hearing beforehand. That hearing should be held at a location and time that is convenient and accessible to the public, particularly the affected South End and Roxbury communities.

Thank you for your time and consideration.

Sincerely,



Sonia Chang-Díaz
State Senator
Second Suffolk District

## Gage, Bill (EEA)

**From:** Vallely Bartlett, Maeve (EEA)
**Sent:** Tuesday, October 11, 2011 3:22 PM
**To:** Gage, Bill (EEA)
**Subject:** FW: Waiver Request

**From:** Jaffe, Seth [mailto:SDJ@foleyhoag.com]
**Sent:** Tuesday, October 11, 2011 2:38 PM
**To:** Vallely Bartlett, Maeve (EEA)
**Cc:** Davis, Gary (ENV); 'Burgay, Stephen P'; Fay, Jamie; Stephen A. Williams Esq. (swilliam@bu.edu); Todd L. C. Klipp Esq. (tklipp@bu.edu)
**Subject:** Waiver Request

Ms. Vallely-Bartlett:

I write to request that EEA not issue a decision on the waiver request for BioSquare Phase II, EOEEA no. 12021, pending submittal by the proponent of certain additional information regarding the scope of and basis for the request.

Regards,

Seth

FOLEY
HOAG LLP

**Seth D. Jaffe | Partner**

Seaport World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2600

617 832 1203 phone
617 832 7000 fax
617 688 5453 mobile

www.foleyhoag.com
Read the Law and the Environment blog at lawandenvironment.com.

For more information about Foley Hoag LLP, please visit us at www.foleyhoag.com.

## Gage, Bill (EEA)

**From:** Hardaway, Kathleen (EEA)
**Sent:** Friday, October 07, 2011 4:05 PM
**To:** Gage, Bill (EEA)
**Cc:** Vallely Bartlett, Maeve (EEA)
**Subject:** FW: letter from Rep. Fox
**Attachments:** Bio letter.pdf

Kathleen Hardaway
Executive Assistant to Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114
(617) 626-1015
Email: Kathleen.Hardaway@state.ma.us



**From:** Tuitt, Mary (HOU) [mailto:mary.tuitt@mahouse.gov]
**Sent:** Friday, October 07, 2011 4:05 PM
**To:** Hardaway, Kathleen (EEA)
**Subject:** letter from Rep. Fox

The Commonwealth of Massachusetts
House of Representatives
State House, Boston, 02133-1054

Gloria L. Fox
STATE REPRESENTATIVE
Room 167, State House
Boston, MA 02133-1054
Tel (617) 722-2810

COMMITTEES:
VICE CHAIR
COMMITTEE ON HOUSING
MEMBER
COMMITTEE ON WAYS AND MEANS

October 14, 2011

**BY EMAIL AND FIRST CLASS MAIL**
Maeve Vallely Bartlett, Esq.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, Massachusetts 02114

**Re: National Emerging Infectious Diseases Laboratories Boston University's Supplemental Filing for MEPA Waiver Request EOEEA #12021**

Dear Ms. Vallely Bartlett:

I represent **Boston, 7th Suffolk district.** I have previously provided comments regarding Boston University's ("BU") request for a waiver from MEPA review of BSL-1, BSL-2, and BSL-3 research facilities at the NEIDL. As my previous comment letters described, I are opposed to BU's waiver request and believe that the project should remain subject to full MEPA review.

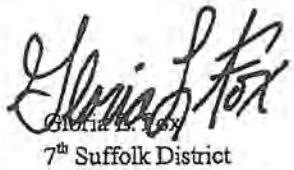
I have learned that, on October 11, 2011, BU notified you that it planned to submit additional information supporting its waiver request and requested that your office refrain from issuing a decision on the waiver request until the supplemental information was submitted. I understand that you granted this request. I am concerned that, through this request, BU seeks to avoid public review of its full submission and I write to request that you ensure that our constituents and other members of the public be permitted to fully participate in reviewing and providing feedback on whatever additional materials BU submits.

I believe that BU's request is yet another example of its attempts to limit meaningful MEPA review of the NEIDL through the provision of piecemeal information to your office in its pursuit of a waiver from full MEPA review. The fact that BU may have finally realized that its original vague, six-page waiver request was incomplete should not shield its proposed supplemental submittal from full public review.

Allowing BU to supplement its waiver request without providing a subsequent opportunity for public review and comment on the supplemental information is especially unacceptable given BU's conduct and the siting of the project in an environmental justice community. BU's prior failures to provide an opportunity for meaningful community input on the NEIDL proposal, and its repeated failures to prepare an adequate and scientifically credible risk assessment, make it all the more important that any supplemental information be subject to the same level of public review as the initial waiver request.

I therefore request that your office publish a notice and copies of BU's supplemental filing in the *Environmental Monitor* and allow an additional comment period to obtain public input on the supplemental filing. Given the history of the project and its presence in an environmental justice community, it would be inappropriate to deny the public a meaningful opportunity to comment on BU's entire waiver request. Thank you for your consideration.

Yours in Community Service,



Gloria L. Fox
7th Suffolk District

cc: Secretary Richard K. Sullivan, EOEEA

ANDERSON & KREIGER LLP

**ARTHUR P. KREIGER**
akreiger@andersonkreiger.com
Direct phone: 617-621-6540
Direct fax: 617-621-6640

October 19, 2011

OCT 20 2011

**BY EMAIL AND FIRST CLASS MAIL**
Maeve Vallely Bartlett, Esq.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re: National Emerging Infectious Diseases Laboratories**
**Boston University's Supplemental Filing for MEPA Waiver Request**
**EOEEA #12021**

Dear Ms. Vallely Bartlett:

This firm represents the plaintiffs in the pending state and federal litigation regarding the proposed National Emerging Infectious Diseases Laboratories (the "NEIDL") at Boston University Medical Center. On September 27, we provided comments opposing Boston University's request for a waiver from MEPA review of BSL-1, BSL-2 and BSL-3 research facilities at the NEIDL. That request should be denied and the project should remain subject to full MEPA review. This letter responds to BU's recent request for an extension regarding its waiver request.

Notice of BU's request for a waiver was published in the *Environmental Monitor* on September 21 as a Notice of Project Change, along with the public comment deadline of September 27. We and several of our clients, along with other members of the public, submitted extensive comments to your office by that date. However, two weeks later, on October 11, BU apparently notified you that it planned to submit additional information supporting its waiver request – with no indication of when it would submit that information or what the information would consist of – and requested that your office delay a decision on the waiver until that additional information was submitted. We understand that you agreed to do so pending that submittal and further discussion on the appropriate public dissemination of that information.

BU apparently now believes that more information is necessary to justify its waiver request for "lower level research." The more information BU submits in support of a waiver request, the clearer it becomes that full FEIR review is necessary to comply with MEPA. A complete FEIR would include a comprehensive and scientifically defensible analysis of the NEIDL's risks and provide robust opportunities for public input and thorough agency review. Instead of proceeding diligently to complete an FEIR, however, BU has chosen to seek ways to limit MEPA review.

BU's attempt to obtain an "expedited" MEPA review through rolling submissions of additional information burdens the community members whose health would be jeopardized by

this project. Each time BU submits another round of information, it forces community members to spend time and resources to thoroughly analyze the information and respond. Meaningful dialogue with BU is impossible if no one knows when BU will make its submission, what it will submit, or what information it will continue to omit or withhold.

BU's extension request also undermines its arguments for a waiver and exposes that BU's waiver request is far from the simple matter it purports to be. BU chose to roll the dice by submitting an unsupported waiver request. Now, by seeking to submit more information, it is tacitly acknowledging that at least some of the comments are valid and that the request needs shoring up. That confirms that the NEIDL's impacts are more complex and serious than BU previously claimed and that those impacts should not be reviewed through an expedited MEPA process. Moreover, BU's gamble has taken up weeks, if not months, undermining its argument that it needs a waiver in order to proceed with certain work immediately and vitiating its protest about delay. The long-awaited supplemental risk assessment is now, presumably, that much closer. This underscores our previous point: BU's "hardship" is entirely a product of its own inability or unwillingness to submit an adequate FEIR.

Merely disseminating BU's new information would be insufficient. When BU does supplement its waiver request, it will be essential for our clients and the public to have a full opportunity to review and comment on any new information and arguments. Any supplemental information should be subject to at least the same public review as the initial waiver request. Anything less would be unfair and unacceptable, particularly where the NEIDL is proposed for an environmental justice community. Paragraph 14 of EOEEA's Environmental Justice Policy requires enhanced public participation during MEPA review of the NEIDL. In order to comply with the EJ policy, and to maintain a fair and transparent process for review of BU's waiver request, your office should publish a notice and copies of BU's supplemental filing in the *Environmental Monitor* and allow an additional comment period on that filing.

Thank you for your consideration.

Sincerely,

Peter Shelley
Conservation Law Foundation

Arthur Kreiger, MSA
Arthur Kreiger
Anderson & Kreiger LLP

Laura Maslow-Armand, MSA
Laura Maslow-Armand
Lawyers' Committee for Civil Rights Under Law of the Boston Bar Association

cc: Secretary Richard K. Sullivan, EOEEA
Gary Davis, Esq., EOEEA
William Gage, EOEEA
Seth Jaffe, Esq.
Klare Allen, The Safety Net (by email)

The Commonwealth of Massachusetts
House of Representatives

**BYRON RUSHING**

Byron.Rushing@state.ma.us

State House - Room 121
Boston, MA 02133-1054
(617) 722-2006
(617) 722-2238 (F)

**9th Suffolk District**
*South End*
*St. Botolph*
*Lower Roxbury*
*Fenway*
*Kenmore*
*Prudential*
*Copley Place*
*West Campus,*
*MIT*

BG



October 20, 2011

Maeve Vallely Bartlett, Esq.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**Re:National Emerging Infectious Diseases Laboratories**
**Boston University's Supplemental Filing for MEPA Waiver Request**
**EOEEA #12021**

Dear Ms. Vallely Bartlett:

I represent the 9th Suffolk District, which includes the South End neighborhood of Boston, in the Massachusetts Legislature.

I have learned that, on October 11, 2011, BU notified you that it planned to submit additional information supporting its waiver request and requested that your office refrain from issuing a decision on the waiver request until the supplemental information was submitted. Did you grant this request?

I am concerned that, through this request, BU seeks to avoid public review of its full submission. I write to request that you ensure that my constituents and other members of the public be permitted to fully participate in reviewing and providing feedback on whatever additional materials BU submits.

I am also concerned that BU's request may be an attempt to limit meaningful MEPA review of the NEIDL through the provision of piecemeal information to your office in its pursuit of a waiver from full MEPA review. The fact that BU may have finally realized that its original vague, six-page waiver request was incomplete (or indefensible) should not shield its proposed supplemental submittal from full public review.

Although I did not comment formally regarding Boston University's ("BU") request for a waiver from MEPA review of BSL-1, BSL-2, and BSL-3 research facilities at

the NEIDL, I do oppose to BU's waiver request and believe that the project should remain subject to full MEPA review.

Allowing BU to supplement its waiver request without providing a subsequent opportunity for public review and comment on the supplemental information is especially unacceptable given BU's conduct and the siting of the project in an environmental justice community. BU's prior failures to provide an opportunity for meaningful community input on the NEIDL proposal, and its repeated failures to prepare an adequate and scientifically credible risk assessment, make it all the more important that any supplemental information be subject to the same level of public review as the initial waiver request.

I therefore for these reasons request that your office publish notice and copies of BU's supplemental filing in the *Environmental Monitor* and allow an additional comment period to obtain public input on the supplemental filing. Given the history of the project and its presence in an environmental justice community, it would be inappropriate to deny the public a meaningful opportunity to comment on BU's entire waiver request. Thank you for your consideration of this letter and please let me know what your office decides.

Yours truly,

Byron Rushing

cc: Secretary Richard K. Sullivan, EOEEA

W C E S Watertown Citizens for Environmental Safety
*Watertown's Voice for Peace, the Environment, and Social Justice*

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

**RE: Boston University National Emerging Infectious Diseases Laboratories, MEPA Waiver Request, EOEEA #12021**

Dear Secretary Sullivan:

I am writing on behalf of Watertown Citizens for Environmental Safety, a 32 year old organization that is Watertown's voice for peace, justice, and the environment. Watertown has followed the issue of this proposed lab complex since its inception and has been extremely concerned that labs of this nature could be located in the center of a densely populated low income urban area. Although we are seven miles from the proposed laboratory, we also feel vulnerable, given the accidents that have happened in such labs that could result in escape of dangerous infectious diseases.

We have received a copy of Boston University's request for a Phase One waiver which would allow use of the NEIDL for BSL-2 and BSL-3 laboratory research without further MEPA review. We strongly oppose this request and urge you to deny it.

The request makes the argument that there are many other BSL-2 and BSL-3 labs in the Commonwealth that have not been required to carry out risk assessment. However, because the funding of these labs came through a program requiring research on bio-weapons agents, work in these labs is inherently more dangerous than that in the other labs. In addition, Boston University (BU) has shown utter disregard for environmental and safety regulations, by failing to report a tularemia outbreak to BPHC, by misrepresenting a Boston regulation banning recombinant DNA work in a BSL-4 lab, and by incurring many infractions of environmental regulations.

BU argues that all research conducted at the NEIDL will be transparent to the public, and they cite the Institutional Biosafety Committee (IBC) and the Community Liaison Committee (CLC). However, to date these committees have not operated in a transparent manner. There have been great concems in the community about the process of appointments to the CLC and about closed meetings. Scientists and community members who represent a point of view not aligned with BU have not been able to gain appointment to these committees; the CLC has not acted to "represent community concerns" nor to "advise the community on planned research activities and any ongoing laboratory issues." The history of BU's relationship with the community and the public at large is one of secrecy and lack of truthfulness.

There has not been a good faith effort to produce a valid risk assessment; the series of documents produced have all been judged inadequate by the National Research Council and the courts. BU's consultants have intentionally chosen scenarios and diseases that would not give an accurate picture of the risks. It seems clear that the reason for this pattern is that is not possible to produce an honest risk assessment showing that this facility is safe in this location.

The BU request states that "in response to NIH concerns regarding the integrity of the risk assessment process, the University has agreed that it will not commence actual BSL-3 level research until the risk assessment has been completed and considered." A MEPA waiver allowing the BSL-3 work would make a mockery of this agreement with NIH and the integrity of the risk assessment process.

The application states that the needed sewer discharge permit "can and should include conditions that will assure that no research at the BSL-4 level would take place in the building" until the appropriate approvals. However, a number of the highly lethal and contagious agents used in BSL-4 work can also be researched in BSL-3 labs, and BSL-3 level work is also extremely risky in a densely populated area. No waiver of MEPA should be given for such work.

As stated in the BU request, "research at the NEIDL at the BSL-2 and BSL-3 levels would be subject to the full range of local, state, and federal agency reviews and approvals that apply to other existing laboratories..." However, there has been a great deal of recent testimony before Congressional committees, as well as before Massachusetts legislative committees, showing the inadequacy of regulation of these biolabs at all levels of government. The number of accidents that have already occurred attest to this fact, and there have been many near misses that could have resulted in catastrophic situations.

For all these reasons we urge you to deny this request to wave the MEPA requirements for the BSL-2 and BSL-3 level research at the NEIDL.

Sincerely,
Ernesta Kraczkiewicz
Treasurer, member of Planning Committee
Watertown Citizens for Environmental Safety

**Gage, Bill (EEA)**

**From:** Vallely Bartlett, Maeve (EEA)
**Sent:** Tuesday, September 06, 2011 4:10 PM
**To:** Gage, Bill (EEA)
**Subject:** FW: Boston Bio-Labs

---

**From:** Hardaway, Kathleen (EEA)
**Sent:** Tuesday, September 06, 2011 4:07 PM
**To:** Vallely Bartlett, Maeve (EEA); Gage, Bill (EEA)
**Subject:** FW: Boston Bio-Labs

One of many!

Kathleen Hardaway
Executive Assistant to Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114
(617) 626-1015
Email: Kathleen.Hardaway@state.ma.us

---

**From:** Chris Knighton [mailto:xknighton@gmail.com]
**Sent:** Tuesday, September 06, 2011 3:07 PM
**To:** Sullivan, Rick (EEA); Hardaway, Kathleen (EEA)
**Subject:** Boston Bio-Labs

Dear Secretary Sullivan,

I'm in opposition to BU's Phase 1 Waiver request to open the BSL1 and 2 labs immediately and to open the BSL3 without a MEPA review of the completed Supplemental Environmental Impact Report.

Your approval of BU's waiver request would create dangerous precedent for developers to bypass the MEPA risk assessment process.

I would also like to request that your office hold a public hearing on the Phase 1 Waiver request before you issue your draft decision at a location and time of the day that is convenient and accessible for the public, particularly the affected South End and Roxbury communities.

Sincerely,

Christopher John Knighton

Jamaica Plain, Boston, MA

BG

OEHN
Occupational & Environmental Health Network
*Optimizing Health and Delivering Results*

RECEIVED
SEP 19 2011
MEPA

September 15, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
Attn: MEPA Office
Maeve Vallely-Bartlett EEA No. 12021
100 Cambridge Street, Suite 900
Boston, MA 02114

We are writing as representatives of Occupational and Environmental Health Network, based in Marlborough, MA. We serve as Occupational Health Medical Directors overseeing many prominent Boston, Cambridge and New England hospital and educational laboratories, including BSL-2, BSL-3 and BSL-4.

We are writing to demonstrate our support for the Commonwealth of Massachusetts to grant a waiver that would allow the opening of the BSL-2 and BSL-3 laboratories at the Boston University (BU) National Emerging Infectious Diseases Laboratories (NEIDL).

If it were not for the BSL-4 part of the project, the lab would already be open. BU already safely operates 350 BSL-2 and three BSL-3 labs on its campus. There is nothing unique or inherently dangerous about the new BSL-2 and BSL-3 labs it wishes to open now. I'd like to bring to your attention, , the letter that the Boston Public Health Commission recently wrote to the EOEEA, in support of the opening of these laboratories stating "Boston University has an excellent record managing hundreds of BSL-2 labs and three BSL-3 laboratories."

If Secretary Sullivan agrees, the building will open for research on tuberculosis in the BSL-2 labs as early as this November, while the BLS-3 research would begin after the Risk Assessment, being conducted by the National Institutes of Health's Blue Ribbon Panel, is considered and completed and the Boston Public Health Commission and the Centers for Disease Control grant their approvals. The opening of the BSL-4 lab will not begin until the Risk Assessment and all legal issues, regarding this type of lab, are resolved.

In conclusion, the NEIDL is a state-of-the-art facility that has cost over $200,000,000, and it is a waste of taxpayers' money not to have this facility opened.

T Winters, MD

Thomas H. Winters, MD, FACOEM
President OEHN,
Chief Medical Officer and Principal

Lee Okurowski, MD, MPH, MBA,
Chief Executive and Financial Officer
Principal

Dieter Affeln
Occupational Health Medical Director

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Christian Ellis

Name Christian Ellis

Address 21 Copley Ave

City/State/Zip Waltham MA 02452

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Kevin P Lydon

Name KEVIN P LYDON

Address 11 LODGE RD

City/State/Zip Wayland MA 01778

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Hilary Caron

Name Hilary Caron

Address 140 Bay State Rd.

City/State/Zip Boston MA 02215

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Yasmari Estrada

Name Yasmari Estrada

Address 35 Fidelis Way, C-44

City/State/Zip Brighton, MA. 02135

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature [illegible] CT

Name Br. Lawrence A. Whitney, CT

Address 252 Western Ave. Apt. 3

City/State/Zip Cambridge, MA 02139

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Madeline W. Jennings

Name Madeline W. Jennings

Address 15 Nourse St

City/State/Zip Arl. MA. 02474

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature [illegible]

Name Richard Fiddler

Address 165 Allen St

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature Wendy S Jennings

Name WENDY S. Jennings

Address 15 Nourse ST.

City/State/Zip Arl, MA 02474

Dear Secretary Sullivan:

I support Boston University's plan to conduct lower-level biosafety research in the National Emerging Infectious Diseases Laboratories (NEIDL).

The supplemental risk assessment process for the BSL-4 laboratories is important and that process should continue. In the meantime, however, BU should be permitted to do lower-level biosafety research in the NEIDL.

I request that the Executive Office of Energy and Environmental Affairs grant the waiver to open the NEIDL for lower-level research.

Thank you for your consideration.

Signature [illegible]

Name John A Ramoska Jr.

Address 60 Harry Dr #21

City/State/Zip Dracut, Ma 01826

# Appendix 6

FEIR RISK ASSESSMENT
RWDI JULY 2004

# SUMMARY REPORT
# HAZARD AND RISK ASSESSMENT
# NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES (NEIDL)
# BOSTON UNIVERSITY MEDICAL CAMPUS
## BOSTON, MASSACHUSETTS

**Project Number:** W04-263

**Date:** July 16, 2004

**Submitted By:** RWDI West Inc.

Senior Technical Coordinator - Sarah Arulanandam, M.A.Sc.

Senior Hazard & Risk Specialist - Arthur Springer, M.Sc., P.Eng.

Senior Project Manager - John Alberico, M.Sc.

Project Director - Ian Dowsett, R.E.T.

**Submitted to:** Boston University Medical School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- Sudbury (705) 523-4535
- Montreal (450) 776-6877
- Windsor (519) 728-2702
- Ottawa (613) 225-5648

**U.S. Contacts:**
**RWDI LLC**
- California (909) 793-7080

# 1. INTRODUCTION

Boston University Medical Campus (BUMC) retained RWDI West Inc. to conduct a risk assessment for the proposed BSL-4 facility at the new National Emerging Infectious Diseases Laboratories (NEIDL) at the BUMC campus.

This report summarizes the results for a screening-level assessment conducted to provide anthrax spore concentration isopleths under a variety of release conditions. Maximum downwind ground-level anthrax spores concentrations were predicted using dispersion modeling techniques following an accidental laboratory release for three conceivable release scenarios to provide an estimate of the maximum possible risk of exposure to these spore concentrations along the path of the dispersing plume.

The following analysis was prepared to support a BUMC review of the public health risk of a "worst-case scenario" at a proposed BSL-4 laboratory. The worst case scenario was defined to include:

- Complete loss of containment systems in the BSL-4 laboratory despite preventative maintenance, testing and HEPA certification programs
- Impacts to individuals not associated with the Boston-NBL, including nearby residents, workers, inmates, patients and pedestrians. Worker exposure is not part of the public health risk assessment.
- The maximum exposure potential is through the release of aerosolized anthrax spores
- The entire release from the facility can be assumed to have elapsed over approximately 30 minutes

Anthrax was selected because of its resistance to environmental factors such as sunlight and lack of humidity and ease of airborne dissemination.

The primary risk associated with the inhalation exposure to anthrax spores by humans are initial symptoms resembling a common cold (e.g., sore throat, mild fever, muscle aches and malaise), and if untreated progressing to severe breathing problems, shock and death.

The literature regarding exposure levels reference a range of exposure criteria, including:

- US Defense Department estimate of $LD_{50}$ for humans - between 8,000 and 10,000 spores (Reference 2)

- Meselson et. al. reference from a forensic study of the release at Svardlosk – "the dose causing 2% fatalities ... is nine spores" (Reference 2)

The references used in this assessment, including the one noted above, are listed in Section 6 of this report.

## 2. ASSUMPTIONS

The following assumptions were used in determining the dispersion modeling results for the Maximum Possible Risk (MPR) scenarios.

Source Characterization Assumptions

- Each 15 cc (cubic centimeter) container of purified anthrax (anthrax vial) contains 10 billion spores of which approximately 400,000 respirable particles are available to become and remain airborne.

- The breathing rate corresponds to the rate of inhalation for an active person, 30 liters per minute to provide a conservative upper bound on the potential number of inhaled spores (Reference 2)

- Ventilation flow rates from the exhaust stacks were assumed to correspond with 12 air changes per hour (corresponding to an exhaust flow rate of 14,000 cubic feet per minute) for the building BSL-4 Laboratory Space.

Dispersion Modeling Assumptions

- Dispersion modeling was conducted from the top of the building exhaust stack.

- Dispersion modeling of the spores was performed using SLAB, a U.S. EPA-approved dispersion model developed at Lawrence Livermore Laboratories to determine the hazard associated with different release scenarios.

- Dispersion modeling was conducted using a range of weather conditions that may be encountered, from sunny, summer windy conditions to calm clear, winter nights (Table 1 summarizes the different weather conditions used in the analyses).

**Table 1:** Description of The Meteorological Conditions Used in Modeling Release Scenarios.

| Stability Class | Wind Speed | | Description |
|---|---|---|---|
| | (m/s) | (km/hr) | |
| B | 2 | 7.2 | Bright sunny afternoons in late spring, summer and early fall. Skies are clear or almost clear and winds are light. Temperatures range from warm to hot. |
| D | 2 | 7.2 | Sunny days in early spring and late fall. Overcast days and evenings with light winds at any time of the year. Hours with rain or snow falling. |
| D | 5 | 18.0 | Partly cloudy to overcast days and nights (anytime of year) with moderate winds. Periods with weak sunshine in early spring and late fall. |
| D | 10 | 36.0 | Strong winds at any time of the day or night, regardless of temperature or cloud cover. |
| E | 3 | 10.8 | Nights with some cloud at any time of the year. Daytime conditions on the coldest days in winter. |
| F | 2 | 7.2 | Cold clear nights in winter or cool clear nights in the rest of the year. |

- In each release scenario, under the specific meteorological conditions modeled, all of the spores are assumed to travel downwind in the same direction to provide an upper bound or maximum value for the estimated ground level concentration.

## 3. RELEASE SCENARIOS

### 3.1 Release Events

In the release events modelled, the number of spores released is expected to vary over time, decaying exponentially (see Figure 4.1), and extending the time of the release event. In these scenarios, the spore cloud mixes with the surrounding air as the fresh air is brought into laboratory space.

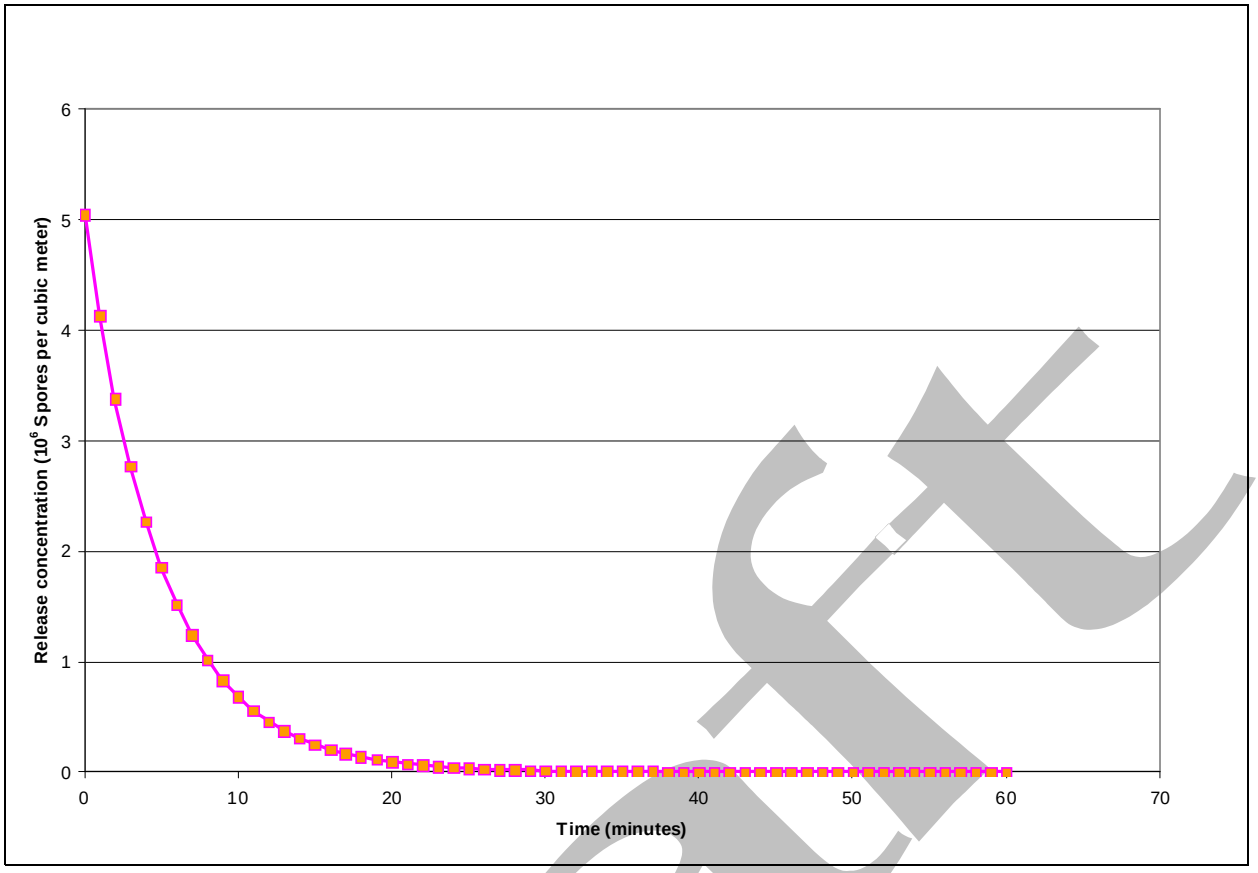


**Figure 3.1:** The concentration of spores released, varying with time, for a ventilation rate of 12 air changes per hour (corresponding to a ventilation rate of 14,000 cubic feet per minute for the BSL-4 laboratory space).

### 3.1.1 Accidental Laboratory Release Scenario - Two HEPA Filters

This scenario simulates an accidental laboratory release where the entire contents of an anthrax vial are released within the BSL-4 Laboratory space in a cloud of spores. Figure 4.2 shows the spore concentration varying with time at a distance downwind of the release where the maximum ground level concentration occurs. The results are considered over the range of weather conditions noted in Table 1.

The calculated maximum number of spores that may be inhaled by an individual standing on the plume centerline at a given downwind distance from the release in this scenario occurs under

B stability (wind speed of 2 m/s). For an individual breathing at a rate of 30 litres per minute (the breathing rate of an active person) for the duration of the release event, the calculated maximum number of spores that may be inhaled is 0.00000000021 spores. Since the release and inhalation of a partial spore is not feasible, this number may be practically considered as zero.

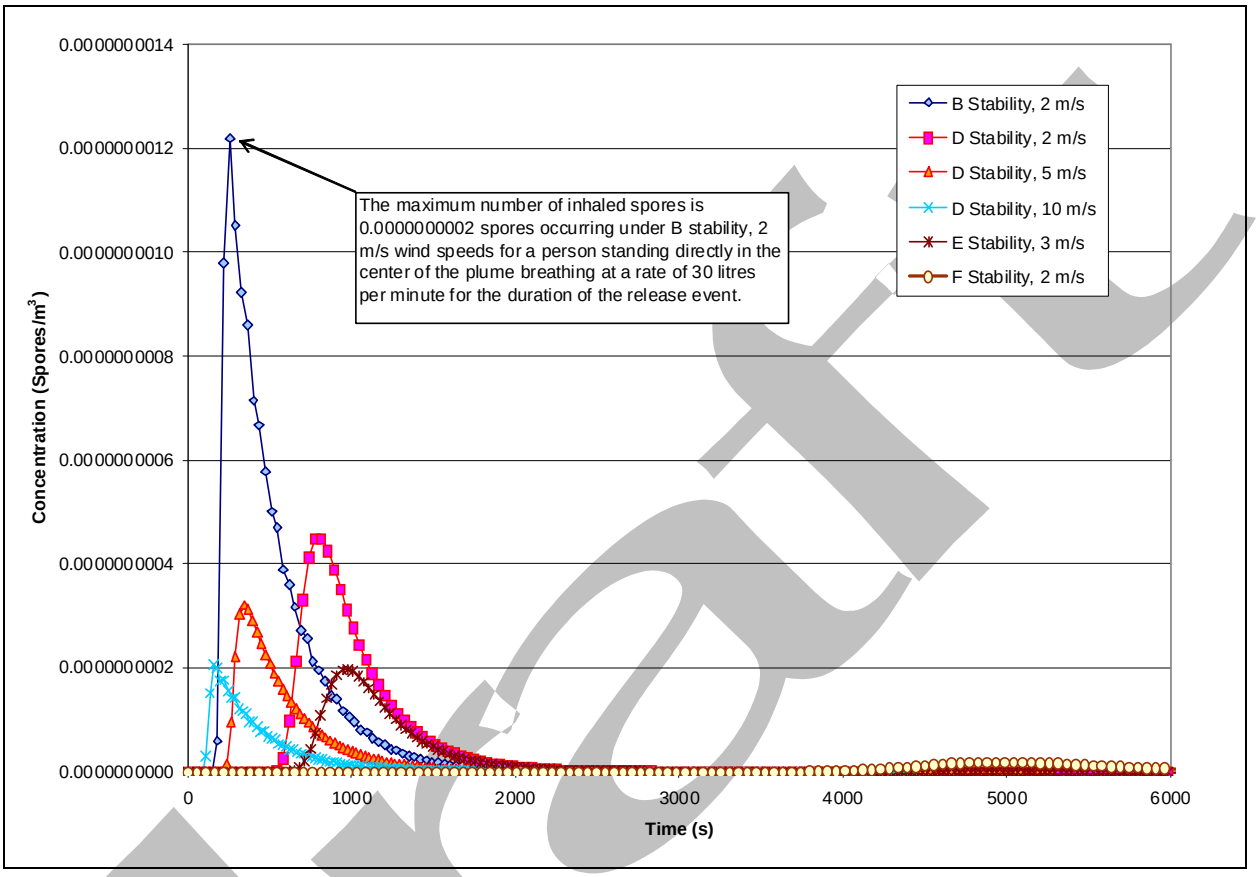


**Figure 3.2:** Accidental Laboratory Release Scenario: *Maximum* predicted ground-level concentration of spores occurring downwind of a release (with two HEPA Filters in place) shown at the maximum point of impingement for the range of meteorological conditions considered.

## 3.2 Accidental Laboratory Release Scenario – Single HEPA Filter Malfunction

This scenario simulates an accidental laboratory release where the entire contents of an anthrax vial are released within the BSL-4 Laboratory space in a cloud of spores when only one of the HEPA filters is not functioning. Figure 4.3 shows the spore concentration varying with time at

a distance downwind of the release where the maximum ground level concentration occurs. The results are considered over the range of weather conditions as noted in Table 1.

The calculated maximum number of spores that may be inhaled by an individual standing on the plume centerline at a given downwind distance from the release in this scenario occurs under B stability (wind speed of 2 m/s). For an individual breathing at a rate of 30 litres per minute (the breathing rate of an active person) for the duration of the release event, the calculated maximum number of spores that may be inhaled is 0.0000007 spores. Since the release and inhalation of a partial spore is not feasible, this number may be practically considered as zero.

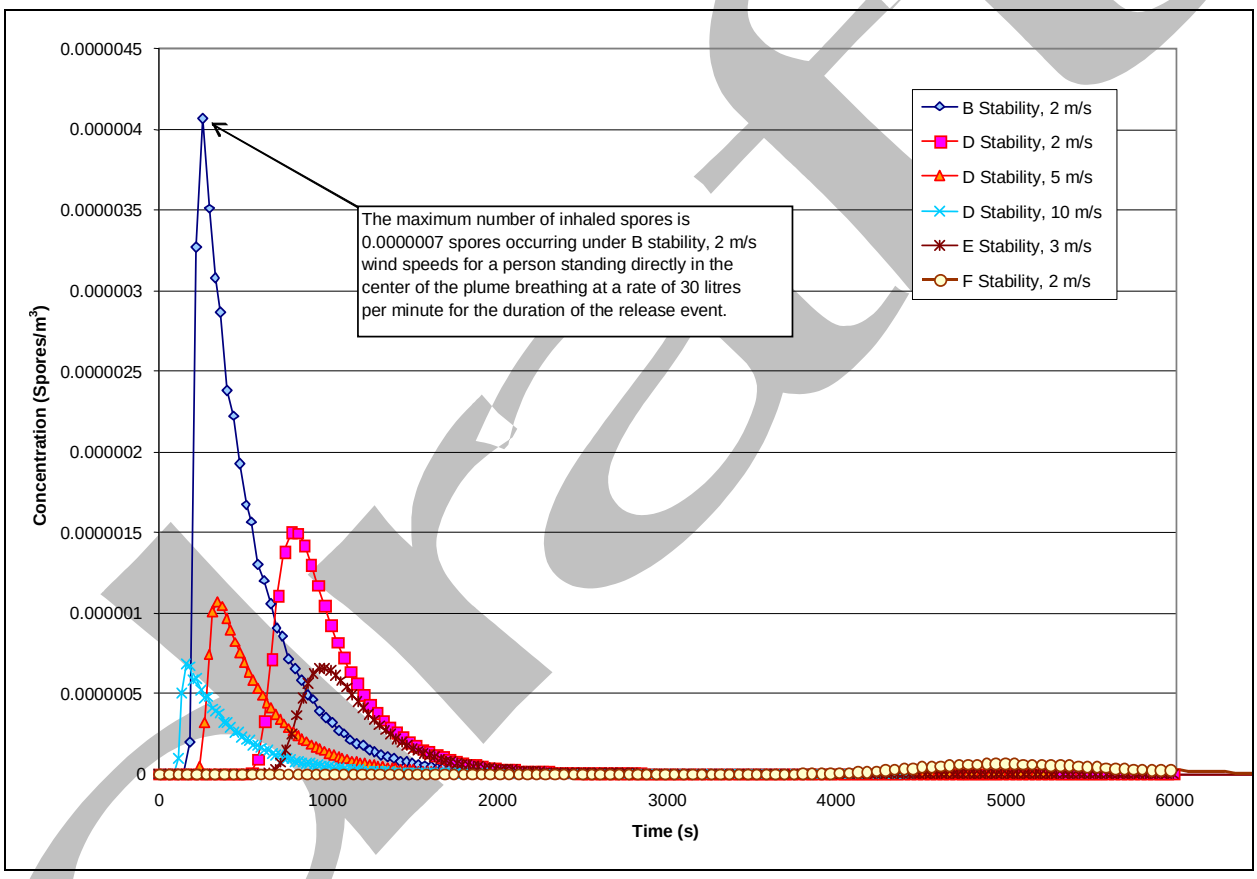


**Figure 3.3:** Accidental Laboratory Release Scenario – Single HEPA Filter Malfunction: *Maximum* predicted ground-level concentration of spores occurring downwind of a release shown at the maximum point of impingement for the range of meteorological conditions considered.

### 3.3 Accidental Laboratory Release Scenario – No HEPA Filters

This scenario simulates an accidental laboratory release where the entire contents of an anthrax vial are released within the BSL-4 Laboratory Space in a cloud of spores with neither of the HEPA filters in operation. Figure 4.4 shows the spore concentration varying with time at a distance downwind of the release where the maximum ground level concentration occurs. The results are considered over the range of weather conditions noted in Table 1.

The calculated maximum number of spores that may be inhaled by an individual standing on the plume centerline at a given downwind distance from the release in this scenario occurs under B stability (wind speed of 2 m/s). For an individual breathing at a rate of 30 litres per minute (the breathing rate of an active person) for the duration of the release event, the calculated maximum number of spores that may be inhaled is 0.0024 spores. Since the release and inhalation of a partial spore is not feasible, this number may be practically considered as zero.

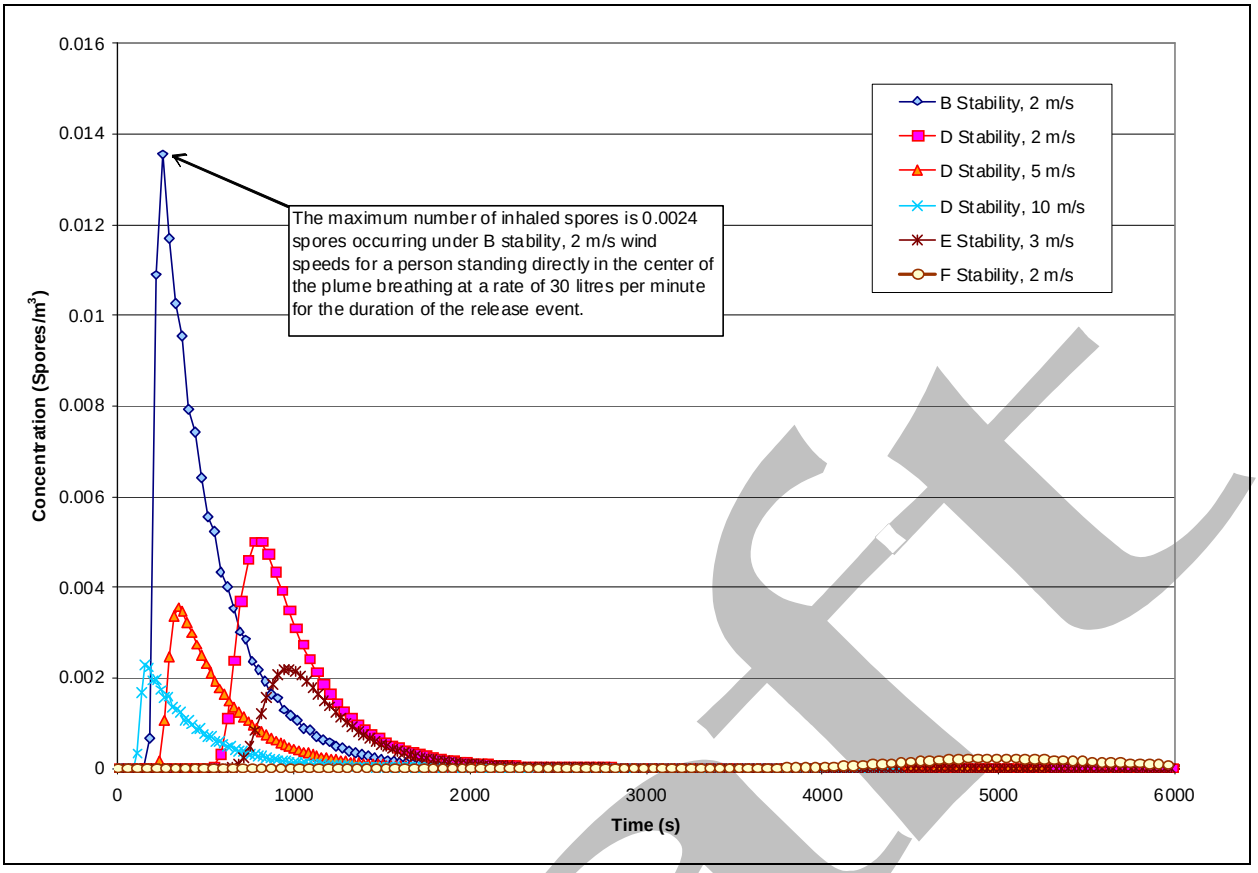


**Figure 3.4:** Accidental Laboratory Release Scenario – No HEPA Filters: *Maximum* predicted ground-level concentration of spores occurring downwind of a release shown at the maximum point of impingement for the range of meteorological conditions considered.

## 4. SUMMARY

The results presented in this report summarize preliminary dispersion modeling results describing the maximum downwind ground-level anthrax spore concentrations predicted for three release scenarios. In each case, the calculated maximum number of spores that may be inhaled by an individual standing on the plume centerline downwind from the release is less than a single spore. Since the release and inhalation of a partial spore is not feasible, this number may be practically considered as zero.

## 5. REFERENCES


1. Emergency response to Anthrax Attack (Lawrence M. Wein, David L. Craft, and Edward H. Kaplan), PNAS, Vol.100, No.7.

2. The Sverdlovsk Anthrax Outbreak of 1979 (M. Meselson et al.), Science, 1994, Vol. 266.

3. Simulation Modeling of Anthrax Spore Dispersion in a Bioterrorism Incident (V. Reshetin and J. Regens), Risk Analysis, Vol. 23, No. 6.

4. Airborne dispersion modeling for outbreak detection (W.Hogan), RODS Conference Presentation.

5. NIH Building 33 Risk Assessment – Executive Summary (NIH Community Liaison Council, November 20, 2003).

6. "User's Manual for SLAB: An Atmospheric Dispersion Model for Denser-Than-Air Releases" (Donald L. Ermak) available through the National Technical Information Services (NTIS).

# Appendix 7

# NEIDL COMPREHENSIVE EMERGENCY MANAGEMENT PLAN

BOSTON UNIVERSITY

# NATIONAL EMERGING INFECTIOUS DISEASES LABORATORY

## COMPREHENSIVE EMERGENCY MANAGEMENT PLAN

BOSTON UNIVERSITY

To All Recipients:

Transmitted herewith is the National Emerging Infectious Diseases Laboratory Comprehensive Emergency Management Plan. This plan provides a framework whereby the staff of Boston University will plan and perform their respective emergency functions during an emergency event at this facility. This plan includes functions that Boston University would rely upon the city of Boston and the Commonwealth of Massachusetts to perform.

This Comprehensive Emergency Management Plan combines the four phases of emergency management, (1) prevention: those activities which eliminate or reduce the probability of disaster; (2) preparedness: those activities that governments, organizations, and individuals develop to save lives and minimize damage; (3) response: to prevent loss of lives and property and provide emergency assistance; and (4) recovery: short and long term activities which return all systems to normal or improved standards.

This plan is consistent with existing federal, state, and local expectations as defined in statute and has been reviewed with agencies providing local support. It will be revised and updated as required. All recipients are requested to advise the Boston University Director of Emergency Response Planning of recommendations for improvement.

The following National Emerging Infectious Diseases Laboratory (NEIDL), Boston University, Boston and Commonwealth of Massachusetts officials or their representatives have participated in the development or review of this plan.

Institutional Official/Associate Vice President of Research Compliance
Executive Director of Public Safety
Executive Director, Research Compliance
Responsible Official/Director of Research Safety
Director, NEIDL
Associate Director of Engineering and NEIDL Operations
Associate Director of Maximum Containment, NEIDL
Director, Laboratory Animal Science Center
Director, Emergency Response Planning
Boston Public Health Commission

The Boston University Emergency Response Planning Division is charged with the responsibility to develop, maintain, and coordinate the implementation of the NEIDL Comprehensive Emergency Management Plan (CEMP).

This plan addresses emergency situations in which response actions must be coordinated.

All Boston University Department Heads and Core Directors assigned a responsibility under this plan are hereby directed to develop detailed implementing procedures for each department, describing how response functions will be carried out

Institutional Official

8/15/12
Date

Director, NEIDL

8-15-12
Date

Director, Emergency Response Planning

8/15/2012
Date

## APPROVAL AND IMPLEMENTATION

The National Emerging Infectious Diseases Laboratory's (NEIDL) Comprehensive Emergency Management Plan (CEMP) is the first CEMP for the facility located at 620 Albany Street, Boston, Massachusetts 02118. It provides a framework whereby the staff of Boston University will plan and perform their respective emergency functions during an emergency event at this facility. This plan includes functions that Boston University would rely upon the city of Boston and the Commonwealth of Massachusetts to perform.

This plan may be modified by the Director, Emergency Response Planning, or designee to reflect changes in personnel, spelling, grammar, nomenclature, and minor changes in procedures that do not change the intent of the plan transmitted today without the approval of the Director of the NEIDL.

Institutional Official

8/15/12
Date

Director, NEIDL

8-15-12
Date

Director, Emergency Response Planning

8/15/2012
Date

## RECORD OF CHANGES

| Change Number and Date | Date of Entry | By Whom Entered |
|---|---|---|



Revised pages shall be dated and marked to show where changes have been made. Copies of revisions shall be forwarded to all organizations and appropriate individuals identified as having responsibility for implementation.

## RECORD OF DISTRIBUTION

The NEIDL CEMP has been distributed to the following organizations and positions within those organizations. All changes to this document will be likewise distributed.

Boston University, Senior Vice President Operations
Institutional Official/Associate Vice President of Research Compliance
Executive Director of Public Safety, Boston University
Executive Director, Research Compliance, Boston University
Director, NEIDL
Responsible Official/Director of Research Safety
Associate Director of Engineering and NEIDL Operations
Associate Director of Maximum Containment, NEIDL
Director, Laboratory Animal Science Center
Director, Campus and Clinical Safety
Radiation Safety Officer/Chief Health Physicist
Director, Emergency Response Planning
Boston Public Health Commission
Massachusetts Emergency Management Agency
Federal Emergency Management Agency



## SECURITY SENSITIVE INFORMATION

Boston University owns and operates the National Emerging Infectious Diseases Laboratories (NEIDL) at its BioSquare site located on Albany Street. BU intends to maintain and protect security sensitive information relating to the NEIDL.

The term "Security Sensitive Information" shall mean information that, if disclosed, would be an unwarranted invasion of personal privacy, reveal a trade secret or privileged or confidential commercial or financial information, or make it easier for hostile elements to disrupt operations or avoid security controls.

Requests for information related to this document should be directed to the Boston University Office of the Associate Vice President for Research Compliance.

**ABBREVIATIONS**

| | |
|---|---|
| ARO | Alternate Responsible Official of the Select Agent Program |
| BAPERN | Boston Area Police Emergency Radio Network |
| BSL-4 | Bio Safety Level 4 or Maximum Containment, as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition. |
| BUMC CC | Boston University Medical Campus Command Center |
| BUPD | Boston University Police Department |
| CEMP | Comprehensive Emergency Management Plan |
| EHS | Boston University Environmental Health and Safety Department |
| ERCS | Emergency Response Communications System: Used by Boston University to notify personnel of an emergency situation and possible response actions. |
| ERP | Emergency Response Planning Division of EHS |
| ERT | Emergency Response Team: Boston University personnel who respond to,assess and mitigate emergency incidents on campus. |
| HAZWOPER | Hazardous Waste Operations and Emergency Response (OSHA Standard 1910.120) |
| HSEEP | Homeland Security Exercise and Evaluation Program : A ..... capabilities and performance-based exercise program that provides a standardized methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning. |
| IAP | Incident Action Plan: Formally documents incident goals, operational period objectives, and the response strategy defined by incident command during response planning. |
| ICS | Incident Command System: A systematic tool used for the command, control, and coordination of emergency response. |
| IC | Incident Commander: The individual responsible for the overall management of the emergency response. |
| NEIDL | National Emerging Infectious Diseases Laboratories |
| NIMS | National Incident Management System: A system used in the USA to coordinate emergency preparedness and incident management among various government and non-government agencies. The system was developed under *Homeland Security Presidential Directive (HSPD)-5, Management of Domestic Incidents.* |
| OSHA | Occupational Safety and Health Administration: A federal agency of the USA that regulates workplace safety and health. |
| POETE | Planning, Organization, Equipment, Training, and Exercises: The elements that support the building and sustaining of an emergency response program consistent with NIMS. |
| RO | Responsible Official of the Select Agent Program |
| ROHP | Boston University Research Occupational Health Program |
| WebEOC | A Web-based Emergency Operations Center crisis information management system used by Boston University and the city and state emergency management agencies to share real-time incident information. |

**PLAN MANAGEMENT**



**PART ONE—BASIC PLAN**



**PART TWO—PLAN DEVELOPMENT AND MAINTENANCE**

# PART ONE—BASIC PLAN

## A OVERVIEW

The National Emerging Infectious Diseases Laboratories (NEIDL) is a 7-story, 193,000 square foot building located within BioSquare on Boston University's Medical Campus. The building is owned and operated by Boston University and includes 3 ½ floors of laboratory space, 2 ¼ floors of mechanical space and 1 ¼ floors of administrative space.

The design and construction of the NEIDL included an assessment of risks and design and construction focused on the mitigation of those risks. Safety measures include specific laboratory safeguards with mechanical and utility systems that allow for redundant systems on standby, and utility delivery and onsite generation systems sized for similar levels of reliability and protective measures implemented at a secure perimeter and throughout the building.

The NEIDL staffing and emergency response plans are integrated into those of Boston University. While dedicated and specialized staff work within the NEIDL, support, expertise, response capabilities, and regulatory oversight are provided through University-wide services.

Incident Command for the NEIDL is consistent with Incident Command for Boston University. Locations to be used as command centers, individuals who will have authority, and resources to be utilized are University-wide.

NEIDL and Medical Campus Public Safety Officers and Boston University Police Officers all report through the Executive Director of Public Safety. In coordination with those trained and qualified to address such issues, NEIDL Public Safety Officers are academy-trained, armed, and experienced in the response to and containment of incidents. NEIDL Public Safety Officers are all trained as first-responders in first aid and CPR, and are supported by BUPD Officers and Medical Campus Public Safety staff.

NEIDL Environmental Health and Safety (EHS) staff is trained and experienced in high and maximum containment operations. They provide oversight, training, and protocol development related to the management of high and maximum containment facilities. These employees all report to the Boston University Office of Research Compliance and are part of the campus-wide EHS Department. EHS includes 24 hour on-call personnel trained extensively in hazardous materials response with expertise in biological, chemical, and radioactive materials response as well as all life safety and environmental response issues. EHS staff will coordinate response to hazards including interacting with responding agencies and will follow up on corrective actions.

NEIDL Emergency Response Planning is managed by a director who oversees the same functions for all of Boston University and is part of EHS. The planning necessary to ensure appropriate response to incidents and the timely communication

of information falls under this function and is supported extensively by both BUPD and the other divisions within EHS. Emergency Response Planning coordinates training for all those assigned to the NEIDL, and given the nature of high and maximum containment work, NEIDL personnel are certified in first aid and cardio-pulmonary resuscitation and automatic external defibrillation.

The NEIDL was constructed with systems designed to minimize risk and to ensure the ongoing provision of safe, secure science. The operations within the NEIDL are similarly focused. The response capabilities of those departments mentioned above will improve as first responders, guides and support to external responders, and participants in drills continue to exercise and critique the process.

NEIDL response plans recognize the need for support from outside the organization for services including, but not limited to, fire suppression, hazardous materials mitigation and extraction, major medical emergencies, patient transport, explosives disposal, and hostage situations.

Boston University has a long history of providing education and training in laboratory operations and response to external responders in the city of Boston and expects to continue doing so with greater frequency. The coordination of plans through drills and exercises as well as other training resources will serve as a significant part of the plan to address safety issues and public concern over those issues.

This Comprehensive Emergency Management Plan relies on the expertise of internal responders, the support of external resources, and a program of ongoing training and exercises involving users and both internal and external responders. This plan addresses emergency communications with both internal and external responders and compliments notification procedures in place with the Boston Public Health Commission.

## B PURPOSE, SCOPE, SITUATION, AND ASSUMPTIONS

### a. Purpose and Scope

The purpose of this plan is to describe a comprehensive emergency management program that seeks to mitigate the effects of a hazard, prepare for measures to preserve life and minimize damage, respond during emergencies and provide assistance, and establish a recovery system in order to return to a normal state of affairs.

This plan attempts to define who does what, when, where, and how in order to prevent, prepare for, respond to, and recover from natural and manmade emergency incidents.

This plan will be activated when an emergency event occurs at the NEIDL.

b. Situation Overview

Boston University, including the NEIDL, is committed to conducting safe, secure research. Boston University is aware of the potential dangers that are inherent in working with biological agents in the NEIDL and has engineered the building to minimize danger to the community and staff.

This NEIDL, the larger campus, and the community could all potentially be exposed to hazards that have the potential for disrupting everyday activities, causing damage, and resulting in casualties. Possible natural hazards include hurricanes, floods, tornadoes, winter storms, and earthquakes. Emergencies that are seen in the workplace can include, but are not limited to, medical emergencies, fires, power outages, and utility failures. There is also the threat of a weapons-related incident involving workplace violence, a terrorist attack, or civil disorder impacting the NEIDL, the larger campus, or the community.

c. Hazard Analysis Summary

Boston University conducts Hazard Vulnerability Assessments in accordance with the Hazard Classifications Section of the FEMA Comprehensive Preparedness Guide (CPG-101). The impacts of these assessments are reflected in the NEIDL CEMP Function Chart attached to Part Four, Section T on page 79 of this document. as part of its evaluation of operations and in accordance with requirements from the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention (Select Agent Program 42 CFR Section 73.14), and the Boston Public Health Commission. The annual Hazard Vulnerability and Risk Assessments are based on the Kaiser-Permanente HVA model. These analyses have resulted in the specific hazards addressed in this NEIDL Comprehensive Emergency Management Plan.

The NEIDL is currently being used as a high-rise laboratory and office building with active BSL-2 laboratories as well as related administrative and support functions

The Hazard Vulnerability Assessment and Risk Analysis have taken into consideration the likelihood that these events may occur in the Boston area and have weighted them accordingly.

NEIDL Public Safety staff is regularly briefed on real or potential threats. EHS staff is regularly updated on regulations, requirements, and risks associated with hazardous materials. Both groups are regularly trained on response to emergencies involving threats and risks. Information from these regulatory and law enforcement bodies are included in training programs and is incorporated into the NEIDL Hazard Analysis.

The NEIDL Hazard Vulnerability Assessment addressed a comprehensive list of hazards, including cyber security threats, chemical, biological, radiological, nuclear, explosive, and pandemic events and evaluated the potential for events using the hazard-specific scale. It was assumed that each event incident occurred at the worst possible time of day.

Issues considered included, but were not limited to:

i. Probability: Included known risk, historical data, and manufacturer/vendor statistics.

ii. Response: Included time to marshal an on-scene response, the scope of response capability, and the historical evaluation of response success.

iii. Human Impact: Included potential for staff death or injury.

iv. Property: Included cost of replacement, cost of temporary replacement, cost of repair, and time to recover.

v. Business Impact: Included business interruption, employees not able to report to work, vendors/suppliers unable to reach facility, NEIDL in violation of contracts/grants, imposition of fines and penalties, interruption of research, reputation and public image, and financial impact/burden.

vi. Preparedness: Included status of current plans, frequency of drills/exercises, training status, insurance, and availability of alternate sources of critical supplies and services.

vii. Internal Resources: Included types and volume of supplies on hand, staff availability and expertise, back-up systems availability, ability of internal resources to withstand disasters/survivability.

viii. External Resources: Included types of agreements with community agencies, coordination with local and state

agencies, and coordination with other healthcare and research facilities.

d. Capability Assessment

The NEIDL capability assessment methodology, as described in the CEMP Function Chart, is based upon the POETE model of the Department of Homeland Security's Urban Area Strategy Initiative. The NEIDL CEMP was evaluated by answering the following questions:

- Do we have **P**lans to respond to the hazards identified through the Hazard Vulnerability Assessment?
- Is there an **O**rganization available to execute those plans?
- Is that organization properly **E**quipped?
- Has the properly equipped organization been **T**rained on the equipment and plans?
- Has the organization **E**xercised those plans while equipped after training?

Boston University has used the POETE model over the past five years and has the capabilities across the University to respond to most of the hazards on campus, including the NEIDL, with minimal assistance from external response organizations. The staff, as described in the Plan Overview, is trained, equipped, and available and work with research employees as has been the practice at existing on-campus BSL-3 laboratory programs.

e. Mitigation Overview

The NEIDL Emergency Response Planning (ERP) Core is responsible for conducting a yearly Hazard Vulnerability and Risk Assessment and sharing the results of that assessment with various University and external emergency responders in developing a mitigation strategy for the NEIDL.

Emergency response planning is based on following the simple premise of the Plan-Do-Check-Act management system. This system requires that the program develop a process for planning the response to emergencies that includes ongoing evaluation and drills with a feedback mechanism in the form of after-action reviews designed to check performance and then modify as appropriate.

During the construction of the facility, Boston University worked with the Boston Fire Department to establish the building's fire

safety features to ensure a full line of communications. ERP has developed the existing emergency response plans for Boston University with the city of Boston emergency responders. These plans have been reviewed, tested, and revised based upon tabletop and full-scale drills and exercises as well as actual emergency incidents that occurred in the existing BUMC BSL-3 laboratories. As the NEIDL is brought online, joint emergency planning, training, and tabletop and full-scale exercises will be conducted with Boston University and NEIDL staff and Boston emergency responders.

Training and Exercises: All training and exercises at the NEIDL will be conducted following the Department of Homeland Security's Homeland Security Exercise and Evaluation Program. Boston University has been using the HSEEP, as it determines appropriate, since 2005.

Interagency Cooperation: Boston University has developed a solid working relationship with its external safety emergency responders through the utilization of sound training, exercise, and planning initiatives with the Boston Public Health Commission, including the following agencies: Boston Emergency Medical Services, Fire Department, Police Department, Brookline Police and Fire Departments, and the Massachusetts State Police.

This interagency cooperation in pre-incident events has shown to be extremely valuable during actual emergency responses to incidents.

Having met the Massachusetts Building Code, the NEIDL is in conformance with earthquake and wind resistance standards.

Fire detection and suppression standards have been met throughout the building, lessening the loss of life and property to fire.

The NEIDL is a state of the art engineered biological laboratory that meets or exceeds the recommendations of the Fifth Edition of the Biosafety in Microbiological and Biomedical Laboratories Manual.

f. Planning Assumptions

   i. Boston University will manage hazards including Select Agents, and will continue to do so is a safe, secure manner.

   ii. Boston University officials recognize their responsibilities with regard to research and community safety.

iii. Boston University officials will continue to develop and improve their emergency management plans.

iv. When properly implemented, these plans will reduce or prevent disaster-related losses.

v. Personnel assigned to the NEIDL will be certified in First Aid, Cardio Pulmonary Resuscitation, and the use of Automatic External Defibrillation as determined appropriate and necessary.

vi. Researchers and animal care workers are trained in emergency response procedures for removing a co-worker from the lab.

vii. Appropriate personal protective equipment (PPE) will be provided for, and utilized by, all personnel in high and maximum containment laboratory suites.

viii. In the event of an emergency incident, it is the responsibility of the laboratory researchers and workers to make the initial notification to the Control Center. The Control Center will make subsequent notifications as specified in the appropriate Emergency Response Plan.

## C CONCEPT OF OPERATIONS

It is the responsibility of Boston University to undertake comprehensive emergency management planning in order to protect life and property from the effects of hazardous events. Boston University will act as primary responder and when the emergency exceeds the University's capability to respond, assistance will be requested from the local external emergency response agencies.

This plan is based upon the concept that the emergency functions for the various groups involved in emergency management will generally parallel their normal day-to-day functions. To the extent possible, the same personnel and material resources will be employed in both cases.

Those day-to-day functions that do not contribute directly to the emergency operation may be suspended for the duration of the emergency. The efforts that would normally be required for those functions will be redirected to the accomplishment of emergency tasks by those concerned.

A CEMP is concerned with all types of emergencies and hazardous situations that may develop in the NEIDL. As shown below, it is more than an operations plan in that it accounts for activities before and after, as well as during, emergency operations.

Boston University operates under the Incident Command System (ICS) in its response to emergency events. The ICS defines critical roles, responsibilities, and authority to rapidly identify, mobilize, and implement strategies. The ICS establishes four categories of function in response to an emergency (management, operations, logistics, and planning) to manage events and foster communication internally and with other emergency response agencies. Activation of the ICS supersedes any and all norms of practice and authority.

In an incident at the NEIDL's BSL-4, initial notification is made to the Boston University's Medical Campus Control Center at (617) 414-6666, who will notify the NEIDL Emergency Response Team (NEIDL ERT) using the Boston University/ Boston Medical Center Emergency Response Communication System (ERCS), an automated phone/email/page system. This system tracks responses and allows responders to communicate their availability and response time. A fully equipped, pre-designated Command Center has been established to serve as a focal point for decision-making in response to an incident, and is equipped with information, data lines, and communications equipment. The Command Center is staffed by incident command staff as required by the event.

The initial response to an incident is by the NEIDL ERT. The senior most qualified person is the initial Incident Commander (IC), determining risk to laboratory personnel, responders, and other affected persons. In the absence of the RO or the Alternate RO, the most qualified EHS representative will act as the Incident Commander of the NEIDL ERT.

The IC, working with the members of the NEIDL ERT, evaluates potential for release, determines PPE and decontamination needs, requests assistance from external agencies as required and notifies the Boston Public Heath Commission.

The NEIDL ERT members have the required Select Agent security clearance, BSL-4 training, and OSHA HAZWOPER training required for such response and include an entry team whose personnel are trained and equipped to respond to and enter BSL-4 laboratories in the event of an incident. Other NEIDL personnel representing Facilities Management, Public Safety, Research, Occupational Medicine, Public Relations, and Administration are designated as emergency responders to support response to events.

*Note: Entry to the BSL-4 suites is highly restricted and is only granted to individuals who have the necessary security clearances, medical surveillance clearance, and both the didactic and hands-on training provided in the*

*facility's Simulator Training Center. These conditions apply to internal and external staff or responders; there are no exceptions unless the facility has been shut down, BSL-4 agents have been securely stowed away, and the areas have been decontaminated.*

## D ORGANIZATION AND ASSIGNMENT OF ROLES

Many departments within Boston University have emergency responsibilities in addition to their normal duties and each department is responsible for developing and maintaining their emergency management procedures. Specific responsibilities are outlined below under the section titled Task Assignments and in individual annexes. Responsibilities for organizations that are not part of local government are also presented.

a. NIMS/ICS

Boston University uses the Incident Command System (ICS) as outlined in the National Incident Management System (NIMS) to manage emergency incidents that occur within the NEIDL. The University will utilize the existing Medical Campus Incident Command Structure for this facility. Upon a declaration of a Phase C Event, the primary Incident Commander will be the Vice President for Operations, the secondary Incident Commander will be the Executive Director of Research Compliance and the tertiary Incident Commander will be the BUMC Director of Public Safety or the Director of Campus and Clinical Safety.

In those circumstances where external emergency response agencies are necessary to mitigate an emergency situation, a unified incident command will be established with Boston University personnel.

b. NEIDL Emergency Response Organization

i. Incident Commander: Responsible for approving all policy relating to emergency management.

ii. Director, Emergency Response Planning: Responsible for implementing all policy decisions relating to emergency management. In the absence of the Director, the Senior Specialist for Emergency Response Planning will assume the duties of the Director.

iii. NEIDL ERT: Once notified, will respond to the event, assess the incident, and implement an action plan to

stabilize and mitigate the potential hazard. Action plans will include appropriate emergency plan and incident command structure activation.

The NEIDL ERT consists of the following personnel:

1. NEIDL Biosafety Officer or NEIDL Lab Safety Specialist
2. BUMC Select Agent Responsible Official or alternate
3. NEIDL Facilities Manager or representative
4. Public Safety Director, Supervisor or Officer
5. Director or Senior Specialist, Emergency Response Planning Division
6. Principal Investigator or designee
7. Research Occupational Health Program Representative
8. Laboratory Animal Science Center Representative
9. Radiation Safety Officer or designee

The NEIDL ERT entry team is comprised of trained individuals who, under the most severe of circumstances, will enter the laboratory suite to implement the NEIDL ERT's action plan.

c. NEIDL Department Heads and Core Directors: Responsible for carrying out the tasks assigned to the respective departments.

d. NEIDL Emergency Response Facilities and Locations

   i. Boston University's Medical Campus Command and Control Center: The primary site for all emergency operations and is located at 750 Albany Street, Boston. NEIDL Building Automation Systems (BAS) and Public Safety Closed Circuit Television (CCTV) cameras can be monitored from this location.

   ii. NEIDL Control Room: Located on the first floor of the building at 620 Albany Street, Boston, is the nerve center for the building. Building Automation Systems (BAS) and Public Safety Closed Circuit Television (CCTV) cameras can be monitored from this location.

   iii. Alternate Facilities and Locations: In the event that the BUMC Command Center should become unusable, the secondary Medical Campus Command Center, located in

the Newton Pavilion 2nd Floor, 80 East Newton Street, may be used as an alternate facility.

e. External Public Safety Agency Roles and Responsibilities

i. Boston Police Department
1. Maintain law and order
2. Traffic control
3. Assist NEIDL Public Safety and BUPD

ii. Boston Fire Department
1. Fire control
2. Fire prevention inspections
3. Hazardous materials response

iii. Boston Emergency Medical Services
1. Provide basic (BLS) and advanced life support (ALS) treatment for the ill or injured
2. Conduct triage
3. Provide emergency ambulance transportation

iv. Boston Public Health Commission
1. Conduct active monitoring of the Public Health Alert Network/Surveillance System
2. Provide public health information announcements
3. Maintain liaison with Massachusetts Department of Public Health and United States Public Health Service and Center for Disease Control
4. Approve/provide steps to be taken in the event of illness or exposure.
5. Permit BSL-3, BSL-4 and Recombinant DNA research

## E DIRECTION CONTROL AND COORDINATION

a. Phases of Management

The ultimate responsibility for emergency management is vested in the Boston University Incident Commander. The Boston University Incident Commander is responsible for all policy level decisions. During emergency operations, the Incident Commander will be available to handle non-routine problems.

The Director, Emergency Response Planning (ERP) has the responsibility for coordinating the emergency management

program. This coordination includes making routine decisions and advising the Incident Commander on courses of action available for decision making. During emergency operations, ERP is responsible for the proper functioning of Boston University's Medical Campus Command Center (BUMC CC) and acts as a liaison with local, state, and federal agencies.

During an emergency incident at the NEIDL, the Unified Commanders will have tactical and operational control of response assets.

Specific persons and departments are responsible for fulfilling their obligations as presented in the Basic Plan and Annexes. Department Heads and Core Directors will retain control over their employees and equipment. Each department will have its own standard operating procedures for department response operations.

During emergency situations certain departments will be required to relocate their center of control to the BUMC CC. The coordination of all operations will be done through the Incident Command System and will be posted for distribution on the Boston University WebEOC specified incident as the current published NIMS IAP.

Each organization assigned emergency responsibilities in this plan will develop detailed implementing procedures. These procedures will be kept current by each organization.

b. Information Collection and Dissemination

   i. The NEIDL Public Safety Department coordinates threat intelligence information from the Boston Regional Intelligence Center, the Massachusetts Fusion Center, and the Joint Anti-Terrorism Task Force. This information is then made available to the NEIDL leadership for action.

   ii. The NEIDL EHS staff coordinates regulatory notifications and the mitigation/resolution of hazard-related incidents.

   iii. ERP is responsible for collecting emergency response information, conducting an After Action Report and Corrective Improvement Plan, and disseminating such information to all relevant parties.

c. Communications

Emergency response communications are established and maintained in a variety of ways: first, via hand-held, portable radios; second, through use of the BU ERCS notification system; and third, through the use of WebEOC.

i. Hand-held portable radios—There are six hand-held portable radios for use of the NEIDL ERT.

ii. Boston University ERCS—This emergency notification system is used to communicate emergency notifications to both internal and external emergency response personnel as well as non-response personnel to keep them informed of an emergency situation at the NEIDL.

iii. WebEOC—Boston University's web-based incident management program that is utilized in planned and unplanned events to support and manage large-scale incidents.

iv. Interoperability—The NEIDL Public Safety Department radios are interoperable with the NEIDL Emergency Response Team radios. BU Police radios are interoperable with the Boston Police Department through BAPERN. The external Boston response Departments have agency interoperability.

## F ADMINISTRATION, FINANCE, AND LOGISTICS

### a. Administration

During a Phase C event at the NEIDL, WebEOC will be used to administer the implementation of the Unified Command of the Incident Command System. This administrative function will be performed at the Boston University Command Center serving as the Emergency Operations Center.

Documentation will be captured on various ICS forms, activity boards, and logs on the Boston University WebEOC. In particular, the Incident Action Plans, Significant Event Board, Operations, Planning, Logistics, and Finance sections' boards will have all relevant documentation for the incident.

External response agencies, as well as the internal responders, will all have access to the Boston University WebEOC.

Incident based information and documentation will be used as part of the After Action Report process to critique the incident, identify lessons learned, develop best practices, and ultimately to better prepare for the future by decreasing the re-occurrence of incidents while minimizing losses.

Any and all agencies that responded to the incident will be given the opportunity to participate in the after action meeting process. During the incident, any agency representative may utilize the WebEOC After Action Board to document issues and propose changes.

i. Command Centers (campus-wide)

1. Primary Command Center: Boston University's Medical Campus Command Center is located in the Power Plant at 750 Albany Street, Boston.

2. Secondary Command Center: Should the primary Command Center become unusable, emergency operations will be relocated to the second floor of the Boston Medical Center's Newton Pavilion, 88 East Newton Street, Boston.

3. Tertiary Command Center: A second backup Command Center, if necessary, is the Boston University Charles River Campus Command Center at 25 Buick Street, Boston.

4. Fire Command Center: Located on the NEIDL's first floor near the loading dock, the Fire Command Center will serve as the primary assembly place for all emergency response activities. External emergency responders will be directed there and met by NEIDL Public Safety Officers to serve as escorts through the facility.

5. NEIDL Control Center: The nerve center for the building. Building Automation Systems (BAS) and Public Safety Closed Circuit Television (CCTV) cameras can be monitored from this location.

ii. Reports

The use of reports will vary according to the type of emergency being handled.

1. Incident Management: The Boston University WebEOC will be the incident management system used for all large-scale emergency events at the NEIDL.

2. Increased Readiness Report: All requests for assistance and all general messages will be handled using the procedures and forms found within Boston University WebEOC.

3. Incident Action Plan: An Incident Action Plan will be posted as appropriate on Boston University WebEOC.

4. Security Log: A record of all persons entering and leaving the BUMC CC will be maintained by public safety personnel at the entrance.

5. After Action Report: The ERP shall convene a meeting of all involved parties and departments for the purpose of an after action meeting to review the event and to develop Lessons Learned that will result in a formal After Action Report.

6. Corrective Improvement Plan: The ERP shall produce a Corrective Improvement Plan that addresses the lessons learned from the After Action Report and identifies responsible departments and/or individuals and a timetable to address those action items.

   ERP is responsible for the implementation of the Corrective Improvement Plan.

iii. Records

Required reports will be submitted to the appropriate authorities in accordance with individual annexes. Records of Boston University emergency management activities will be maintained by ERP.

iv. Preservation of Records

In order to provide normal operations following an emergency, vital records must be protected. The principal

causes of damage to records are fire and water; therefore, essential records are protected accordingly.

b. Logistics

During the POETE Gap Analysis (page 15), equipment necessary to respond to an emergency was identified. This equipment is maintained by the various NEIDL Cores. It is the responsibility of ERP to ensure that the equipment and supplies are on hand in a state of readiness.

ERP shall convene an annual meeting of the NEIDL Core Directors to identify resources needed to respond to those identified hazards from the NEIDL annual Hazard Vulnerability Assessment. This equipment will be restocked after the incident conclusion and before the affected laboratory space is allowed to be brought back into service.

Any resources that are not available on site at the NEIDL are available by the external response agencies as identified in the Capability Assessment as reflected in CEMP Function Chart. These resources are requested through the Control Center or through the Unified Incident Commanders.

The NEIDL Research and Operations staff are trained and equipped to handle most emergencies from the identified hazards. They possess the training to effectively mitigate these events. Proper personal protective equipment is available on site to support these operations. NEIDL staff, being first aid and CPR trained and certified, is capable of responding to medical emergencies while awaiting external responders for assistance and transport. It is expected that local external responders have sufficient equipment and personnel to supplement the response to the identified hazards.

Boston University has two hazardous materials vendors under contract to support cleanup at its buildings, including the NEIDL. These companies are Triumvirate Environmental Services and Clean Harbors Environmental Services.

# PART TWO—PLAN DEVELOPMENT AND MAINTENANCE

## G PLAN DEVELOPMENT AND MAINTENANCE

If a plan is to be effective, its contents must be known and understood by those who are responsible for its implementation. The Boston University Emergency Response Planning Division (ERP) of Environmental Health and Safety (EHS) will brief the appropriate responders concerning their role in emergency management and this plan in particular.

All NEIDL Cores, University Departments, and External Agencies will be responsible for the development and maintenance of their respective segments of the plan as set forth earlier on page 19 of this document. All NEIDL Cores and University Departments will be responsible for reviewing and updating their portion of this plan annually or as necessary taking into account changes identified by tests and exercises. External Agencies will be provided with changes to this plan through the Boston Public Health Commission.

a. Emergency Preparedness Program Review and Maintenance Cycle

   ERP will be responsible for ensuring that an annual review of the plan is conducted and will coordinate all review and revision efforts.

   The plan shall be activated at least once a year in the form of a test exercise in order to provide practical controlled operational experience to those individuals who have Command Center responsibilities.

b. Vulnerability Assessments and Mitigation Strategy

   The Boston University Office of Research Compliance is responsible for overseeing an annual Hazard Vulnerability and Risk Assessment of the NEIDL and ensuring that a NEIDL Mitigation Strategy based upon that assessment is developed and implemented across the NEIDL Departments.

c. Emergency Response Planning (ERP)

   ERP is responsible for conducting an annual review of the NEIDL Comprehensive Emergency Management Plan. The review of the Plan shall include all Operational and Scientific Cores of the NEIDL and will address internal response issues as well as external response issues as identified through the Boston Public Health Commission.

   ERP is responsible for revising this plan and keeping track of all revisions in the Record of Changes found on page 5 of this document. ERP is responsible for disseminating those changes to

NEIDL Cores and the participants listed in the front of this document.

d. Emergency Response Procedures

ERP will ensure that all Emergency Response Plans are reviewed annually and revised as necessary. Those revisions will be documented and disseminated to all affected NEIDL Cores and to external emergency response personnel through the Boston Public Health Commission.

i. Training: Emergency Response, Hazard Specific Response, NIMS/ICS Training Cycle.

ERP is responsible for the maintenance and updating of all Emergency Response Plans including those addressing Hazard Specific Responses, Material Safety Data Sheets for Infectious Agents, First Aid and CPR/AED Certification, and NIMC ICS Training for NEIDL employees.

The training cycle will be coordinated through the Office of Research Compliance and will involve those responsible for NEIDL compliance, occupational health, safety, and training.

e. Exercises: HSEEP Based Approach, Exercise Cycle.

ERP is responsible for developing and coordinating a comprehensive exercise program for the NEIDL. This program will be conducted using the Homeland Security Exercise and Evaluation Program (HSEEP). The Exercise Design Team will include internal participants from NEIDL Cores and University Departments as well as the Boston Public Health Commission and other external emergency responders as determined necessary and will be based upon the current hazard Vulnerability and Risk Assessment.

## H REGULATORY OVERSIGHT

a. City of Boston
   i. Boston Public Health Commission, Biological Laboratory Regulations, 9/19/2006

ii. Boston Public Health Commission: Guidelines for Implementation and Enforcement of the Boston Public Health Commission Biological Laboratory Regulations 9/19/2006
iii. Boston Public Health Commission: Disease Surveillance and Reporting Regulation, March 30, 2004, and amendment October 13, 2011
iv. Boston Public Health Commission: Regulation for the Isolation and Quarantine of Individuals with Infectious Disease Dangerous to the Public Health, November 5, 2003
v. Boston Fire Department, Laboratory Registration Ordinance, 2007
vi. Boston Fire Department, Fire Prevention Code, Ordinances of 1979-1
vii. Boston Fire Prevention Order 72-1: Regulation and Procedure for Building Evacuation
viii. Boston Fire Prevention Order 86-1:Regulation and procedure for Laboratory Safety
ix. Boston Inspectional Services Department; Board of appeals Ruling, re: NEIDL Training Requirements

b. Commonwealth of Massachusetts 105 CMR 300
   i. Massachusetts Department of Public Health, Exposure to Select Agent or Toxin
   ii. Massachusetts Department of Public Health, Theft, Loss or Release of Select Agent or Toxin
   iii. CMR: Board of Fire Prevention Regulations 10.0

c. United States of America
   i. OSHA, 29 CFR, 1910.38
   ii. OSHA, 29 CFR, 1910.39
   iii. OSHA, 29 CFR, 1910.120, Hazardous Materials Operations
   iv. DHHS, 42 CFR, Part 73.14, Select Agent Incident Response
   v. DOA, 7 CFR, Part 331.14, Select Agent Incident Response
   vi. DOA, 9 CFR, Part 121.14, Select Agent Incident Response
   vii. CDC, MMWR, 12/6/2002
   viii. CDC, BMBL, 5th Edition

I SUPPORT ANNEXES

a. Agreements and Understanding

In the event that Boston University resources prove to be inadequate during an emergency, requests for assistance will be made of the City of Boston. Such assistance may take the form of equipment, supplies, personnel, or other available capabilities.

b. Incident Specific Emergency Response Procedures

Incident Specific Emergency Response Procedures are found in Part Four: Hazard Specific Information.

c. Position Specific Emergency Response Procedures

Position Specific Emergency Response Procedures may be found in Part Three, Section J, Annex A, starting on page 33 of this document.

## PART THREE—FUNCTIONAL ANNEXES

## J. ANNEX A: DIRECTION AND CONTROL

The purpose of this annex is to provide a description of the procedures to be used by the NEIDL staff and emergency response personnel during an emergency operation or a planned event, to allow for a centralized, coordinated effort.

Boston University response occurs upon notification from sources including, but not limited to, staff, alarms or detecting devices, CCTV images, mass notification systems, external calls from agencies or others. Procedures developed by Emergency Response Planning, Environmental Health & Safety, Public Safety, Facilities, and others in operations and research determine the appropriate response to identified issues.

Boston University will notify external emergency responders of incidents or requests for assistance, as normal, through automatic alarm systems or via a telephone call to 911. Requests for assistance from external agencies include, without being limited to those described in Section IV.

Boston University will notify the Boston Public Health Commission when information needs to be shared or assistance is requested within or related to BSL-4 research. These notifications will occur as soon as information is available and will therefore be presumptive until the nature of the incident, accident, exposure, etc. is confirmed.

Notification procedures are defined in Annex A, Direction and Control on page 44 of this document.

Reports to the Boston Public Health Commission include, without being limited to:

a. Fires (also reported via alarm and/or 911)
b. Biological Exposure (also reported via 911 if assistance is needed)
c. Bomb Threat
d. Biological exposure
e. Suspicious Package
f. Investigation of Unauthorized Access/Personnel/Use
g. Loss of security system integrity
h. Hazardous Material release
i. Significant Property/Structural Damage
j. Concerns related to Anticipated Acts of Nature
k. Loss of Containment (from internal or external utility failure or other cause)
l. Loss of systems/equipment resulting is unsafe working conditions (breathing air, HVAC, environmental release, elevator failure, etc).

m. Exposure, injury, or fatality.

Reports will be delivered via notification system and will be in addition to alarms or calls notifying 911.

a. Situation and Assumptions

i. Situation: An emergency event at the NEIDL will be classified under the existing Boston University emergency event classifications: Phase A, B, or C.

Phase A: The initial response to a potential emergency situation or an actual event when the impact on the NEIDL is uncertain. This is a minor, localized emergency and/or an unplanned event that is not likely to adversely impact or threaten life, health, or property. The area of impact is contained to a small, localized area. The duration of incident is short term and does not affect NEIDL operations outside of the immediate incident area. Control of the incident is within the normal scope of NEIDL operations and does not require assistance beyond the NEIDL staff.

Phase B: An actual emergency that impacts the NEIDL and cannot be handled by NEIDL-specific personnel in a routine fashion. At this level, the NEIDL Emergency Response Team (ERT) would be activated to coordinate a response from a single location. This is a medium incident that disrupts NEIDL operations.

Phase C: A large-scale emergency that requires the recall of off-duty personnel or contractors and transfers overall NEIDL coordination to the Command Center. A Phase C Emergency involves the campus and community.

In order to provide the most effective response to an incident or emergency situation, the initial responders must assess the situation, seek needed response resources and mitigate the situation.

ii. Assumptions: In order to provide the most effective response to an incident or emergency situation, the initial responders must assess the situation, seek needed response resources, and mitigate the situation.

The response activities presented are generally applicable to emergency situations and will provide adequate direction for proper emergency management.

The majority of emergency events at the NEIDL, similar to events in other research facilities, will fall under the category of Phase A events.

Phase B events will involve the activation of the NEIDL Emergency Response Team (ERT).

A Phase C event would likely require external responders and would be coordinated through the BUMC Command Center.

Any emergency or training exercise at the NEIDL will be conducted using the Unified Command Model of the National Incident Management System's (NIMS) Incident Command System (ICS).



b. Concept of Operations

The Boston University Medical Campus Command Center (BUMC CC) is the key to successful response operations during a Phase C event. With decision-makers together at one location, manpower and resources can be utilized more effectively. Coordination of activities will ensure that all tasks are accomplished with little duplication of effort.

The BUMC CC is the institutional equivalent of a government emergency operations center (EOC) as defined in NIMS. The Incident Command Post is a physical location that provides appropriate resources to administer the on-scene incident command and the other major incident management functions. As defined in NIMS EOC, it is a physical location that is separate from the on-scene Incident Command Post and supports the on-scene response by providing external coordination and securing additional resources.

i. Phases of Management

1. Prevention
    a. Development of the BUMC CC.
    b. Provide adequate communications capabilities.

c. Ensure BUMC CC can be activated on short notice.

2. Preparedness
   a. Train officials on BUMC CC operations.
   b. Provide for adequate quantities of administrative supplies.
   c. Maintain a constant schedule of testing, maintenance, and repair of equipment to ensure an advanced state of readiness.

3. Response
   a. Activation of the BUMC CC as necessary.
   b. Initiation of response activity.
   c. Coordination of all operations through the BUMC CC.

4. Recovery
   a. Continue response operations as needed.
   b. Begin recovery activities.
   c. Release unnecessary personnel and begin to deactivate the BUMC CC.

ii. Response Operations

Based on the nature and circumstances of the incident, the initial Incident Commander will establish a restricted area to minimize traffic and potential for any cross-contamination. The specifics of each perimeter will depend on the specific location of the incident, its nature, the agents involved, as well as whether or not there are any individuals who require medical attention. However, the overall restricted area will include two basic "compartments:"

1. An Inner Perimeter: The immediate vicinity of the scene of the emergency. Access to the inner perimeter is restricted to those essential emergency personnel actively involved in the occurrence.

2. An Outer Perimeter: A larger area surrounding the inner perimeter. This area will serve as the coordination and assembly point for essential emergency personnel. This area will be designated as the Incident Command Post. Access to the outer perimeter is restricted to essential emergency

personnel as determined by the initial or subsequent Incident Commander.

3. Upon notification, NEIDL ERT members responding according to the NEIDL ERT Incident Notifications List will meet in the first floor loading dock of the NEIDL, 620 Albany Street. In the event that the NEIDL is not available, the first floor lobby of 610 Albany Street Garage will act as the secondary meeting place for the NEIDL ERT.

Once on-scene, the NEIDL ERT will assess the incident, and implement an action plan to stabilize and mitigate the potential hazard.

iii. NEIDL Emergency Response Team (NEIDL ERT)

1. Purpose: The purpose of the NEIDL ERT Protocol is to define the responsibilities and operation of the NEIDL ERT.

2. Team Members
   a. NEIDL Associate Director of Maximum Containment Safety or alternate
   b. BUMC Select Agent Responsible Official or alternate
   c. NEIDL Facility Management representative
   d. Public Safety Director, Supervisor, or Officer
   e. Director or Senior Specialist, Emergency Response Planning
   f. Principal Investigator or designee
   g. Research Occupational Health Program Representative
   h. LASC Representative
   i. BMC Emergency Preparedness Representative

3. The NEIDL ERT also has a separate Entry Team for BSL-2 and BSL-3 laboratories, comprised of trained individuals who will enter the laboratory suite to implement the NEIDL ERT's action plan. The Entry Team will include individuals with specific training and experience in responding to laboratory incidents.

4. BSL-4 researchers and animal care staff already in the maximum containment laboratory at the time of an emergency incident will conduct response and rescue operations in the BSL-4 space. If necessary, additional BSL-4 staff will be contacted for response.

5. All members of the NEIDL ERT will be notified of an incident in the NEIDL. They will refer to the NEIDL ERT Incident Notifications List for their response responsibilities.

6. All members of the NEIDL Entry Team will have security clearance for access to the high containment laboratories.

7. All members of the NEIDL Entry Team will have appropriate medical clearances as defined by the Research Occupational Health Program.

8. The NEIDL ERT is comprised of individuals with expertise in the following areas:
    a. BSL-3 and BSL-4 Lab Operating Procedures
    b. BSL-3 and BSL-4 Emergency Response Plans
    c. Biological Safety
    d. Animal Care and Safety
    e. Security
    f. Hazardous Materials
    g. First Aid and CPR
    h. Decontamination Techniques
    i. Gown Up and Gown Down Procedures
    j. Building Systems
    k. Biological Regulations
    l. Incident Management Systems

9. External agency emergency responders will need to coordinate with BU counterparts and know NEIDL Site Entry procedures. In the event that external resources are required, the NEIDL ERT IC will ensure that the appropriate personnel and resources have the access required to provide assistance. Site Entry procedures will be included as part of the training provided to external responders.

10. Roles and Responsibilities

a. The Director of Emergency Response Planning (ERP) will be the director of the NEIDL Emergency Response Team and Program. As such, the Director will be responsible for recruitment, training, and exercising of the NEIDL ERT.

b. ERP will convene a monthly meeting of the NEIDL ERT.

c. ERP will develop an exercise program for the NEIDL.

d. The Director, ERP or most qualified onsite individual will act as the Incident Commander for the Emergency Response Team.

e. The NEIDL ERT will respond to and conduct an initial risk and security assessment of the situation, including, but not limited to: personnel conditions and locations; agent involvement, if any; contamination, if any; and the need to notify and request additional local resources.

f. The NEIDL ERT, under the direction of the IC, will develop an action plan to stabilize and mitigate the hazard or situation.

g. When appropriate or necessary, the IC will activate the NEIDL Entry Team for response efforts in the high containment laboratory.

h. When applicable and directed by qualified personnel, the NEIDL Entry Team will act to mitigate the situation and rescue from harm and decontaminate any injured personnel.

i. The NEIDL ERT, under the direction of the IC, will ensure that all notifications to

NEIDL and Boston University staff, contractors, and appropriate local, state, and federal agencies are made as required in a timely fashion.

j. The NEIDL IC will establish Unified Command with the Boston Emergency Responders' IC for any incident requiring a response by City of Boston emergency responders and will provide support in the establishment of such with state and federal responders if necessary and appropriate.

k. The NEIDL IC will coordinate with the BU ICS structure to ensure that all appropriate communications and coordination occur including but not limited to:
    i. All appropriate care and follow-up treatment.
    ii. All regulatory follow-up.
    iii. Notification and Reports.

l. The Control Center will notify the NEIDL ERT Group via the University's automated Emergency Response Command System (ERCS) of any emergency incident in the BSL-3 and BSL-4 laboratories in the NEIDL building.

m. The NEIDL IC will ensure that notifications to Boston University staff, contractors, and appropriate local, state, and federal agencies are made as required in a timely fashion.

n. The NEIDL IC will insure that all regulatory follow-up occurs.

11. Procedures

a. Upon notification, NEIDL ERT members responding according to the NEIDL ERT Incident Notifications List will meet in the first floor loading dock of the NEIDL, 620 Albany Street. In the event that the NEIDL is not available, the first floor lobby of 610 Albany Street Garage will act as the

secondary meeting place for the NEIDL ERT.

b. The NEIDL ERT will conduct a risk and security assessment of the situation, including, but not limited to: personnel conditions and locations; agent involvement, if any; contamination, if any; and the need to notify and request additional local resources.

c. The NEIDL BUMC Public Safety Supervisor will have a master key for all non-high containment doors in the BSL-4 Suite for use in the event that the security override does not unlock all doors for emergency response entry.

d. Develop an action plan to isolate and contain the area and stabilize and mitigate the hazard or situation.

e. When appropriate and necessary and under the direction of qualified personnel, activate the NEIDL ERT Entry Team for response efforts in the BSL-4 suite.

f. Entry team members will report to the NEIDL Loading Dock area outside the Fire Command Room to be briefed on the situation and finalize the entry team action plan.

g. The entry team members will then proceed to appropriate entry point of the BSL-4 suite to gather and don their PPE for entry. PPE for Entry Team members will be the same as that of the lab workers.

h. The entry team members will have a suited back-up team available and stationed on the 2nd floor of NEIDL prior to entering the BSL-4 suite.

i. The entry team members will follow the procedures for suiting up, decontamination,

and unsuiting as per the SOP for the BSL-4 lab.

j. The entry team will follow all proper decontamination SOPs.

k. If the ERT determines that additional notification of BUMC personnel and employees is necessary, that notification will take place through the Command Center. If the ERT determines that evacuation of the NEIDL is necessary, that evacuation will take place in accordance with the NEIDL's Emergency Evacuation Plan ERP.

l. If there is a need for additional emergency response assistance from the city of Boston, the Control Center will make such notification through the respective department's dispatch center. These communications will occur in the absence of alarms (heat or smoke detector) that trigger an automatic notification to the Boston Fire Department.

m. The BU Select Agent Responsible Official will ensure that all regulatory notifications are made in the manner prescribed in those regulations.

12. External Emergency Responder Access

a. Vehicle Access shall occur through the Vehicle Access Gate located on BioSquare Drive across from the entrance to the 610 Albany Street Parking Garage. The Public Safety staff at that location will:

i. Collect the fire department personnel fighter riding list from all Fire Department apparatus and immediately direct them to the loading dock.

ii. Coordinate so that upon arrival of the District Fire Chief, the Incident

Command Technician will be posted at the vehicle gate with Public Safety to assist in identification of responding units and apparatus staging.

iii. Ensure that external agency emergency responders are subject to emergency response vehicle screening that includes visual inspection of ambulance vehicles entering the site.

iv. Ensure that only necessary emergency responders access the site, as determined by the City of Boston's incident commander on scene.

v. Request BUPD or BU Medical Center Public Safety Officer (PSO) remove all bystanders from the site entrance.

vi. Deny pedestrian egress from this location unless cleared by the NEIDL Public Safety Operations Supervisor.

vii. Return the fire department personnel riding list to the Apparatus upon exiting the site; ensuring numbers on board are accounted for.

b. Pedestrian Access shall occur through the Pedestrian Access Gate House located off East Newton Street and having the address of 620A Albany Street. The Public Safety staff at that location will:

i. Ensure that only necessary emergency responders are permitted access to the site, as determined by the incident commander on scene.

ii. Request BUPD or BU Medical Center PSO remove all bystanders from the site entrance.

c. Once inside the NEIDL's outer perimeter, external agency emergency responders will be directed to the loading dock area and the Fire Command Center. At this location, they will be met by a member of the NEIDL ERT who will:

i. Update the external emergency responders with information.

ii. Give the senior member of the external agency an update on the situation and act as an escort for those responders to take them to the incident location as necessary.

d. Staging Areas for local agency responders

i. Boston Fire Department vehicles will be staged on the north side of Biosquare Drive, west of the Vehicle Entrance Gate House to the NEIDL.

ii. Boston EMS will be staged on the north side of Biosquare Drive, east of the Vehicle Entrance Gate House.

iii. Boston Police Department will be staged in the cutout sections on either side of the East Newton Street Extension on the west side of the NEIDL in front of the Pedestrian Entrance Gate House.

c. Notifications

i. Emergency Event Discovery

1. All NEIDL personnel are trained to contact Boston University's Medical Campus (BUMC) Public Safety Department at 4-4444 for a "public safety" issue.

2. All NEIDL personnel are trained to contact the Medical Campus Control Center at 4-4144 for a "facilities" related event.

3. The NEIDL Control Center Technician is notified of building system alarms.

4. Activation of a smoke detector and water flow detector are reported automatically to the Boston Fire Department and the Medical Campus Control Center.

ii. Initial Notifications—NEIDL Emergency Response

1. Event Notification Groups

a. Initial Notifications—Primary Response Notification Groups
   i. NEIDL Code Red Team
   ii. NEIDL Emergency Response Team
   iii. NEIDL Public Safety
   iv. NEIDL Facilities
   v. Boston Fire Department—Alarms

b. Secondary Notifications—Secondary Response Notification Groups
   i. Boston Emergency Medical Services (911)
   ii. Boston Fire Department (911)
   iii. Boston Police Department (911)
   iv. Boston Public Health Commission (mass notification system including email, text, etc))

c. Tertiary Notifications—Situational Awareness Notification Groups
   i. Boston Mayor's Office of Emergency Management (by PHC)
   ii. Massachusetts Department of Public Health (telephone)
   iii. Massachusetts Executive Office of Public Safety (telephone)
   iv. BU Research Event Advisory Group (electronic notification)

iii. Procedures

All employees are instructed to call the BUMC Control Center at 4-4144 in the event of a building emergency.

Boston University emergency responders are notified via an automated multi-nodal (i.e. phone/email/page) system (ERCS).

1. ERCS allows BU/BMC to communicate immediately with hundreds or thousands of people using any device, any modality, at anytime, from anywhere.

2. Text and voice messages are simultaneously delivered to multiple contact points for each individual contacted.

    a. ERCS alerts reach users immediately and provide the ability to receive real-time responses from those recipients. The two-way communication on all modalities tracks outgoing messages and incoming responses, maintaining an audit trail of all alerts sent and of the responses.

    b. ERCS is capable of targeting pre-defined groups of individuals based on the category of the incident. This feature enables customized messages to be sent to the targeted groups during an emergency response with specific instructions for each group, as appropriate.

d. Organization and Assignment of Roles

During emergency operations, the NEIDL response and the BUMC CC staff are organized into the standard Incident Command System (ICS) structure. It is expected that when an incident occurs, the Unified Command model of ICS will be utilized when external agency emergency responders are requested and on site.

i. Command Staff: Supports the Incident Commander and Unified Commanders.

ii. General Staff: Develops and implements the Incident Action Plans.

iii. NEIDL Emergency Response Team
1. Initial incident responders
2. Assesses the situation and develops the initial mitigation plan
3. Stabilizes the incident
4. Calls for additional resources, if necessary

iv. External Agency Emergency Responders: Upon arrival, external responders work under Unified Command to resolve the emergency situation.

v. Plan Development and Maintenance

ERP is responsible for the contents of this Annex and for its maintenance. All BUMC CC staff members will be responsible for being familiar with its contents.

e. Lines of Succession

The line of succession for Boston University ERP is as follows:
i. Director
ii. Senior Specialist

f. Crisis Augmentation

Should there be a need for augmenting the Direction and Control staff during an emergency, a request for Boston emergency response assistance will be made through the Boston Police Dispatch Center by contacting 911 and through the Boston Public Health Commission.

i. Response—Scope and Sequence of Planned Events

1. Event Assessment and Classification Process

The NEIDL Event Classification System is a three-phase system consistent with the system that is currently in place at Boston University.

The NEIDL Event Assessment Process will begin with the initial notification to the Control Center. Based upon information from the telephone caller and by reviewing the situation, a conference call

will be conducted with key members of the NEIDL ERT to determine the need for a declaration of an emergency phase as described on page 33 of this document.

2. Notifications/Event Notification System is as described on page 44 of this document.

3. Response Actions

   Are as described in the NEIDL CEMP Function Chart.

   The Boston University Medical Campus Command Center (BUMC CC) is the key to successful response operations during a Phase C event. With decision-makers together at one location, manpower and resources can be utilized more effectively. Coordination of activities will ensure that all tasks are accomplished with little duplication of effort.

   The BUMC CC is the institutional equivalent of a government Emergency Operations Center (EOC) as defined in NIMS. The Incident Command Post is a physical location that administers the on-scene incident command and the other major incident management functions. As defined in NIMS EOC is a physical location that is separate from the on-scene Incident Command Post and supports the on-scene response by providing external coordination and securing of additional resources.

   Command Centers are located as described on page 24.

   Due to its remote camera capabilities, during a large-scale event at the NEIDL the Fire Department Incident Commander may elect to send a representative to the NEIDL Control Room to monitor the situation.

   Incident Management: Boston University uses Web EOC as its incident management software. It is utilized in planned and unplanned events to support and manage large-scale incidents. Boston Police, Fire, Emergency Medical Services, and the Public

Health Commission have user accounts into this system to remotely access incident information.

Command Center Operations: While the activation of the BUMC Command Center is mandated under a Phase C Emergency Declaration, the Incident Commander has, at his or her discretion, the ability to activate the Command Center to manage incidents or lower level emergency declarations. Boston University operates its Command Centers under standard protocols and procedures for Emergency Operations Centers and its Command Level Staff are trained in FEMA ICS and NIMS courses on incident command and EOC Operations.

Members of the NEIDL ERT

| | | |
|---|---|---|
| EHS | Primary | Assoc. Director, BSL-4/ARO |
| | Secondary | Manager, BSL-3/ARO |
| | Secondary | Responsible Official |
| BSL-2 & 3 | Primary | Research Safety Specialist |
| | Secondary | Research Safety Specialist |
| | Secondary | Research Safety Manager |
| | Secondary | Assoc. Director, Env. Mgmt |
| Research | Primary | Assoc. Dir. Biomolecular Prod. Core |
| | Primary | BSL-4 Researcher |
| | Secondary | Core Dir. Immunology Core |
| | Secondary | Core Dir. Aerobiology Core |
| Facilities | Primary | Facilities Core Director |
| | Secondary | Facilities Core Manager |
| | Secondary | Facilities Core Manager |
| NEIDL Public Safety | Primary | Deputy Director |
| | Secondary | Deputy Director |
| | Secondary | Operations Manager |
| | Secondary | NEIDL Security Supervisor |
| LASC | Primary | Veterinarian |
| | Secondary | Operations Director |
| Occupational Health | Primary | Occ. Health Officer |
| Control Center | Primary | Coordinator |
| | Secondary | Coordinator |
| Emergency Response | Primary | Director |
| | Secondary | Coordinator |

## K. ANNEX B: CONTINUNITY OF OPERATIONS

### a. Continuity of Operations

All NEIDL departments have Continuity of Operations Plans on file within their own department records, with the Emergency Response Planning Division (ERT), and in the Command Centers.

During emergency situations, NEIDL response plans are incorporated into University-wide response plans under the direction of the University Incident Command structure. However it is important to address leadership and succession planning specific to the NEIDL in the event that the incident being addressed results in longer term localized management

### b. Executive Succession

In the event of an emergency situation it is essential that operations at all levels be maintained. In order for the NEIDL to continue to function, it is necessary that there be duly authorized persons to operate it. The probability exists that in most emergency situations the NEIDL Director would be readily available to exercise the executive powers and duties of his/her office.

However, in order to ensure that a successor is designated and appropriately empowered with authority to act, the emergency lines of succession are:

i. The automatic interim succession to the NEIDL Director if she/he becomes unavailable to exercise the power and duties of his office is as follows:
    1. Associate VP, Research Compliance/Institutional Official
    2. NEIDL Chief Safety Officer/Responsible Official

    The successor to the NEIDL Director is authorized to exercise all the powers and duties of the NEIDL Director. The emergency interim successor will obtain neither title nor tenure. He/she will be divested of all authority by the return of the incumbent or filling of the vacancy in the usual manner.

ii. It is equally important that a succession plan be in place for the chain of command in the event of an emergency. That succession plan is:
    1. Executive Director of Public Safety, Boston University

2. Deputy Director of Public Safety, Boston University
3. Director, Emergency Response Planning

## L. ANNEX C: COMMUNICATIONS

This annex provides guidelines for disseminating adequate and timely warnings and updated incident information in the event of an impending or occurring emergency situation. It also provides information about the communications equipment and capabilities that are available during emergency operations.

a. Situation and Assumptions

i. Situation: The need to warn the Boston University Community of impending danger could arise at any time. In order to mitigate damage, minimize loss, and most importantly reduce the likelihood for injury or loss of life, adequate and timely warnings must be provided. Appropriate action-oriented information will be supplied from the BUMC CC.

ii. Assumptions

1. A warning period will be available for most emergency situations although the amount of lead-time will vary from hazard to hazard.

2. This annex will provide direction for the proper coordination of all communications during an emergency situation.

3. Coordinated utilization of warning systems and communications networks may protect property, reduce injuries, and/or save lives, by facilitating quick and timely response actions.

4. Adequate communications equipment is available to provide necessary support for emergency situations.

5. Boston University has appropriate communications equipment to communicate with its emergency response personnel, incident command team, Boston response agency responders, and the greater Boston University community.

6. Boston University will use all methods at its disposal to provide information to external agency responders to allow for their communication with the local community concerning an emergency at the NEIDL.

7. Boston University will communicate through 911 and directly with the Boston Public Health Commission.

b. Concept of Operations

i. General

1. Warnings: The most common warnings are those issued for severe weather and tornadoes. Other natural hazards that call for warnings are floods, hurricanes etc. A man-caused emergency, such as a chemical spill or a facility related incident, would also necessitate prompt warning to the Boston University community.

2. Communications: After initial reactions to warnings take place, communications then play a crucial role in emergency operations. Extensive communications networks and facilities are already in existence throughout Boston University. When these capabilities are properly coordinated, response activities become more effective and efficient.

Boston University understands the importance of providing updated incident information to the City of Boston and Commonwealth of Massachusetts' agencies when an emergency incident occurs at the NEIDL.

c. Phases of Management

i. Prevention

1. Develop and maintain a warning and communications system.

ii. Preparedness

1. Provide for a constant schedule of testing, maintenance, repair of equipment, and the updating of notification databases.
2. Stock replacement parts for communications equipment in the Command Center and ensure that

arrangements are in place for additional repair facilities.

3. Provide for training of personnel on the appropriate equipment as necessary.

iii. Response

1. The primary action point for all warnings is the BUMC Control Center. Upon notification of an emergency situation, the Control Center technicians will notify the appropriate personnel using the ERCS.

2. Upon receipt of the information, the BUMC CC technicians and ERP will issue the appropriate warnings using all systems necessary. All communications will continue until such time as they are no longer required.

3. When emergency operations are initiated, the NEIDL ERT IC will determine which communications personnel will be required to report to duty. Staff requirements will vary according to the incident.

iv. Recovery

1. The Boston University community will be informed through the use of the notification system at the conclusion of the incident or emergency situation.

d. Organization and Assignment of Roles

i. Assignments and Responsibilities

1. Boston University Emergency Response Planning Division (ERP)
   a. The development, coordination, maintenance, and general oversight of adequate warning and communications systems.
   b. The design of processes for the issuing of all warning messages.
   c. Ensuring that updated incident information is communicated to the Boston University community, leadership and incident response command team, and the Boston Public Health Commission.

2. Information Officer (IO)

a. Responsible for disseminating warning messages provided by authorized sources to the Boston University community as rapidly as possible in the event of impending or actual disaster.
b. Maintaining a constant state of readiness to implement the dissemination of critical information during periods of increased readiness, response, and recovery of disaster.
c. Activates the BU Alert System (BUAS) when directed by an appropriate officer.
d. Involved with the Joint Information Center (JIC) if the occasion arises and represent the University in that Center.
e. Coordinates messages with other PIOs to ensure that the public information speaks in a "single voice" to public and media.

3. Communications Officer (CO)
   a. Responsible for supervision of all communications activities within the BUMC CC.

e. Direction and Control

i. General

1. The warning process may be activated from any of several points in the system including the BUMC Control Center, BUPD Dispatch, or from ERP offices.

2. ERP, under direction of the BUMC Incident Commander, is the overall authority for activating the warning system and directing the activities of the BUMC Command Center.

3. Coordination of Communication and Warning Services will take place in the BUMC Command Center.

ii. Existing Communication and Warning Systems and Use

1. StormReady: Boston University has attained StormReady certification from the National Weather Service. StormReady is a nationwide community

preparedness program that uses a grassroots approach to help communities develop plans to handle all types of severe weather, from tornadoes to tsunamis. The program encourages communities to take a new, proactive approach to improving local hazardous weather operations by providing emergency managers with clear-cut guidelines on how to improve their hazardous weather operations.

To be officially StormReady, a community must:

a. Establish a 24-hour warning point and emergency operations center.
b. Have more than one way to receive severe weather warnings and forecasts and to alert the public.
c. Create a system that monitors weather conditions locally.
d. Promote the importance of public readiness through community seminars.
e. Develop a formal hazardous weather plan, which includes training severe weather spotters and holding emergency exercises.

2. NOAA Weather radios are located in all Boston University Command Centers, the BUMC Control Center, the Boston University Police Department Dispatch Desk, the NEIDL Control Center, and the offices of the Emergency Response Planning Division.

3. Emergency Response and Incident Management Systems: Emergency response communications are established and maintained in a variety of ways. First, via handheld portable radios; second through use of the BU ERCS notification system; and third, through the use of WebEOC.

4. Hand-held portable radios: There are six handheld portable radios for use of the NEIDL ERT. These radios are interoperable with NEIDL Public Safety radios.

5. Boston University ERCS: Used to communicate emergency notifications to both University and external agency emergency response personnel as well as non-response personnel to keep them

informed of an emergency situation at the NEIDL. Communications through the ERCS will be initiated through a Boston University Control or Dispatch Center under the direction of the Responsible Official or the NEIDL IC.

ERP updates the personal information database of all contacts on a quarterly basis.

BU Alert: The BU emergency system (ERCS) is used to communicate emergency notifications to the Boston University community of students, faculty, and staff. The 42,000+ contact database is updated on a daily basis.

6. WebEOC: Boston University's web-based incident management software that is utilized in planned and unplanned events to support and manage large-scale incidents.

   Boston Police, Fire, Emergency Medical Service, Public Health Commission, and Mayor's Office of Emergency Management have user access to the Boston University WebEOC system.

7. Boston University has user access to The Boston Urban Area Security Initiative (UASI) Region and the Massachusetts Emergency Management Agency WebEOC systems.

   The UASI program consists of Boston, Winthrop, Revere, Chelsea, Everett, Somerville, Cambridge, Brookline, and Quincy areas. It addresses the unique multi-discipline planning, organization, equipment, training, and exercise needs of the high-threat/high-density Boston urban area, and assists them in building and sustaining capabilities to prevent, protect against, respond to, and recover from threats or acts of terrorism.

iii. Interoperability: The NEIDL Public Safety Department radios are interoperable with the NEIDL Emergency Response Team on the BUMC Disaster Channel. The BU Police radios have the ability to interoperate with the Boston Police Department through BAPERN.

iv. Alertus Beacons: Emergency Notification Beacons located in Command Centers, BUMC Control Center, Charles River Campus Facilities Control Desk, Boston University Police Dispatch Desk, and each campus' Environmental Health and Safety Department offices to facilitate initial emergency information notification.

f. Administration and Logistics

i. Warning System

1. All components of the warning and communications systems are tested on a periodic basis.

2. ERP is responsible for maintaining and repairing this equipment.

ii. Government Emergency Telecommunications Service

1. The Government Emergency Telecommunications Service (GETS) is a White House-directed emergency phone service provided by the National Communications System (NCS) within the Department of Homeland Security. GETS supports federal, state, local, and tribal government, industry, and non-governmental organization (NGO) personnel in performing their Emergency Preparedness (NS/EP) missions. GETS provides emergency access and priority processing in the local and long distance segments of the Public Switched Telephone Network (PSTN). It is intended to be used in an emergency or crisis situation.

2. Key members of the Boston University Incident Command Response Team have been issued GETS card to facilitate information processing during an emergency.

iii. Training

1. Each organization assigning personnel to the Command Center for communications purposes is responsible for making certain that those persons are familiar with their agency's unique operating

procedures so that they may integrate those procedures with Boston University's Plan activations.

2. Additional training on Emergency Management equipment and procedures will be provided by ERP or the CO.

g. Plan Development and Maintenance

ERP in conjunction with the Communications Officer is responsible for maintaining and improving this annex.

h. Lines of Succession

The line of succession for the Communications and Warning Service is as follows:

1. Director, Emergency Response Planning Division
2. Senior Specialist, Emergency Response Planning Division
3. Communications Officer

i. Crisis Augmentation

In the event that augmentation of these communications and warning related services providing emergency public information is required during an emergency, a request for support will be made to the Boston Public Health Commission.

## M. ANNEX D: EMERGENCY PUBLIC INFORMATION

The purpose of this annex is to provide for the effective collection, control, and dissemination of emergency public information and for the minimization of confusion, misinformation, and rumors during times of emergency.

a. Situation and Assumptions

i. Situation

During an emergency at the NEIDL, the public will need detailed information regarding actions to be taken for minimizing loss of life and property. There are times, however, when an emergency occurs without warning and the public information system cannot react quickly enough

to properly inform the public about the hazard. For this reason it is important that prior to the occurrence of an emergency the public be made aware of potential hazards and the protective measures that can be employed.

ii. Assumptions

An effective program combining both education and emergency information will significantly reduce emergency-related casualties and property damage, as well as confusion and fear.

b. Concept of Operations

Emergency information efforts will focus on specific event-related information. This information will generally be of an instructional nature focusing on such things as warning, evacuation, and shelter. It is also important to keep the public informed of the general progress of events. Rumor control will be a major aspect of the informational program so as to control and reduce the flow of erroneous and misleading information to the public. Along with this will be the use of public feedback as a measure of the program's effectiveness. Education efforts will be directed toward increasing public awareness about potential hazards and response.

c. Phases of Management

i. Prevention
   1. Hazard awareness programs
   2. Coordination with local officials
   3. Coordination with local media

ii. Preparedness
   1. Public education programs
   2. Prepare emergency information for release during emergencies

iii. Response
   1. Release public information
   2. Coordinate rumor control
   3. Schedule news conferences

iv. Recovery
   1. Provide public information
   2. Compile record of events
   3. Assess effectiveness of information and education programs

d. Organization and Assignment of Roles

i. Task Assignments

1. NEIDL Director
    a. Appoint an Information Officer

2. Communications Officer (CO)
    a. Oversee an ongoing information and education program
    b. Maintain a working relationship with the media

3. Information Officer (IO)
    a. Direct all emergency public information efforts
    b. Provide news releases for the media
    c. Check all print media for accuracy of reports
    d. Maintain a recent record of events
    e. Coordinate the messages with other PIOs to ensure that the public information speaks in "single voice" to public and media

e. Direction and Control

The CO is ultimately responsible for all education and information programs conducted by the NEIDL. The Emergency Public Information Program will be directed by the CO, in coordination with the Boston Public Health Commission, and during an emergency, will operate from the BUMC CC.

i. Educational Programs

There are many activities involved in the educational programs. The media is constantly provided with information on new developments affecting emergency management activities. Thus, much information reaches the public via television, radio, and newspapers. Lectures and other presentations are often requested by various organizations, presenting another opportunity for public education. Educational brochures and films are also distributed to the general public and organizations.

ii. Emergency Public Information

Specific emergency public information will be prepared in advance of an emergency. Information will be contingency-based, that is, specific to various hazards (i.e., agent specific) and will be provided to the Boston Public Health Commission in case it is needed for public distribution during an emergency.

Special instructions for emergency personnel and other essential workers must be developed on a contingency basis as well; this information will be delivered by the IO staff to each of the emergency service departments.

f. Administration and Logistics

i. Reports

All Public Information releases as well as periodic situation reports should be provided to the NEIDL Director and the Director, ERP.

g. Plan Development and Maintenance

The CO will be responsible for the development and maintenance of the entire education and information programs.

h. Lines of Succession
The line of succession for the Public Information Service will be as follows:
i. Vice President, Marketing and Communications
ii. Communications Officer (CO)
iii. NEIDL Information Officer

N. ANNEX E: EMERGENCY RESPONSE TRAINING

The purpose of this annex is to outline procedures for providing emergency preparedness and operations training for BUMC CC staff members, NEIDL Emergency Response Team personnel, other NEIDL staff, and off-site emergency response personnel.

a. Situation and Assumptions

i. Situation
Emergency situations by any origin will occur. These events may require the assistance of off-site emergency

responders. The emergency will be compounded by the fact that a lack of trained personnel would seriously handicap preparation, response, and recovery.

ii. Assumption
Effective training programs, which are scheduled on a regular basis and which encompass the areas of specialized skill requirements, will generate skills necessary to implement effective operations. Increased readiness training during a tension period will provide the emergency forces capable of translating workable plans into essential actions.

Drills and exercises simulate or are based on possible real-life scenarios in order to improve emergency management, and should be based on the vulnerabilities identified in the NEIDL's Hazard Vulnerability Assessment.

b. Concept of Operations

i. Training

The type and degree of training will vary with the task(s) a person is assigned to do within the total system of preparation, response, and recovery. The following section will detail the training for all NEIDL staff, NEIDL Emergency Response Team and External Emergency Responders. Specific training is addressed.

The Environmental Health & Safety Department, including the Emergency Response Planning Division, will provide annual training to external emergency responders. This training will be delivered three times a year, will include internal responders, and will address both general laboratory safety issues as well as information unique to responding to scenarios and incidents in which the emergency response agency resources are required for incidents including those reflected in Part Four. Training dates will be selected in consultation with the Boston Public Health Commission on an annual basis and will be communicated to external agencies as the Commission deems appropriate.

ii. Drills and Exercises

A critical element of the preparedness cycle is the coordination of discussion and operations-based drills and exercises that are designed, developed, and evaluated in a manner that is consistent

with the guidance issued by the Department of Homeland Security in its Homeland Security Exercise and Evaluation Program (HSEEP). BUMC recognizes that NEIDL personnel and those supporting them should participate in realistic exercises designed to evaluate the performance of personnel in accomplishing the exercise objectives using a pre-determined set of criteria. This evaluation criteria would be used to assess how well personnel understand the training they have received, their adherence to SOPs, the performance of their assigned functions during an emergency situation, and how well resources or specialized equipment performed and supported a simulated response.

1. BUMC's approach to NEIDL drills and exercises would be based on conducting and designing those drills and exercises in a progressive manner, or utilizing the crawl-walk-run approach exemplified by the HSEEP methodology. Utilizing this approach, a discussion-based exercise would be performed before an operations-based exercise so that each new exercise builds upon the lessons learned from the discussion, and then expands the scope of the element of operations or response discussed.

    a. Discussion-Based Exercises: Normally used as a starting point in the building-block approach to the cycle, mix, and range of exercises. Discussion-based exercises include seminars, workshops, and/or tabletop exercises (TTXs). These types of exercises typically highlight existing plans, policies, and procedures, and are exceptional tools to familiarize agencies and personnel with current or expected departmental or jurisdictional capabilities. Discussion-based exercises typically focus on strategic, policy-oriented issues, whereas operations-based exercises tend to focus more on tactical, response-related issues. Facilitators usually lead the discussion and keep participants on track to meet exercise objectives. BUMC will utilize discussion-based exercises consisting of an interactive, simulated scenario-driven discussion conducted between key personnel. The discussion-based exercises will be facilitated in a manner so as to compel the various personnel to communicate and discuss the types of functional responses that could be deployed during a response to an incident at varying stages of escalation and recovery. A discussion-based exercise will evaluate the

effectiveness of an organization's emergency management plan and procedures and highlights issues of coordination and assignment of responsibilities. Discussion-based exercises do not physically simulate specific events, do not utilize equipment, and do not deploy resources.

b. Operations-based exercises: A category of exercises characterized by actual response, mobilization of apparatus and resources, and commitment of personnel; usually held over an extended period of time. Operations-based exercises can be used to validate plans, policies, agreements, and procedures. They include drills, Functional Exercises, and Full Scale Exercises. They can clarify roles and responsibilities, identify gaps in resources needed to implement plans and procedures, and improve individual and team performance. These types of exercises are a more advanced and complex type of exercise that follow after and validate, the lessons learned from discussion-based exercises.

   Functional Exercise (FE): Involve conducting and testing different divisions or departments within the NEIDL and/or BUMC organization in response to pre-established scenarios. A FE simulates a disaster in the most realistic manner possible without mobilizing personnel or equipment to an actual site. FEs utilize a carefully designed and scripted scenario with timed messages and communications between players and simulators. The BUMC CC, the facility or area from which disaster response is coordinated, is usually activated during a FE and actual communications equipment may be used.

   Full Scale Exercise (FSE): Involves conducting and testing different divisions or departments within the NEIDL and/or BUMC organization and may include public safety agencies in response to pre-established scenarios. At all times in its exercise programs, NEIDL ERP will design corrective or improvement action plans to implement based on lessons learned from training and exercises, and either alter, refine, or design new mitigation plans, planning documents, procedures, and future training

or exercise programs. A FSE is the culmination of previous drills and exercises. It tests the mobilization of all or as many as possible of the response components, takes place in real time, employs actual equipment, and tests several emergency functions. Controllers maintain order and ensure that the exercise proceeds according to plan, are also usually used. FSEs are generally intended to evaluate the operations capability of emergency management systems and to evaluate interagency coordination when responding to research related risk such as exposure.

2. BUMC NEIDL ERP develops, conducts, and evaluates three separate exercise series each year that entail using separate scenarios for each exercise series. The following are the classes of scenarios that would be utilized to drive the exercise development each year:

    a. Research-related risk such as exposure
    b. Building-related risk such as utility loss
    c. Security-related risk such as theft/loss of agent

    Two scenarios (example: scenario A and B) are selected for the development of internal exercises and one scenario (example: scenario C) is selected for a joint or internal and external exercise series. In this manner, NEIDL ERP and Boston University are able to focus on developing, conducting, and evaluating both internal and joint (internal and external) exercises each year. The type of risk-based scenarios identified above will be presented to the Boston Public Health Commission each year. The Boston Public Health Commission will select one of the three scenarios/risks and will participate in the design of the exercise. The exercise will be a full scale, HSEEP compliant exercise involving all potential participants. Participating external departments will provide subject matter experts to perform the roles of participants, controllers and evaluators for the exercise.

3. The Typical Annual Exercise Schedule for the NEIDL would include the following activities:
    a. Annual Exercise Design meeting (BU and BPHC) to discuss exercise scenarios.
    b. Review of all scenarios and determination of two scenarios (example: scenario A and B) to be used

for the internal TTX and FE or FSE and the one scenario (example: scenario C) to be used for the joint internal and external TTX and FSE.

c. Invitation to BPHC to attend all NEIDL drills and exercises.
d. Determination of Exercise Schedule including:
    i. Development, conduct and evaluation of all scenarios (A, B, and C).
    ii. Development of After Action Report and Improvement Plans for all scenarios (A, B, and C).
    iii. Annual Post Exercise Discussion meeting with BPHC.
e. Development of exercise to be used for the joint internal and external TTX and FSE.
f. Review of other two scenarios to be conducted internally.

4. The After Action Report and Improvement Plan is the final stage of the exercise process and includes a post-exercise review to assess the effectiveness of the response, and to develop an After Action Report and Improvement Plan (AAR-IP). The AAR-IP is a critical component of BU's exercise program that is used following preparedness drills and exercises, such as those outlined above and enable BU to:
    a. Identify problems and successes during emergency operations.
    b. Analyze the effectiveness of the different components of ICS, including the coordination with external agencies in the exercise that they participate in.
    c. Describe and define a plan of corrective action for implementing recommended improvements to existing emergency response efforts, regardless of participation of external agencies.
    d. Determine the causes of the incident and corrective actions required to prevent their reoccurrence.
    e. Provide a work plan for how these improvements can be implemented.
    f. Provide a schedule for the completion of corrective actions and/or reporting on status or corrections to be reviewed and distributed internally and with BPHC.

5. The Exercise Director and/or NEIDL Director of Emergency Response Planning will:
    a. Conduct an After Action evaluation of the various exercise participants, controllers, and evaluators immediately after the exercise to gain immediate feedback on the exercise.
    b. Convene an After Action Report Meeting, within one week, with the exercise controllers and evaluators. Typically, the meeting includes a general discussion of the overall exercise and the evaluations, followed by a discussion session for suggestions of ideas for improvement.
    c. Prepare the draft After Action Report, which is distributed to participants and final comments are incorporated.
    d. Prepare a Corrective Improvement Plan outlining the corrective actions, responsible parties, and timeline for the completion of those corrective actions. The Emergency Response Planning division is responsible for monitoring the progress of the Corrective Improvement Plan.

There are a number of Training Tracks that will be available to each category of employee and responder.

c. Training Tracks

i. All NEIDL Employees

All employees will need to have Orientation training, Incident Response for Non-Laboratory Personnel, First Aid, CPR and Automatic External Defibrillator training, as well as Emergency Response Preparedness training.

1. General Orientation

a. Learning Objectives
i. Understand the role of the NEIDL as a national resource that will enable the conduct of basic, translational, and clinical research and the development of vaccines and other products related to emerging infectious diseases.

ii. Understand the basic principles of biosafety.
iii. Understand how personnel and physical security requirements prevent unauthorized persons from gaining access to the NEIDL.
iv. Awareness of Institutional and Regulatory Oversight.
v. Awareness of the NEIDL Disease Surveillance Program.
vi. Understand individual responsibilities for access control, reporting requirements, and response to emergency incidents.
vii. Describe how persons outside of the laboratory and the public health are protected from research hazards.

b. Course Content
i. Introduction to the NIAID Biodefense Program; role of National Biocontainment Laboratories
ii. NEIDL building design concept.
iii. Principles of biosafety—risk assessment, microbiological practices, primary containment, and secondary containment.
iv. Personnel and physical security measures—DHHS and USDA access authorization, safeguards that prevent unauthorized access, security plan.
v. Brief description of BU, CDC, NIH/BPHC oversight functions.
vi. Safeguards for protecting the public health—safe practices, containment, compliance oversight, emergency response planning.

2. Incident Response for Non-laboratory NEIDL Personnel

a. Learning Objectives
i. Describe the types of incidents that could occur in the NEIDL.

ii. Describe site evacuation procedures.
iii. Describe individual responsibilities in responding to an incident involving a shut down of a secondary barrier.

3. Emergency Response Preparedness

a. Learning Objectives
i. Describe the types of emergencies that could occur in the NEIDL.
ii. Describe site emergency procedures.
iii. Describe individual responsibilities in responding to an emergency.

b. Course Content
i. Emergency Response Procedures.

4. First Aid, CPR and Automated External Defibrillator (AED)

a. Learning Objectives
i. Demonstrate proficiency in First Aid.
ii. Demonstrate proficiency in CPR.
iii. Demonstrate proficiency in AED.

b. Course Content
i. An accepted certification program.

ii. Facility Management, Building Operations, and Maintenance Staff

In addition to the All Employees Training listed above, initial training will include the following topics. The Operations and Maintenance Training Track includes several courses that provide a broader understanding of the principles of biosafety, biosecurity, facility operations, and equipment that maintain containment, as well as incident response with an emphasis on work assignments, duties within the NEIDL, and emergency response preparedness. This track is designed specifically for facility operations staff that has assigned duties in the NEIDL, but do not have authorization to access operating BSL-4 suites.

1. Introduction to Microbiology and the Control of Infectious Diseases

    a. Learning Objectives
        i. Become familiar with the types of living organisms that cause infection.
        ii. Understand what "the chain of infection" means.
        iii. Describe the ways that biosafety can break the chain of infection.
        iv. Learn how the work of operations and mangement staff supports biosafety.

    b. Course Content
        i. Basic characteristics of bacteria, viruses, fungi, parasites.
        ii. Modes of transmission.
        iii. Causes of laboratory infections; the chain of infection; breaking the chain of infection.
        iv. Preventing laboratory associate infections;
        v. The role of the operations and management staff in infection control; health surveillance program.

2. NEIDL Emergency Response Team Incident Response Procedures

    a. Learning Objectives
        i. Describe the basic elements of the NEIDL Incident Response Procedures.
        ii. Describe the onsite coordinating roles between the NEIDL Emergency Response Team and the public safety emergency responders.

    b. Course Content
        i. NEIDL BSL-4 Select agent incident response procedures.
        ii. Drills and Exercises that test NEIDL ERT response readiness.

iii. NEIDL Emergency Response Team Training

The NEIDL Emergency Response Team (ERT) training track includes the General Orientation Course and additional training in biosafety, biocontainment, and biosecurity; NEIDL ERT incident response procedures and protocols.

1. Introduction to Microbiology and the Control of Infectious Diseases

   —As described on page 70

2. NEIDL Emergency Response Team Incident Response Procedures

   —As described on page 70

iv. External Emergency Responders NEIDL Emergency Response Team Training.

Prior to opening, first due companies of the Boston Fire Department, Boston Police District 4 supervisors and superior officers and Special Operations personnel and Boston EMS supervisors should undergo general building and emergency response orientation training.

1. General Orientation

   a. Learning Objectives
      i. Understand how personnel and physical security requirements prevent unauthorized persons from gaining access to the NEIDL and the process for authorized personnel entering and exiting including external emergency responders.
      ii. Describe how persons outside of the laboratory and the public health are protected from research hazards.

2. NEIDL Emergency Response Team Incident Response Procedures

   a. Learning Objectives

i. Describe the basic elements of the NEIDL Incident Response Procedures.
ii. Describe the onsite coordinating roles between the NEIDL Emergency Response Team and the public safety emergency responders.

b. Course Content
i. NEIDL incident response procedures.

3. NEIDL Incident Response Procedures

a. Learning Objectives
i. Describe the types of emergencies that could occur in the NEIDL.
ii. Describe site emergency procedures.
iii. Describe individual responsibilities in responding to an emergency.

b. Course Content
i. NEIDL Emergency Response Procedures.
ii. Drills and Exercises that test coordination for emergency response.

d. Drills and Exercises

Drills and exercises are valuable training tools and provide an opportunity for staff to practice their skills and to identify future areas for training as addressed on page 63 of this document.

e. Organization and Assignments of Roles

i. Task Assignments

1. Director, ERP: Responsible for the overall Emergency Response Training.

2. Senior Specialist, ERP: Responsible for assisting with the Emergency Response Training.

f. Direction and Control

To ensure effective emergency operations, there will be a continuous and detailed training program that covers all aspects of NEIDL emergencies.

g. Administration and Logistics

i. Training Materials: Training materials, which include but are not limited to medical self-help, individual survival, rescue skills and techniques, fire service, law and order training, industrial emergency management, shelter development, radiological monitoring, increased readiness, radiological defense and control of communicable diseases are kept on hand at the EOC. Additional aids will be gathered as they become available.

ii. Reports: A report of current status of the training service should periodically be made to the NEIDL Director.

h. Plan Development and Maintenance

The Director of ERP will be responsible for the contents of this Annex and for its maintenance. All BUMC CC staff will be responsible for being familiar with its contents.

i. Lines of Succession

The line of succession for the ERP shall be as reflected on page 58.

j. Crisis Augmentation

If additional assistance is required, a request should be made to EHS.

k. References

i. NEIDL Comprehensive Emergency Management Plan.

## O. ANNEX F: POPULATION PROTECTION ACTIONS

This Annex describes the actions that may be taken to protect the population of the NEIDL during an internal or external event.

a. Situations and Assumptions

i. Situations

1. There are two types of protective actions that will be taken to protect the staff and visitors of the NEIDL—Shelter-in-Place, and Evacuation.

2. Shelter-in-Place protection has been adopted by many organizations as a realistic measure to replace mass evacuations. Shelter-in-Place can be used in response to shootings, hostage situations, minor chemical spills, or natural disasters where evacuation is not required.

3. NEIDL personnel have been trained on Shelter-in-Place procedures.

4. There are several emergency situations, which might require an evacuation of the NEIDL, such as a fire or a hazardous materials incident.

5. NEIDL personnel have been trained on evacuation procedures and the location of their rally points outside the NEIDL.

6. A medical extraction from a containment laboratory may be necessary when a laboratory worker is injured and non-ambulatory.

ii. Assumptions

1. All protective actions listed in this Annex are for NEIDL staff and visitors only.

2. Evacuation may not be the best course of action for an external hazardous materials release, particularly one that is widespread such as a local chemical company explosion. If the area is enveloped by the plume of hazardous material, the use of sheltering-in-place should be considered.

3. The advantage of sheltering-in-place is that it can be implemented more rapidly than evacuation. The protection sheltering in place provides is variable and diminishes with the duration of the emergency.

4. Shelter-In-Place Operations outside the NEIDL on Boston University's Medical Campus property will be the responsibility of the IC Response Team.

b. Concept of Operations

i. Shelter-In-Place

1. The issuance of a shelter-in-place order will be made by the NEIDL Emergency Response Team Leader or the Senior NEIDL Public Safety Official.

2. The shelter-in-place order will be given for an event that may impact the safety of NEIDL staff and visitors.

3. NEIDL visitors will follow the instructions of their escorts if a shelter-in-place order is issued during their visit.

4. NEIDL Public Safety Officers will implement their Lockdown Procedure.

ii. Evacuation

1. Partial

a. The primary objective during an evacuation is to get personnel out of the NEIDL as quickly as possible while maintaining biosafety procedures to maintain containment within the building.

b. The high rise procedures for the NEIDL are the same as any other high rise in the city of Boston. Evacuations are given for impacted floors as well as the floor above and below upon activation of a detector, device, or resulting from an actual fire.

2. Full

a. A full evacuation of the NEIDL will take place as the partial evacuation except that the entire building will be evacuated.
b. Personnel shall report to their rally points.
c. Once an evacuation of a containment suite is ordered, the personnel in containment will begin the evacuation process. They cannot simply leave the containment laboratory.
d. Each protocol will require various steps to safeguard the laboratory before the researcher can safely leave the lab. There may be circumstances where animals may need to be returned to cages and

holding areas or euthanized. Biological materials may need to be either secured or neutralized. The objective remains the same: get out safely and as fast as possible, while maintaining biosafety and biosecurity.

# PART FOUR—HAZARD- OR THREAT-SPECIFIC ANNEXES OR APPENDICES

This Annex describes the actions that may be taken in response to hazard or threat-specific incidents. These operating procedures will be maintained within the NEIDL and available for ongoing review with both internal and external responders. Specific procedures include without being limited to the following:

NATURAL HAZARDS

- Earthquakes
- Flood
- Hurricane
- Severe Weather

HUMAN-CAUSED HAZARDS

- Medical Emergencies
  - Minor Injuries
  - Serious Injuries
  - Sudden Death
- Suicide Threat or Attempt
- Workplace Violence
- Bomb Threat, Suspicious Package or Mail, Bomb or Suspicious Device
- Dangerous Person On Site
- Hostage Situation
  - On Site
  - Off Site
- Security Breach
- Protest
  - On Site
  - Off Site
- Information Technology Incidents
  - Cyber Attack
  - Information Systems Failure
- Terrorism
- Civil Unrest

TECHNOLOGICAL HAZARDS

- Fire or Explosion
- Hazardous Materials
- Chemical Agents
  - Chemical Spill
  - Chemical Spill on Body
- Radiological Incident
  - Radioactive Spill
  - Radioactive Spill on Body
  - Gamma Irradiator Failure
- Biological Emergencies
  - Biological Spill
  - Biological Pathogen Exposure

CRITICAL SYSTEMS HAZARDS

- Equipment Related Incidents
  - Bio Safety Cabinets
  - Supplied Air Failure
  - Effluent Decontamination System Failure
  - Alkaline Hydrolysis System Failure
  - Broken Glass
- Utility Failure
  - Loss of Gas
  - Loss of Water
  - Loss of Electricity
  - Water Leak
  - Gas Leak
  - Loss of Safety Systems
- HVAC Failure
- Elevator Failure/Entrapment
- Transportation Incident


| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Natural Events** | *Specific Vulnerability Assessment* | *Description of Natural Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| The type or name of the event | A description of the specific vulnerability that was identified for the NEIDL regarding this event. While some natural events such as earthquakes strike without warning, other natural events typically allow for advance planning and preparation. | A description of the event and the potential impacts specific to the local area. | A description of the mitigation measures that have been taken, including: Facility design, equipment redundancy, plans and procedures developed, and training of personnel. In addition, the University is designated as StormReady by National Weather Service. Weather alerts, watches, and warnings are received via email, NOAA weather radio, and private weather forecasting service.<br><br>Further, each of the NEIDL response plans have actions that will be taken in advance of a storm that may impact BU. | A description of the specific impact to NEIDL operations caused by this event regarding systems, equipment, or personnel and resulting in effect to operational capabilities. The impact to the NEIDL will be dependent on many factors such as, wind speed, storm track, water content and duration. | An estimation of the anticipated severity and range of the Event Phases that this particular event may generate from its origin through escalation. With advance warnings of a storm, or other natural events, the University will escalate and deescalate its emergency phases from A | The emergency response actions expected to be undertaken by the NEIDL ERT. The BU Incident Command Team and response personnel will mobilize to conduct response and recovery operations in a timely fashion. The University's Public Safety, Facilities and | Community Safety: The outcome of this event regarding safety of the surrounding community.<br><br>External Response: The emergency response actions expected to be undertaken by the public safety |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Natural Events** | *Specific Vulnerability Assessment* | *Description of Natural Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | | to B to C as conditions demand. | EH&S Departments will perform damage assessments of facility and peripheral systems and determine what level of operations would continue. | agencies. |
| Earthquake | The NEIDL vulnerability assessment for a seismic event considers that an earthquake of Modified Mercalli Intensity VIII-IX, or magnitude 5.75 to 6.75 may occur in the Boston area. | Moderate to major damage to ordinary, unreinforced construction. Chimneys and walls collapse. Minor damage to specially designed buildings. | The NEIDL has been designed and constructed to the Earthquake Standards Class D of the Massachusetts State Building Code.<br><br>However, the surrounding buildings and supporting infrastructure may not be designed to these standards. | Only minor damage is expected to the NEIDL with minor impact to NEIDL operations.<br><br>However, the surrounding buildings and supporting | · A seismic event is anticipated to result in an event classification of Phase A, B, or C given anticipated damage to surrounding | NEIDL ERT will perform damage assessments of facility and peripheral systems and determine what level of operations will continue. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | | infrastructure may not be designed to these standards and if damaged by the event, may result in an impact to NEIDL operations. | areas. | | Public safety agencies may be called upon for assistance. |
| Flood | The NEIDL does not fall into any special flood zone within the city. However, the area has experienced street flooding during heavy rains as late as 1998. While floods in the Boston area have not approached the | A general and temporary condition of partial or complete inundation of two or more acres of normally dry land area or of two or more properties (at least one of which is the policyholder's property) from:<br>Overflow of inland or tidal waters; or<br>unusual and rapid accumulation or runoff of surface waters from any source. | BU has a Flood Response Plan:<br>Laboratories are on the second through sixth floors, there is no basement in the building that mitigates flooding into the building through rising groundwater. Emergency generators are located on the roof with utilities that support the NEIDL on Floors 3 and 7. BU Facilities has the capability to fill and place sandbags at entrances to exterior first floor doors to | Minor flooding to first floor office spaces. | Phase A, B, or C. | NEIDL ERT will implement the BU Flood Response Plan and NEIDL Continuity of Operations Plan. | Community Safety:<br>No expected outcome regarding safety of surrounding community.<br><br>External Response:<br>No anticipated emergency response |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | level of the Midwest floods, we anticipate this type of event. | | prevent water seepage from street flooding. | | | | actions expected from Public Safety agencies. |
| Hurricane | Although a CAT 5 hurricane is possible, a CAT 2 or 3 is most likely. The most severe hurricane in New England history was the Hurricane of 1938, a CAT 3. The region has experienced CAT 3 storms in the 1950's and 60's, but Cat 1 or tropical storms have been the recent | CAT 1, 74-95 mph: Very dangerous winds. Extensive damage to power lines and poles will likely result in power outages. CAT 2, 96-110 mph: Extremely dangerous winds. Extensive damage; near-total power loss is expected that could last into weeks. Potable water could become scarce as filtration systems fail. CAT 3, 111-130 mph: Devastating damage; electricity and water unavailable for up to a few weeks after storm passes. CAT 4, 131-155 mph: | Building construction should allow for survival during a major hurricane; building power redundancies should allow for power and water continuity. BU has an exercised Hurricane Response Plan.<br><br>Building design specifications and specialized construction will allow the NEIDL to withstand the effects of a major hurricane. Building power redundancies are designed for the loss of water and power up to 10 | The NEIDL has been designed and constructed to mitigate the impact of major damage from a hurricane<br><br>No significant impact to NEIDL Operations. Due to the design and construction standards utilized for the NEIDL, the building is designed to minimally withstand a CAT | Phase A, B, or C. | NEIDL will conduct critical emergency repairs as quickly as possible and conduct damage assessment and begin recovery operations as soon as storm has passed. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Public safety agencies may be called upon for assistance. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | experience. | Catastrophic damage; power outages up to possibly months. Long-term water shortages increase human suffering. CAT 5, > 155 mph: Catastrophic damage; power outages up to possibly months. Long-term water shortages will increase human suffering. | days. Further, BU has an exercised Hurricane Response Plan.<br><br>Based upon intensity and track, select agent stocks may be neutralized as a precaution to an impending and catastrophic hurricane.<br><br>Preparatory actions for hurricane as defined in the BU Hurricane Response Plan. | 3 hurricane.<br><br>However, the surrounding buildings and supporting infrastructure may not be designed to these standards and if damaged by the event, may result in an impact to NEIDL operations. | | | |
| Severe Weather | Historically, a variety of severe weather has occurred in this area including: severe thunderstorms, downbursts or micro bursts, and winter | The National Weather Service defines a severe thunderstorm as having large hail, at least 3/4 inches (0.75 inches) in diameter, and/or damaging winds, at least 58 mph. A severe thunderstorm watch is issued when severe thunderstorms are | BU has an exercised Severe Weather Response Plan. In addition, BU has been certified by National Weather Service as being StormReady for 2010–2013.<br><br>Based upon intensity and track, select agent stocks may be neutralized as a | No significant impact to NEIDL Operations. Due to the design and construction standards utilized for the NEIDL, the building is designed to withstand severe | Phase A, B, or C. | NEIDL will conduct critical emergency repairs as quickly as possible and conduct damage assessment and begin recovery | Community Safety: No expected outcome regarding safety of surrounding community. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | storms. | possible. It generally covers a large area, perhaps several states. A severe thunderstorm warning is issued when a severe thunderstorm is occurring or expected to occur within a matter of minutes. A downburst or microburst is a sudden rush of cool air toward the ground that can impact with speeds greater than 70 mph and produce damage similar to that of a tornado. Viewing the damage from the air does not reveal a twisting motion or convergence toward a central track, as in a tornado. For the purpose of this analysis, winter storms are categorized as Severe Weather. | precaution to an impending severe weather system.<br><br>Preparatory actions for severe weather as defined in the BU Severe Weather Response Plan. | weather and is safe from major damage from these types of events.<br><br>However, the surrounding buildings and supporting infrastructure may not be designed to these standards and if damaged by the event, may result in an impact to NEIDL operations. | | operations as soon as storm has passed. | External Response: None anticipated, but public safety agencies may be called upon for assistance. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| The type or name of the event | A description of the specific vulnerability that was identified for the NEIDL regarding this event. | A description of the event and the potential impacts specific to the affected area of the NEIDL. | A description of the mitigation measures that have been taken including: facility design, equipment redundancy, plans procedures developed, and training of personnel. | A description of the specific impact to NEIDL operations caused by this event regarding systems, equipment, or personnel and resulting in effect to operational capabilities. | An estimation of the anticipated severity and range of the Event Phases that this particular event may generate from its origin through escalation. | The emergency response actions expected to be undertaken by the NEIDL ERT. | Community Safety: The outcome of this event regarding safety of the surrounding community.<br><br>External Response: The emergency response actions expected to be undertaken by the public safety agencies. |
| Bio Safety Cabinets Power Failure—BSL- | A Critical Power Failure may cause a | A Critical Power Failure may cause a potential loss of Primary Containment | Response Protocols for Bio Safety Cabinets are in place and BSL-3 personnel have | Cease work in affected BSL-3 Bio Safety Cabinet, | Phase A | NEIDL ERT will conduct an Exposure/ | Community Safety: No expected |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| 3 | potential loss of Primary Containment associated with the BSL-3 Bio Safety Cabinet. | under the following conditions:<br>Due to a slight delay in switching over to emergency power, the BSC will go to static at that time (no air flow). The individual working in the cabinet must secure their agents and decontaminate the cabinet. However, since the air in the cabinet will be momentarily static, there is the small chance that movement of the worker's arms within the cabinet may cause potentially contaminated air to be drawn out of the Bio Safety Cabinet.<br><br>Potential impact to affected area is the possible | been trained to respond to this event. | secure agents, decontaminate the area, and investigate possible breach in containment. | | Contamination Assessment. If this event results in a select agent loss of containment, then the appropriate notifications will be performed associated with the Select Agent Program. | outcome regarding safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of select agents must be reported to the SAP). |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | contamination outside of the Bio Safety Cabinet. | | | | | |
| Bio Safety Cabinets Power Failure—BSL-4 | A Critical Power Failure may cause a potential loss of Primary Containment associated with the BSL-4 Bio Safety Cabinet. | A Critical Power Failure may cause a potential loss of Primary Containment under the following conditions: Due to a slight delay in switching over to emergency power, the BSC will go to static at that time (no air flow). The individual working in the cabinet must secure their agents and decontaminate the cabinet. However, since the air in the cabinet will be momentarily static, there is the small chance that movement of the worker's arms within the cabinet may cause potentially contaminated air to be | In BSL-4, the laboratory serves as the secondary containment. Response Protocols for Bio Safety Cabinets are in place and BSL-4 personnel have been trained to respond to this event. | Cease work in affected BSL-4 Bio Safety Cabinet, secure agents, decontaminate the area. | Phase A | NEIDL ERT will conduct an Exposure/ Contaminati on Assessment. If this event results in a select agent loss of containment, then the appropriate notifications will be performed associated with the Select Agent Program. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of select agents must be reported to the SAP). |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | drawn out of the Bio Safety Cabinet.<br><br>Potential impact to affected area is the possible contamination outside of the Bio Safety Cabinet. | | | | | |
| Rapid Transfer Cart —Failure | A Rapid Transfer Cart Fan failure in conjunction with a simultaneous glove leak. | If the fan fails during transport there is no impact (air is static). The only indication that a leak may have occurred would be the blower ceasing to function. In the event of a blower failure, the cabinet would be unloaded (in the animal housing space), decontaminated, and then leak-tested.<br><br>Potential impact to affected area is the possible contamination of | The Rapid Transfer Cart (RTC) and the integrity of the gloves are inspected prior to each usage. Any time the gloves are replaced the RTC is leak-tested. The RTC is designed with its own independent blower (powered from an on-board rechargeable battery), a HEPA filter on the exhaust side and a gauge to indicate negative pressure in the cabinet. Even if a glove comes off, the air will flow into the cabinet provided the | Contamination of common space could lead to cross contamination and compromise research. May require decontamination, leading to a suspension of ongoing activity. | Phase A | NEIDL ERT will conduct an Exposure/ Contamination Assessment. If this event results in a select agent loss of containment, then the appropriate notifications will be performed | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of |

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|---|---|---|---|---|---|---|---|
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| | | immediate environment. | blower unit is functioning. The only time a leak could possibly cause contamination of the environment is during transport of an infected animal in which the blower stops working and there is a breach of a glove (or other source for air to flow out of the cabinet).<br><br>Response protocols (no opening of cabinet until unit is in animal facility with room doors closed) are in place and personnel have been trained to respond to this event. | | | associated with the Select Agent Program. | select agents must be reported to the SAP). |
| Bio Safety Cabinets Exhaust Failure—BSL-4 | An Exhaust Fan Failure may cause a potential loss of Primary | Working with agent in BSC. Positive pressurization possible is active | There are two types of fans exhausting air from the bio safety cabinet. First, there is a blower on the BSC, and | Cease work in affected Bio Safety Cabinet, secure agents, | Phase A | NEIDL ERT will conduct an Exposure/ Contaminati | Community Safety: No expected outcome |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | Containment associated with the BSL-4 Bio Safety Cabinet. | aerosolization (if using supplied air) contamination.<br><br>Potential impact to affected area is the possible contamination outside of the Bio Safety Cabinet. | second, the BSC duct is connected to a HEPA filtered exhaust in the mechanical space on the floor above (before exhausting the air from the building). If the blower on the BSC were to fail, there would remain some exhaust within the building exhaust system. If the building exhaust system were to fail, there are backup fans that would take over. The worst case scenario is outlined in the table: if both the blower on the BSC and the redundant backup fans fail, the response protocol is for the BSL-4 worker to cease work in the cabinet, shut down all equipment and secure any agents—the BSC | decontaminate the area. | | on Assessment. If this event results in a select agent loss of containment, then the appropriate notifications will be performed associated with the Select Agent Program. | regarding safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of select agents must be reported to the SAP). |

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| | | | air would become static but remain contained in the BSC. In BSL-4, the laboratory serves as the secondary containment. Response Protocols for Bio Safety Cabinets are in place and BSL-4 personnel have been trained to respond to this event. | | | | |
| Breathing Air System Failure—BSL-4 | A Total Compressor Failure or Total Power Failure may cause a loss of the BSL-4 Breathing Air System. | A Total Compressor Failure or Total Power Failure may cause a potential life safety condition for BSL-4 personnel utilizing the Breathing Air System. | The breathing air system is equipped with two fully redundant compressors. In this case the system is n+2. In addition there is a stored backup volume of breathing air on site, separate of the main compressors to provide full egress capability from the laboratory. Inspections and Checks, Daily Safety Meetings, | If all primary compressors were compromised the laboratory would require evacuation under the backup air system. The laboratory would remain out of service until such time a required volume of reserve | Phase B or C | NEIDL ERT will perform evacuation and accountability of affected laboratory personnel. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None |

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| | | | Maintenance SOPs, Alarms, Emergency Response Plans, and Response Protocols are in place and BSL-4 personnel have been trained to respond to this event. | and primary compressors is returned. | | | anticipated. |
| Powered Air Purifying Respirators (PAPR) Failure—BSL-3 | A Battery Failure, Blower Failure, Clogged Filter or Breach of Hose may cause a failure of a BSL-3 PAPR. | A Battery Failure, Blower Failure, Clogged Filter or Breach of Hose may cause a loss of supplied air to the individual utilizing a PAPR and working in a BSL-3 laboratory environment. | Daily checks and maintenance, spare batteries, and Response Protocols are in place and BSL-3 personnel have been trained to respond to this event. | PAPR failure may result in a loss of supplied clean air and potential exposure to the individual working in a BSL-3 laboratory environment. | Phase A or B | NEIDL ERT will perform possible decontamination if required. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None anticipated. |
| Effluent Decontamination System (EDS) Failure | An Equipment Failure, Power Failure, Tank | An Equipment Failure, Power Failure, Tank Failure, or Loss of Steam | The EDS system is equipped with three redundant units. The cycle is auto resetting | The throughput of the laboratory can be impacted by a | Phase A, B, or C. | NEIDL ERT will perform cleanup and | Community Safety: No expected |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | Failure, or Loss of Steam may cause a failure of the EDS. | may cause a Minor or Catastrophic Failure of the Effluent Decontamination System and result in the cessation of BSL-4 work, potential loss of containment and a shutdown of water system. | and will reinitiate a sterilization cycle if during a run a parameter fails to be maintained. The system is not gravity drain and requires a completed cycle to initiate a pumped discharge. Secondary decontamination, as primary, is accomplished prior to disposal to EDS. The EDS has n+2 redundancy and uses a validation program to ensure proper operation. | reduction of cycle time. Use of the laboratory would be restricted in volume in coordination with the ability for the EDS to operate. | | assessment of possible exposures; assist in evacuation, accountability and decontamination.<br><br>NEIDL ERT will coordinate with private contractor for assistance if utilized. | outcome regarding safety of surrounding community.<br><br>External Response: None anticipated. |
| Tissue Digester Failure | An over pressurization of the vessel or failure of equipment may | An over pressurization of the vessel or failure of equipment may cause a Minor or Catastrophic Failure of the Tissue | Maintenance and validation programs, isolated room design, and PPE/protocols. Response Protocols are in place and BSL-3 personnel | The ability to dispose on site of the material would be impacted. The materials would | Phase A, B, or C. | NEIDL ERT will perform possible extraction of injured or | Community Safety: No expected outcome regarding |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
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| | cause a failure of the Tissue Digester. | Digester and result in the inability to dispose of sterilized organic materials as well as the release of high pH chemicals and personnel exposure. | have been trained to respond to this event. | require storage until the tissue digester is returned to service, or offsite disposal is arranged. Suspension of animal research operations, possible personnel exposure (chemicals), environmental release of high pH chemicals | | chemical exposed personnel and subsequent clean-up operations.<br><br>If this event results in a release of high pH chemicals to the sanitary sewer, then appropriate notifications will be performed to BWSC, EPA, MWRA, and/or | safety of surrounding community.<br><br>External Response: The BWSC, BPHC, EPA, MWRA, and/or MEPA may receive notifications if high pH chemicals are released to the sanitary sewer. |

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| | | | | | | MEPA. | |
| Broken Glass | Breakage of equipment or lab supplies. | Breakage of equipment or lab supplies may cause personal injury and potential exposure to agent. | Training, EHS approval for glass usage (with substitution if possible), cleanup protocols in place, sharps handling. | Possible medical incident response protocol, with potential exposure to agent. | Phase A | Cleanup will be performed by lab personnel. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None anticipated. |
| Loss of Gas | Loss of gas is considered a highly unlikely event. | A loss of gas to the NEIDL would be a temporary interruption and have minimal to no impact on NEIDL operations or research. | The natural gas boilers are backed up by the Veolia city steam grid and vice versa. Loss of gas to the building will transition boiler operations to District steam. Transition should be seamless to the end user, as | The building's ability to heat and sterilize would be interrupted during the outage window. Sterilization cycles would be aborted and would restart | Phase A | NEIDL personnel would coordinate with Facilities to bring the boilers on | Community Safety: No expected outcome regarding safety of surrounding community. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | a loss of boiler pressure will be picked up by the district.<br><br>If we are operating on district steam and service is interrupted we would need to transition to the boilers. This would not be seamless, the building would be without steam until either the grid is restored or the boilers could be brought on line. | upon utility restoration; in the meantime waste would need to be stockpiled for future decontamination. The building's ability to heat and sterilize would be interrupted during the outage window. Sterilization cycles would be aborted and would restart upon utility restoration. In the meantime waste would need to be stockpiled for future decontamination. | | line. | External Response: None anticipated. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| Loss of Water | Loss of water is considered a highly unlikely event. | A loss of water service to the NEIDL would be caused by a breakdown in the delivery of water from MWRA and if a sustained interruption, would result in impact to the NEIDL's operations. | The water service is a loop service with feeds separated by city blocks. If service is interrupted on one end it may be isolated and full service from the other end. Note: The disinfection site storage is enough for full exit of the facility without the need to replenish. | A total loss of water service would impair the ability to provide potable water, fire suppression systems, and process loads. Upon a sustained interruption, the facility until restored would not have the ability to provide life safety systems, cooling and process water to sustain operations eventually requiring the suspension of operations | Phase B or C | NEIDL ERT will coordinate and work with state and city officials for safe restoration of service and resumption of research. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Limited to restoration of services and Inspectional Services Department requirements. |
| Loss of | Life Safety | The Loss of the NEIDL's | The water service is a loop | A total loss of | Phase C | NEIDL ERT | Community |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| Life Safety Systems | Systems are reliant on electrical power and water supply. A loss of all life safety systems is considered unlikely. | Life Safety Systems would be caused by the failure of the MWRA to deliver water to the building and the failure of the primary electrical power provided by NSTAR and a subsequent failure of both emergency generators. | service with feeds separated by city blocks. If service is interrupted on one end it may be isolated and full service from the other end. Note: The disinfection site storage is enough for full exit of the facility without the need to replenish. The electrical service has four independent feeds from the utility company. Each one is capable of serving the facility's critical needs. The utility service is backed up by two generators, each sized to carry the critical loads. | water service would impair the ability to provide fire suppression systems, and process loads. Upon a sustained interruption, the facility until restored would not have the ability to provide life safety systems, cooling and process water to sustain operations eventually requiring the suspension of operations. If the both utility and onsite generation were to | | will conduct building operation assessments. | Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Inspectional Services Division will need to inspect life safety systems before reoccupying building. |

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|---|---|---|---|---|---|---|---|
| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | fail, and Life Safety Systems were not able to operate, laboratory operations would need to be curtailed and the building evacuated of non-critical personnel. | | | |
| Loss of Electricity | Loss of electricity is considered a highly unlikely event. | No electrical supply available from public utility. While a loss of electricity into the building is possible and anticipated, the building's electrical service as defined in column four, makes a total electrical failure in the building extremely low. | The electrical service has four independent feeds from the utility company. Each one is capable of serving the facility's critical needs. The utility service is backed up by two generators, each sized to carry the critical loads. | If the both utility and onsite generation were to fail, the containment operations would be suspended and the laboratories left in a static state of no ventilation. | Phase A or B | NEIDL ERT will conduct building operation assessments and ensure continued replenishing of generator fuel supply. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Technological Events** | ***Specific Vulnerability Assessment*** | ***Description of Technological Event and Potential Impact*** | ***Specific Mitigation Measures*** | ***Impact to NEIDL*** | ***Possible Event Classification/ Notification Level*** | ***Internal Response*** | ***External Response*** |
| Water Leak | Water leaks may result from broken piping or human error. | Water damage to NEIDL facility resulting in loss of workspace and possible mold. | The water services within the facility are designed with both system floor level and end device isolation. If a leak is detected and found un-repairable the piping will be isolated and the water service impaired until a full repair can be made. | The standing water would need to be contained and disposed of accordingly. In the period between isolation and final repair the system past the isolation valve will be without service. | Phase A or B | NEIDL ERT will perform containment, control, cleanup, damage assessment and monitoring of water leak conditions. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated. |
| Gas Leak | Gas leaks may result from broken piping or human error. | Failure of gas supply piping or human error causing explosion or fire, injuries, asphyxiation and building evacuation resulting in cessation of research at NEIDL. | The gas services within the facility are designed with both system floor level and end device isolation. Response Protocols are in place and personnel have been trained to respond to this event. | The detection of a gas leak will initiate an investigation dependent on its potential size. Minor leaks such as lab spigot valves may be isolated until repaired. A | Phase A, B, or C. | NEIDL personnel will shut off gas, assist in evacuation and personnel accountability. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | major leak would initiate a building evacuation, the utility isolated from outside the facility and emergency response from outside agencies. | | | Response: Response by City of Boston agencies in accordance with 911 protocol. |
| HVAC Failure | A critical power failure, equipment failure, or duct collapse (through pressure event) may cause a failure of the HVAC System. | A critical power failure, equipment failure, or duct collapse (through pressure event) may cause a loss of directional airflow and result in the potential for a biological agent release and result in suspension of NEIDL activities. | The HVAC systems are equipped with n+1 redundant fan sets (3 each BSL-3 and 4 each BSL-4). Each system is designed to operate in parallel where the loss of a fan is compensated by the remaining fans. Upon the loss of multiple fans the pressure relationships are maintained with reduction of air exchange. Upon loss of all exhaust fans the HVAC fails, leaving the | The laboratories may be restricted in operations with the loss of redundancies and shutdown upon complete loss of HVAC. Work may be suspended, personnel may be evacuated from affected spaces. | Phase A, B, or C. | NEIDL ERT will assist in evacuation and personnel accountability.<br><br>NEIDL ERT will conduct an Exposure/ Contamination Assessment. If this event | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
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| | | | laboratories in a static airflow state. Additionally, the HVAC system has redundant fans, BAS/alarms, and backup generators. Response Protocols are in place and both research and facility staff personnel have been trained to respond in the event of an HVAC failure. | | | results in a select agent loss of containment, then the appropriate notifications will be performed associated with the Select Agent Program. | release of select agents must be reported to the SAP). |
| Elevator Failure | Elevators occasionally fail in their operations. | An elevator car can stop working. Occupants would be made to use other elevators. | Multiple elevators per service area are provided to ensure traffic flow if a unit is out of service. The university has a service contract with emergency response windows for events such as entrapments and dangerous conditions. The maintenance staff has the | Minor impact to NEIDL operations, the affected elevator will be out of service until repaired and the remaining elevators will be utilized. | Phase A | NEIDL personnel would coordinate with Facilities to address the affected elevator. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | ability to remove a car from service if it is operating sporadically. | | | | Response: None Anticipated. |
| Elevator Entrapment | Occupied elevators in buildings have stalled, trapping its occupants. | If an elevator stops between floors with occupants, they will be trapped until set free. | The University has a service contract with emergency response windows for events such as entrapments and dangerous conditions. | Minor impact to NEIDL operations. NEIDL personnel will respond to an elevator entrapment and will assist occupants. | Phase A | NEIDL personnel will respond to an elevator entrapment and will assist occupants. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by City of Boston agencies in accordance with 911 protocol. |
| Transportation | While highly | A shipment could be | BU has implemented a | Delay in shipment | Phase C with | NEIDL ERT | Community |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
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| Incident involving transport of select agent, | unlikely, an incident could occur during a select agent transport. | compromised by an accident, theft, or release resulting in the delay or loss of the select agent. | Transportation Materials Management Policy that ensures that only certified transporters are used to safely transport and track select agents to the NEIDL. Transporters are limited to state and federal highway systems where possible. These plans have been used and exercised with Boston public safety agencies. | or loss of select agent. | required regulatory notifications. | will perform notifications as per SOP.<br><br>NEIDL ERT will conduct an Exposure/ Contamination Assessment with emergency responders. If this event results in a select agent loss of containment, then the appropriate notifications will be performed as | Safety: There should be no to limited environmental outcome regarding community safety.<br><br>External Response: Response by City of Boston agencies in accordance with 911 protocol, as well as BPHC, Select Agent Program (any |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | | | outlined in the Select Agent Program. | potential release of select agents must be reported to the SAP). In addition, response by first responders in jurisdiction having authority upon notification by transporter and BU. |
| Information Systems Failure | While highly unlikely, an information systems failure may occur due to equipment | An equipment failure and/or personnel error may result in the information system or data not being available. | Redundant Systems are in place in multiple sites to prevent an information systems failure. | Information stopped, data recovery necessary, cessation of research, BAS recovery. | Phase A | NEIDL personnel would coordinate with IS staff to address | Community Safety: No expected outcome regarding safety of |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Technological Events** | *Specific Vulnerability Assessment* | *Description of Technological Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | failure and/or personnel error. | | | | | information system failure. | surrounding community.<br><br>External Response: None Anticipated. |
| Cyber Attack | While highly unlikely, connectivity to the internet results in vulnerability to cyber attacks. | Security hardware and software intercepts the attacks. Not stopping the attack triggers additional security measures. | BU Intrusion Response Team (BUIRT) monitors networks (10. And 155 networks), BAS is a closed network within the building, additionally monitored at BUMC CC. | Suspension of use of server and computer until all impacts are identified, addressed and reported as appropropriate. | Phase A | BU IRT monitors traffic and disconnects either server or compute until attack is identified or stopped. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| The type or name of the event | A description of the specific vulnerability that was identified for the NEIDL regarding this event. | A description of the event and the potential impacts specific to the affected area of the NEIDL. | A description of the mitigation measures that have been taken including: Facility design, equipment redundancy, plans/procedures developed and training of personnel. | A description of the specific impact to NEIDL operations caused by this event regarding systems, equipment, or personnel and resulting in effect to operational capabilities. | An estimation of the anticipated severity and range of the Event Phases that this particular event may generate from its origin through escalation. | The emergency response actions expected to be undertaken by the NEIDL ERT. | Community Safety: The outcome of this event regarding safety of the surrounding community.<br><br>External Response: The emergency response actions expected to be undertaken by the public safety agencies. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| Minor Injury | Possible equipment failure, human error, minor animal bite/scratch. | Personnel injury, no loss of consciousness, ambulatory. | The University has instituted a culture of safety throughout to reduce injuries and accidents. Lab Safety Training is mandatory for all personnel working in laboratories. First aid training is also required of all personnel working in high and maximum containment as well as all personnel assigned to the NEIDL. | Temporary disruption of work. | Phase A; animal bites or scratches are a potential exposure and notification must be made by ROHP to BPHC. | NEIDL personnel would coordinate with BEMS response and transport if required. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by City of Boston agencies in accordance with 911 protocol;. report to BPHC. |
| Minor Injury in Containment | Possible equipment failure, human error, minor | Personnel injury, no loss of consciousness, ambulatory. | The University has instituted a culture of safety throughout to reduce injuries and accidents. Lab Safety | Temporary disruption of work, injured party must be decontaminated | Phase A; animal bites or scratches are a potential | NEIDL personnel will provide assistance | Community Safety: No expected outcome |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | animal bite/scratch. | | Training is mandatory for all personnel working in laboratories. First aid training is also required of all personnel working in high and maximum containment as well as all personnel assigned to the NEIDL. | and removed from containment. | exposure and notification must be made by ROHP to BPHC. | decontaminating the injured party if required.<br><br>NEIDL personnel would coordinate with BEMS response and transport if required. | regarding safety of surrounding community.<br><br>External Response: Response by City of Boston agencies in accordance with 911 protocol;. report to BPHC. |
| Serious Injury | Possible equipment failure, human error, severe animal bite/scratch, resulting in a medical | Personnel injury, loss of consciousness, non-ambulatory. | The University has instituted a culture of safety throughout to reduce injuries and accidents. Lab Safety Training is mandatory for all personnel working in laboratories. First aid and AED/CPR training is also | Suspension of work, administration of first aid/CPR/AED (if appropriate). | Phase A or B; animal bites or scratches are a potential exposure and notification must be made by ROHP to | NEIDL personnel would coordinate with BEMS response and transport if required. | Community Safety: No expected outcome regarding safety of surrounding community. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | emergency. | | required of all personnel working in high and maximum containment as well as all personnel assigned to the NEIDL | | BPHC. | | External Response: Response by City of Boston agencies in accordance with 911 protocol;. report to BPHC. |
| Serious Injury in Containment | Possible equipment failure, human error, severe animal bite/scratch, medical emergency. | Personnel injury, loss of consciousness, non-ambulatory. | The University has instituted a culture of safety throughout to reduce injuries and accidents. Lab Safety Training is mandatory for all personnel working in laboratories. First Aid and AED/CPR training is also required of all personnel working in high and maximum containment as well as all personnel | Suspension of work, administration of first aid/CPR/AED (if appropriate), decontamination of injured party, removal from containment, transfer to medical care. | Phase B; animal bites or scratches are a potential exposure and notification must be made by ROHP to BPHC. | NEIDL personnel will provide assistance decontaminating the injured party if required.<br><br>NEIDL personnel would | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | assigned to the NEIDL. | | | coordinate with City Responders to transport if required. | City of Boston agencies in accordance with 911 protocol; report to BPHC. |
| Sudden Death | Cardiac arrest or other acute cause of death. | Loss of life. | All NEIDL personnel are medically screened upon hiring, as well as annually checked by ROHP. They are trained and certified in first aid, CPR and AED. AED units are installed on every floor. | First Aid treatment by internal staff and/or NEIDL public safety. | Possible Phase A or B. | NEIDL personnel would treat as a medical emergency. Public Safety would secure scene. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by City of Boston agencies in accordance |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
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| | | | | | | | with 911 protocol;. notify BPHC |
| Suicide Threat or Attempt | While a highly unlikely event due to psychological screening prior to hiring and daily security screening, a suicide threat or attempt may occur. | Serious psychological impact to staff. | ROHP conducts pre-employment psychological screening. | Serious psychological impact to staff. Possible loss of research space. | Phase B | NEIDL personnel would perform a site assessment and implement security dependent on location of incident. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by BUPD and City of Boston agencies in accordance with 911 protocol.. |
| Workplace | Possible, but | Workplace violence could | Security screening, 100% | Injuries or death | Phase A, B, or | NEIDL | Community |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| Violence | unlikely event. | result in threats, assault, blackmail, domestic violence, injuries or death hostile work environment, loss of work or agent. | access control, multiple layers of security barriers, employees' assistance programs. | hostile work environment, loss of work or agent. | C; Code Green Declaration. | personnel would coordinate to shelter in place, assist with cleanup, conduct employee support, implement site security determined necessary by NEIDL Public Safety. | Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by BUPD and City of Boston agencies in accordance with 911 protocol and FBI, If select agent involved. |
| Bomb Threat | Possible, but unlikely event. | A bomb threat could result in work stoppage, possible evacuation and securing the | Building is secured at all times. | Implement Bomb Threat Response Plan and put | Phase A | NEIDL personnel would | Community Safety: No expected |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | building. | | building in "safe mode." Notification to occupants to search their areas; common areas are searched by NEIDL Public Safety. | | investigate and determine if the event is a false threat or escalate to an actual found device. | outcome regarding safety of surrounding community.<br><br>External Response: Notifications to BUPD and BPD. |
| Suspicious Package or Mail | Possible, but unlikely event. | A package or piece of mail is received that meets the definition of "suspicious." | All incoming packages and mail are screened. All deliveries are known prior to arrival and are received at the loading dock. | Possible evacuation, building put in "safe mode." | Phase B or C. | NEIDL Public Safety would take lead on suspicious package or mail event. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Notifications to BUPD and |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | | | | | BPD. |
| Bomb or Suspicious Device | Possible, but unlikely event. | Bomb or Suspicious Device is found on property. | All incoming packages and mail are screened. All deliveries are known prior to arrival and are received at the loading dock. All bags carried in by employees are screened. | Possible evacuation, building put in "safe mode." | Phase C | NEIDL ERT would assist in evacuation and accountability. | Community Safety: Community may be impacted by road closings and media interest.<br><br>External Response: Response by BUPD and City of Boston agencies in accordance with 911 protocol.. |
| Dangerous Person Onsite | Possible, but unlikely event. | A dangerous person onsite may result in threats, assault, blackmail, domestic | 100% access control, Visitor Access Policy in place, limited access through | Shelter in place, building put in "safe mode." | Phase B or C. | NEIDL Public Safety would | Community Safety: No expected |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | violence, injuries or death, hostile work environment, loss of work or agent. | building. | | | coordinate response and implement site security as determined necessary. | outcome regarding safety of surrounding community.<br><br>External Response: Response by BUPD and City of Boston agencies in accordance with 911 protocols. |
| Hostage Situation | Highly unlikely event. | A hostage situation would result in someone held against his/her will. Threats, assault, blackmail, domestic violence, injuries or death, hostile work environment, loss of work | 100% access control, Visitor Access Policy in place, limited access through building. | Shelter in place, building put in "safe mode." | Phase B or C. | NEIDL ERT response is location-dependent. NEIDL Public Safety has | Community Safety: No expected outcome regarding safety of surrounding |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
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| | | or agent. | | | | lead (advice needed due to technical hazards in location). | community.<br><br>External Response: Response by BUPD and City of Boston agencies in accordance with 911 protocol.. |
| Security Breach | Possible, but unlikely event. | Security breach occurs when someone defeats existing security measures. This may result in theft, loss or release of a select agent inventory or record and result in cessation of select agent research. | Pre-employment screening, PATRIOT ACT requirements, access control, inventory control, video surveillance. | Cessation of select agent research, loss of agent, loss of reputation. | Phase C | NEIDL ERT will conduct inventory audit and access investigation and notify all required agencies such as CDC, FBI, BPHC and | Community Safety: Possible community outcome.<br><br>External Response: Response by CDC, FBI, BPHC and possibly BPD |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | | | | possibly BPD. | as necessary. |
| Protest | Possible | Rallies, demonstrations on Albany Street. Possible traffic impact on South End streets. | Security Plan is always in effect through physical security, informational technologies, and facility design. BU receives intelligence reports from Boston Regional Intelligence Center, MA Fusion Center and the DHS Anti-Terrorism Advisory Council. | Building put into "safe mode" Heightened awareness of staff. | Phase C | NEIDL ERT response is activity-dependent; NEIDL Public Safety has lead addressing trespass activity and monitoring CCTV for perimeter control. | Community Safety: Possible community outcome Traffic, Police presence, media, crowds. External Response: Response by BPD for crowd control on public ways. |
| Terrorism | Possible | Terrorism may take the form of any man-caused event previously listed in | Security Plan is always in effect through physical security, informational | Increased security; Building put into "safe mode." | Phase C | NEIDL ERT response is activity- | Community Safety: Possible |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | this form. | technologies, and facility design.<br>BU receives intelligence reports from Boston Regional Intelligence Center, MA Fusion Center and the DHS Anti-Terrorism Advisory Council. | Appropriate response to event. | | dependent. NEIDL Public Safety has lead on appropriate response to event. | community outcome; Traffic, Police presence, media, crowds.<br><br>External Response: Response by City of Boston agencies in accordance with 911 protocol and FBI as necessary. |
| Civil Unrest | Possible | Rallies, demonstrations on Albany Street.<br>Possible traffic impact on South End streets. | Security Plan is always in effect through physical security, informational technologies and facility design. | Building put into "safe mode" Heightened awareness of staff. | Phase C | NEIDL ERT response is activity-dependent. NEIDL | Community Safety: Possible community outcome. |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | BU receives intelligence reports from Boston Regional Intelligence Center, MA Fusion Center and the DHS Anti-Terrorism Advisory Council. | | | Public Safety has lead addressing trespass activity and monitoring CCTV for perimeter control. | Traffic, Police presence, media, crowds.<br><br>External Response: Response by BPD for crowd control on public ways. |
| Fire or Explosion | Possible | Loss of space, injuries and fatalities. | Fully sprinklered building, fire response and evacuation plan in place. Yearly fire drills conducted. | Loss of space, injuries and fatalities, cessation of research. | Phase B or C. | NEIDL ERT will assist in off-site response, evacuation and personnel accountability. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | | | | | Response by City of Boston agencies in accordance with 911 protocol and notification of BPHC. |
| Chemical Spill | Human error and/or equipment failure. | Possible personnel exposure and/or environmental impact. | Training, PPE, Spill response/spill kit usage. | Momentary disruption of laboratory activities. | Phase A, B, or C, as event conditions warrant. | NEIDL ERT will assist in spill cleanup. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: Response by City of Boston agencies in |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
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| | | | | | | | accordance with 911 protocol; report to BPHC. |
| Chemical Spill on Body | Human error and/or equipment failure. | Possible personnel exposure and/or environmental impact. | Training, PPE, Spill response/spill kit usage. | Momentary disruption of laboratory activities. | Phase A, B, or C, as event conditions warrant. | NEIDL ERT will assist in personnel extraction, decontaminating personnel (for transfer to medics) and spill cleanup. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated. Report to BPHC. |
| Radioactive Spill | Even under the best of training and conditions, | Based on our BSL-2 experience, Typical quantities used during BSL- | Lab design, training and SOPs, and radiation protection safety controls. | Momentary disruption of laboratory | Phase A; RSO notification. | NEIDL RSO will oversee cleanup of | Community Safety: No expected |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | a radioactive spill may occur in a laboratory. | 2 research are less than 0.05 millicurie and with volumes varying from 0.1ml to 20 ml, Minimal impact is expected during the spill. | All work with volatile compounds will be done in biosafety cabinets or functioning ducted hoods. | activities. | | spill area and approve continuation of research. | outcome regarding safety of surrounding community.<br><br>External Response: Notification of DPH. |
| Radioactive Spill on Body | While highly unlikely due to PPE, a failure in laboratory equipment may cause a spill in very small amounts on a body part. | A researcher not properly attired in PPE and not following SOPs might cause a radioactive spill on exposed skin. This may also happen due to an equipment failure. The impact depends on the type of radioactive material resulting in radioactive skin contamination. | PPE, equipment design, SOPs and radiation safety controls. | Radiation skin contamination, potential internal exposure, research cessation, containment, control and decontamination. | Phase A; RSO notification. | NEIDL RSO will oversee response and evaluation; cleanup of area, decontamination of exposed area. RSO will determine, and if necessary, | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated Notification |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | | | make any and all required regulatory notifications. | of DPH and BPHC. |
| Gamma Irradiator Failure | Equipment failure may cause Gamma Irradiator to fail. | This event may be due to a failure of the compressor or the door interlock mechanism or a source jam. The door may open and not close, resulting in the irradiator being inoperable or the source may jam in the up or down position with no elevated radiation levels. | The equipment is designed in a fail-safe mode. | The irradiator is out of order. Any research requiring irradiation will stop until the irradiator is repaired. | Phase A; RSO notification. | NEIDL RSO investigates and has repairs made by manufacture r. | Community Safety: No expected outcome regarding safety of surrounding community.<br><br>External Response: None Anticipated. |
| Biological Spill | Human error and/or equipment failure. | Environmental contamination. | Training, PPE, Spill response/biohazard spill kit usage. | Momentary disruption of laboratory activities. | Phase A, B, or C, as event conditions warrant.. | NEIDL ERT will assist with spill cleanup. NEIDL ERT | Community Safety: No expected outcome regarding |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | | | will conduct an Exposure/ Contaminati on Assessment. If this event involves a select agent, then the appropriate notifications will be performed associated with the Select Agent Program. | safety of surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of select agents must be reported to the SAP). |
| Biological Exposure | Human error and/or equipment failure., and animal bite/scratch. | Personnel exposure, possible contamination of space or equipment. | Medical surveillance, immunizations (if available). | Possible illness or death could result from biological exposure. Laboratory activities | Phase B | NEIDL will assist with extraction, decontamina tion and transfer to | Community Safety: No expected outcome regarding safety of |

| Threat and Vulnerability Assessments | | | Threat/Hazard Mitigation Strategy | Potential Event Internal Impact | NEIDL Event Classification and Notification Level(s) | POETE Gap Analysis | |
|---|---|---|---|---|---|---|---|
| **Man Caused Events** | *Specific Vulnerability Assessment* | *Description of Man Caused Event and Potential Impact* | *Specific Mitigation Measures* | *Impact to NEIDL* | *Possible Event Classification/ Notification Level* | *Internal Response* | *External Response* |
| | | | | suspended, exposed person, decontaminated, first aid administered and then the exposed person removed from containment, transferred to medical care. | | medical care. ERT will conduct an Exposure/ Contaminati on Assessment. If this event involves a select agent, then the appropriate notifications will be performed associated with the Select Agent Program. | surrounding community.<br><br>External Response: BPHC, Select Agent Program (any potential release of select agents must be reported to the SAP). |

# Appendix 8

## REPRESENTATIVE PUBLICATIONS FROM THE NEIDL WEBSITE


The Boston University
National Emerging Infectious
Diseases Laboratories
Finding Cures. Saving Lives.
BOSTON
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**The Boston University National Emerging Infectious Diseases Laboratories (NEIDL)**

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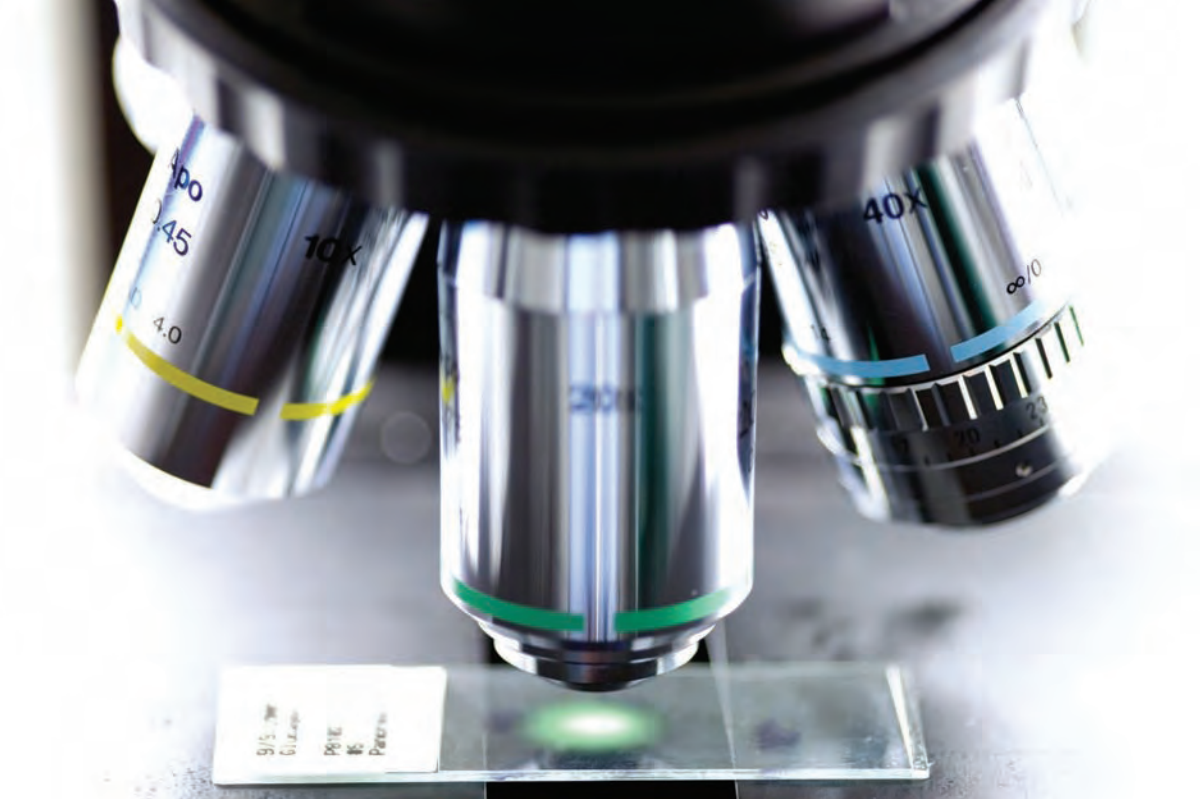



## Our mission

The National Emerging Infectious Diseases Laboratories (NEIDL) is part of a national network of secure facilities that study infectious diseases that are of major public health concern—whether they occur naturally or are introduced deliberately through bioterrorism. Our facility is located in BioSquare, a biomedical research and business park adjacent to Boston University Medical Campus.

### Our mission is threefold:

- To perform cutting-edge basic and clinical research on emerging infectious diseases and to develop diagnostic tests, treatments, and vaccines to promote the public's health through combating infectious diseases
- To provide training in these areas of research and to support a national response in the event of a biodefense emergency
- To establish a research facility with the highest attention to community and laboratory safety and security

State-of-the-art technologies were employed in the NEIDL's design and will be used to conduct research in safe and secure environments. The comprehensive core research

facilities will enable basic, translational, and clinical research and the development of products related to emerging infectious diseases. World-renowned experts in emerging and re-emerging infectious diseases lead each of our multidisciplinary research programs.

The NEIDL represents a major step forward in advancing public health and complementing the region's reputation as the biomedical research hub of the nation.

## Our research cores are state of the art.

The research cores at the NEIDL will facilitate discoveries about emerging infectious diseases for the institution, the region, and the nation.

As a national resource, we must anticipate the research needs of investigators over at least a 20-year period and "add value" to existing and planned facilities. To meet these needs, we will use flexible core facilities devoted to a comprehensive array of research methodologies. Together, these cores contribute to the entire product development continuum from basic science to clinical research.

The NEIDL includes facilities for:

- Basic research to identify mechanisms of pathogenesis and potential targets for new diagnostics, vaccines, biologicals, and therapeutics
- Translational research to identify molecules/reagents/leads that might be useful as diagnostics, immunogens, biologicals, or therapeutics
- Clinical studies involving human volunteers

We strongly emphasize the core facilities that are housed in high-containment areas since these resources are the most urgently needed and least available nationwide. The following are some of the NEIDL's research core facilities. More information on each of the cores is available at www.bu.edu/neidl.

## Aerobiology Core

A fully functional, productive infectious diseases aerobiology core is a critical lynchpin in any emerging infectious diseases research laboratory. Since many severe diseases are contracted through the respiratory route, we must develop and study models that mimic the natural transmission of these infections as well as novel drugs, treatments, or prophylactic measures that would be effective via aerosol.

The design of the NEIDL incorporates both BSL-3 and BSL-4 Aerobiology Core laboratories. This design maximizes the efficiency of research to be performed under high containment by minimizing downtime required for conversion of a single flexible laboratory module. Moreover, it allows for concomitant use of both high-containment laboratories, thereby more than doubling the total workflow in this core.

## Biomolecule Production Core

For NEIDL researchers, this core provides the necessary infrastructure for the expression and purification of biologic molecules including antigens, proteins, carbohydrates, nucleic acids, and other biologics from the Risk Group 3 and 4 agents. As in the Aerobiology Core, incorporating both BSL-3 and BSL-4 Biomolecule Production Core laboratories maximizes efficiency by reducing downtime and increasing workflow.

The Biomolecule Production Core at BSL-4 will have dedicated facilities and production capabilities to grow Risk Group 4 viruses and isolate biologic molecules of interest under BSL-4 containment. The scope of work for the BSL-4 facility will be strictly governed by the NIH Guidelines for Recombinant DNA Research and by City of Boston regulations.

## Cell and Tissue Imaging Core

Because new technologies allow high-resolution imaging of living cells and tissues that may be infected with viable microorganisms, the Cell and Tissue Imaging Core (CTIC) will be in BSL-4 containment. It will offer multiple state-of-the-art imaging systems to analyze specimens. As a result, fine-scale topography of fixed tissues gathered from transmission or scanning electron microscopy can be integrated with information gathered from multi-probe, live-cell analyses using deconvolution or laser confocal microscopy.

Existing facilities for electron and conventional microscopy of fixed, nonviable specimens are part of the research infrastructure at Boston University Medical Campus and will be available to NEIDL investigators.

### Clinical Research Core

The Clinical Research Core (CRC) design was based upon extensive experience with clinical research, including studies of the prevention and diagnosis of infectious diseases.

The fundamental goal of this core is to provide a dedicated location and trained staff for the network of researchers in the NEIDL, the Regional Centers of Excellence in Emerging Infectious Diseases, the Regional Biocontainment Laboratories, and the Galveston National Biocontainment Laboratory, as well as private entities doing sponsored research to fulfill the strategic plan of the National Institute of Allergy and Infectious Diseases.

The Clinical Research Core will not provide care for or research on patients with infectious diseases. It will enable investigators to conduct approved studies on normal human volunteers. We anticipate that researchers will conduct studies of vaccines (Phase 1), lot consistency, novel immunogen delivery systems by various routes, candidate vaccine stability, pharmacokinetics of novel therapeutics, delivery of therapeutics through alternative routes (e.g., respiratory, oral, mucosal, transdermal), and Phase 1 safety trials of biologicals (e.g., therapeutic antibodies).

## Extramural Investigator Research Collaboration Cores

As a National Biocontainment Laboratory, the NEIDL will give extramural investigators access to BSL-3 and BSL-4 high-containment laboratories as well as scientific and administrative cores. These investigators will come from both academic and commercial entities whose research has reached the stage where high containment is required. For example, *in vivo* challenge studies for determining vaccine and/or therapeutic development efficacy would be an appropriate phase for engaging the Collaborative Research Group Cores.

At least two Collaborative Research Group Cores will be established to host research from extramural investigators. These teams will be employed by the NEIDL and dedicated to the hands-on execution of all extramural research conducted here. Extramural investigators guiding the research may be either on-site for the duration of this work, directing work on a daily basis from their home institutions, or a combination of the two.

## Immunology Core

The Immunology Core will provide the infrastructure for characterizing innate and adaptive immune responses to infectious agents. It will also accommodate standardized testing of vaccine candidates, including biologics produced within the NEIDL's Biological Molecule Production Core.

Under most circumstances, the Immunology Core will concentrate on analysis of specimens obtained from animals challenged with agents requiring BSL-3 or BSL-4 containment. To allow investigators to monitor both *in vivo* and *in vitro* immune responses, the core will provide four essential services:

- Basic cell enumeration and separation for human and animal cells using magnetic separation, and cell subset identification by flow cytometry in high containment
- Elucidation of cytokine profiles of responding cells by flow cytometry, and cytokine production in serum and in culture by BioPlex analysis

- Antibody assays by ELISA or ELISPOT for enumerating antibody-producing cells and neutralizing antibodies using automated plaque and colony-counting assays
- Consultation services and help in developing other immunological assays as needed by investigators in the NEIDL.

### Core for the Study of Insect Vectors

Many of the most widely distributed infectious diseases are transmitted to humans by insects—mosquitoes, ticks, mites, lice, and biting flies, for example. Some of the most important emerging infectious diseases are examples of vector-borne diseases. These include dengue, West Nile virus, the encephalitis viruses such as eastern equine encephalitis, and bacteria such as *Francisella tularensis* and *Yersinia pestis.*

Arthropod Containment Levels 3 and 4 are required for research on many of these diseases. Critical research involving vector-borne pathogens includes:

- Natural infection studies with hemorrhagic fever viruses
- Vector competence experiments to determine which insects are capable of transmitting the microorganisms
- Testing of immune and non-immune mediated strategies to eliminate pathogens from vectors (so-called vector interruption strategies)

## Specimen Processing Core for BSL-4 Research Projects

The Specimen Processing Core and its associated laboratory equipment and capabilities will support NEIDL investigators in the study of emerging infectious diseases, including NIAID Category A, B, and C agents.

Coordination with the Animal Cores (including Pathology/Necropsy) will ensure that specimens are processed immediately following collection and transported to the laboratory quickly and safely. We will have the ability to flash-freeze the specimens and autoclave them or treat with gamma radiation prior to transportation out of the BSL-4 area.

This core will include the following laboratories and equipment:

- A microbiology laboratory equipped for classical non-molecular as well as state-of-the-art molecular diagnostics. This lab will complement the research and serve, if required, in the event of a national emergency.
- A molecular biology laboratory for identifying the presence of select agents in tissue, cell culture, or environmental specimens.
- A clinical chemistry laboratory using the Abaxis VetScan VS2 analyzer for routine analysis of samples obtained from control and experimental animals.
- A hematology laboratory using the Beckman Coulter ACT10 and HEMAVET 950FS for routine analysis of blood cells from control and experimental animals.

## Multimodal Whole Animal Imaging Core

The Multimodal Whole Animal Imaging Core will operate a unique animal imaging facility under BSL-4 containment in which the synergies of multiple imaging modalities will be available for discoveries about infectious diseases studied at the NEIDL. Elucidation of *in vivo* kinetics of organism pathogenesis, treatment response, and immune protection studies of agents, such as tuberculosis and the hemorrhagic fever viruses in whole animals, have been severely hampered by the lack of advanced whole animal imaging systems capable of routine operations in a BSL-4. This is particularly true for the assessment of pathogen-induced cellular and structural changes in larger animals, in which cross-sectional post mortem studies had to substitute for the more desirable longitudinal *in vivo* studies.

CLEAN STEAM
SOFT WATER
SOFT WATER

The primary objective of this core will be to circumvent technical challenges and utilize recent and anticipated innovations in multimodal imaging technologies, including a custom-designed, one-of-a-kind BSL-4 compatible 4.7 Tesla whole animal MRI scanner, fluorescence optical tomography, and X-ray computed tomography. In-house developed multimodal imaging software packages designed specifically for emerging infectious diseases' needs will facilitate further the quantitative and multimodal analyses of the data to gain insights into the pathogenesis and treatment of major infectious diseases that are public health concerns.

## Our work will be critical, comprehensive, and transparent.

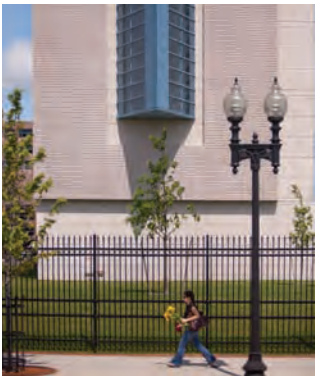
The NEIDL is dedicated to developing diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. To that end, we will study a wide range of NIAID Category A, B, and C agents, including the viruses that require BSL-4 containment:

- Central European tick-borne encephalitis
- Congo-Crimean hemorrhagic fever
- Ebola
- Guanarito
- Hendra
- Junin
- Kyasanur Forest disease
- Lassa
- Machupo
- Marburg
- Nipah
- Omsk hemorrhagic fever
- Russian spring-summer encephalitis
- Sabia

We will also study agents such as mycobacteria, tuberculosis, influenza viruses, West Nile virus, and others that require BSL-3 containment.

A wide variety of safeguards are in place to minimize risks and protect our researchers and the community. In addition to building design and construction, these include the recruitment of experienced researchers; the rigorous observance of standard operating procedures for safety, security, and operations; limited access to the NEIDL; and extensive security checks of persons and property. There will be collaborative training programs with city agencies and integration of our institutional protocols with Boston Medical Center clinicians. We will follow guidelines and regulations of the Boston Public Health Commission, the National Institutes of Health, and the Centers for Disease Control.

Beyond safety, we are committed to providing transparency in our work. Oversight by several committees ensures community access to information about our work and opportunities for open dialogue. The Institutional Biosafety Committee, which has oversight responsibility for all biosafety programs at Boston University and Boston



Medical Center, includes public representation. The Community Liaison Committee was created specifically to promote community outreach and feedback. The five-member NEIDL Institute Executive Committee also includes a public member-at-large as a key representative of public interests.

Furthermore, our External Scientific Advisory Committee, the Boston Public Health Commission, and the Massachusetts Department of Public Safety all provide important links between our activities and our community. Finally, the NEIDL is accountable to independent public health and safety officials in more than a dozen local, state, and federal agencies and organizations.

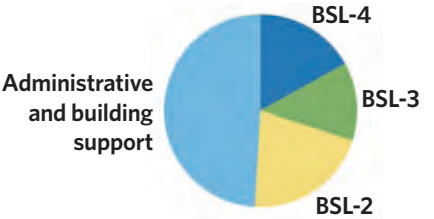
## Our facility meets the most stringent guidelines.

The NEIDL is a 192,000-square-foot, 7-story building, designed in accordance with the most stringent and protective measures defined by the National Institutes of Health. It was built on the experience of six existing BSL-4 facilities in North America, none of which has ever had a release or community incident.

Our facility provides BSL-2, -3 and -4 capacities. The containment areas include imaging, aerobiology, insectary, and other specialized cores and support areas. The building also offers a BSL-4 training simulator to provide hands-on training for all research staff.

The NEIDL is constructed to maximize research capacity.
Total building area includes:

- 16% BSL-4 research
- 13% BSL-3 research
- 20% BSL-2 research
- 3% BSL-2 clinic
- 48% Administrative and building support




All critical building systems within the NEIDL have a redundant system to ensure safety and uninterrupted operations at all containment levels. Operating procedures will be based on best practices and government standards (CDC/NIH).

For more information about the NEIDL facilities, work, researchers, and safety systems, please visit www.bu.edu/neidl.


SUIT ROOM
MICROSCOPY PREP

**The Boston University National Emerging Infectious Diseases Laboratories (NEIDL)**

**www.bu.edu/neidl**



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# About

## Mission and Safety


John R. Murphy, PhD, Director ad interim, and Tom Robbins, Executive Director of Public Safety, discuss the NEIDL's mission, commitment to community safety, and lab security features. Director of Research Safety Ron Morales explains biosafety training and procedures.

The National Emerging Infectious Diseases Laboratories (NEIDL) is part of a national network of secure facilities studying infectious diseases that are—or have the potential to become—major public health concerns. The laboratories are dedicated to the development of diagnostics, vaccines, and treatments to combat emerging and re-emerging infectious diseases. In addition to BSL-2 and BSL-3 laboratories, the NEIDL houses a BSL-4 laboratory. The NEIDL adds to the growing life sciences industry in the region, throughout the Commonwealth of Massachusetts, and across the country.

The NEIDL uses state-of-the-art technologies designed to conduct research in safe and secure environments. In fact, the facility was designed and constructed with the highest attention to community and laboratory safety and security. The laboratories emphasize comprehensive core research facilities that enable basic, translational, and clinical research and the development of products related to emerging infectious diseases. Core support laboratories containing sophisticated facilities—including high-power microscopes, Magnetic Resonance Imaging (MRI) machines, and diagnostic tools to study new vaccines and drugs—are housed at the NEIDL.

The NEIDL represents a major step forward in advancing public health and solidifying the New England area's reputation as the biomedical research hub of the nation. Supported by all local research institutions, the 192,000-square-foot, seven-story building serves as a venue and resource for training researchers in infectious diseases. The facility is located within BioSquare, a biomedical research and business park adjacent to the Boston University Medical Campus.

- Read more about the background and planning for the NEIDL.

Our Mission
Video: Virtual Tours
Fact Sheet
Design & Construction
Background & Planning
Contact Us

### NIH Final Supplementary Risk Assessment

Download the Final Supplementary Risk Assessment (Requires NIH registration)

### News & Events

**Public Meeting**
September 4, 2012
Public Meeting Pursuant to Section 2.03 of the Boston Public Health Commission's Biological...

**Public Comment Period Extended by NIH Blue Ribbon Panel**
July 24, 2012
In order to provide the public with additional time to review and...

**NEIDL Website Puts Research on Display**
July 23, 2012
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# Research Information

**Core facilities that contribute to the availability of emerging infectious diseases research for the institution, the region, and the nation**

As a national resource, we must anticipate the research needs of investigators, over at least a 20-year period, and "add value" to existing and planned facilities. To meet these needs, we will use flexible core facilities devoted to a comprehensive array of research methodologies. Together, these cores contribute to the entire product development continuum, from basic science to clinical research.

For more information on the NEIDL, please download a copy of the NEIDL brochure or click here for an introduction to the research cores.

**The NEIDL is one part of a national network of secure facilities that study infectious diseases.**

Other laboratories, such as the newly opened Integrated Research Facility at Rocky Mountain Laboratories (RML) in Hamilton, Montana, also play a key role in the national effort to study, diagnose, treat, and ultimately prevent the spread of emerging and re-emerging infectious diseases.

We invite you to take a video tour of the Rocky Mountain Laboratories facilities in Hamilton, Montana, courtesy of Rocky Mountain Laboratories.

Introduction to Research Cores
NEIDL Researchers
Video: BSL-2 Researchers
University Research Partners
Statement on Classified Research

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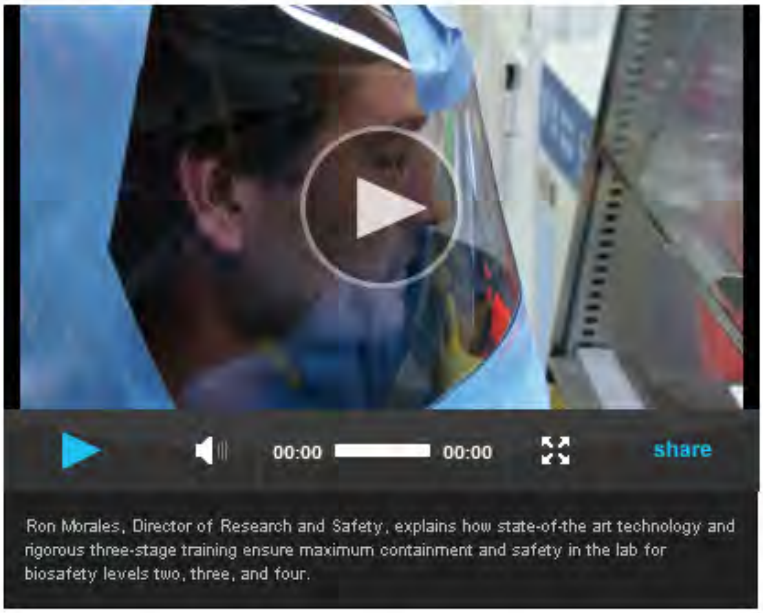
# Safety




Ron Morales, Director of Research and Safety, explains how state-of-the art technology and rigorous three-stage training ensure maximum containment and safety in the lab for biosafety levels two, three, and four.

A wide variety of safeguards are in place to minimize risks and protect our researchers and the community. In addition to building design and construction, these include:

- The recruitment of experienced researchers
- The rigorous observance of standard operating procedures for safety, security, and operations
- Limited access to the NEIDL
- Extensive security checks of persons and property

The NEIDL offers collaborative training programs with city agencies and integration of our institutional protocols with Boston Medical Center clinicians. We follow guidelines and regulations of the Boston Public Health Commission, the National Institutes of Health, and the Centers for Disease Control.

Beyond safety, we are committed to providing transparency in our work. Oversight by several committees ensures community access to information about our work and opportunities for open dialogue. The Institutional Biosafety Committee, which has oversight responsibility for all biosafety programs at Boston University and Boston Medical Center, includes public representation. The Community Liaison Committee was created specifically to promote community outreach and feedback. The NEIDL Executive Committee also includes a public member-at-large to represent public interests.

Furthermore, our External Scientific Advisory Committee, the Boston Public Health Commission, and the Massachusetts Department of Public Safety all provide important links between our activities and our community. Finally, the NEIDL is accountable to independent public health and safety officials in more than a dozen local, state, and federal agencies and organizations.

**Related:**

- Read biological agent specific information from the University's Office of Research Compliance.

Research Compliance
Institutional Biosafety Committee
Education & Training
Safety Plans
External Scientific Advisory Committee
Public Health & Safety Partners
Video: State-of-the-Art Security

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# Community Engagement

The South End neighborhood is rich in both history and culture. Its residents are highly diverse in terms of race, ethnicity, and household income. The National Emerging Infectious Diseases Laboratories is located in BioSquare—the City of Boston's only biomedical research park—adjacent to Boston University's Medical Campus (BUMC), in the southeast portion of the South End neighborhood.

The involvement of the community is important to the success of the NEIDL. BUMC has participated in numerous meetings, with different groups, neighborhoods, businesses, industries, and organizations, in order to educate the community, solicit feedback, and address concerns about the laboratories. In direct response to the input received during outreach meetings and discussions, BUMC worked to expand access to information about the laboratory as well as facilitate open dialogue and meaningful exchange through the creation of the Community Liaison Committee.

## Community Events Calendar

| Date | Topic |
|---|---|
| 4/17/12 | CLC Meeting |
| 4/19/12 | NIH Meeting |
| 5/22/12 | CLC meeting |
| 6/19/12 | CLC Meeting |
| 7/17/12 | CLC Meeting |
| 9/18/12 | CLC Meeting |
| 10/16/12 | CLC Meeting |
| 11/20/12 | CLC Meeting |
| 12/18/12 | CLC Meeting |
| 1/15/13 | CLC Meeting |

Community Liaison Committee
Institutional Biosafety Committee
Executive Committee
Employment
BioScience Academy

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# Resources

This section contains a listing of resources and information on biosafety. These are suggested references only. Inclusion on this list does not convey recommendation or endorsement by the National Emerging Infectious Diseases Laboratories.

Although the NEIDL makes frequent efforts to revise, update, and improve these selections, we assume no liability for the accuracy, completeness, or usefulness of the resources included here.

- Biosafety in Microbiological and Biomedical Laboratories Safety (PDF)
- BioScience Academy
- BioSquare
- Boston Medical Center
- Boston Public Health Commission
- Boston Redevelopment Authority Report: Boston as a Leader In NIH Awards
- Boston University
- Boston University Medical Campus
- Centers for Disease Control and Prevention
- Draft Supplementary Risk Assessment (90%)
- Draft Supplementary Risk Assessment Reader's Guide
- Executive Office of Public Safety and Security, MA
- Final Environmental Impact Statement, NIH
- National Institute of Allergy and Infectious Diseases
- National Institute of Allergy and Infectious Diseases: The Need for Biosafety Facilities
- National Institutes of Health
- NIH Blue Ribbon Panel
- National Research Council Report: Continuing Assistance to the NIH on Preparation of Additional Risk Assessments for the BU NEIDL, Phase 2
- NRC Report: Continuing Assistance to the NIH on Preparation of Additional Risk Assessments for the BU NEIDL, Phase 3

Frequently Asked Questions

Library Repositories

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# All News

## Public Meeting

September 4th, 2012 in *events*, *featured*

Public Meeting Pursuant to Section 2.03 of the Boston Public Health Commission's Biological Laboratory Regulation, the Institutional Biosafety Committee (IBC) of Boston University will hold its annual public meeting on September 25, 2012 from 2:30 p.m. – 4:00 p.m. at BMC Newton Pavilion, 88 East Newton Street, 2nd Floor, Conference Room... *more*

## Public Comment Period Extended by NIH Blue Ribbon Panel

July 24th, 2012 in *featured*, *lab updates*

In order to provide the public with additional time to review and comment on the final supplementary risk assessment, the National Institutes of Health (NIH) has decided to extend the public comment period for the final supplementary risk assessment until August 24, 2012. A notice of this extension was... *more*

## NEIDL Website Puts Research on Display

July 23rd, 2012 in *featured*, *in the news*

BU Today 7/23/12 by: Leslie Friday Long a source of apprehension for some neighbors and community activists, the National Emerging Infectious Diseases Laboratories (NEIDL) on the Boston University Medical Campus is working hard to become an open book: the research facility has launched a new website where visitors can read about its research... *more*

## BU biolab shoots for transparency with revamped website, community concerns remain

July 23rd, 2012 in *in the news*

The Daily Free Press July 23, 2012 By Chris Lisinski Although the Boston University National Emerging Infectious Diseases Laboratories' revamped website provides research information to increase transparency, community members said they still have unaddressed concerns about the lab's risks. "We felt it was important to let people know what was going on inside the lab,"... *more*

## NEIDL Website Puts Research on Display

July 23rd, 2012 in *in the news*

BU Today 07.23.2012 By Leslie Friday Long a source of apprehension for some neighbors and community activists, the National Emerging Infectious Diseases Laboratories (NEIDL) on the Boston University Medical Campus is working hard to become an open book: the research facility has launched a new website where visitors can read about its research... *more*

## Federal Register Notice

July 9th, 2012 in *featured*, *in the news*

Federal Register Notice - July 6, 2012 EIS No. 20050514, Final EIS, NIH, ME, National Emerging Infectious Diseases Laboratories, Construction of National Biocontainment

In The News
Press Releases
Lab Updates

### NIH Final Supplementary Risk Assessment

Download the Final Supplementary Risk Assessment (Requires NIH registration)

### News & Events

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### Translate This Page

Select Language

# Meeting Minutes

**Location: E720**

**August 14, 2012**

**Start time: 12:00PM**

**End time: 2:30 PM**

**Present: A. Henderson, R. Morales, T. Winters, D. Stearns-Kurosawa, N. Broude, S. Ghosh, J. Gonsalves, G. Bain, K. Bossart, J. Levin, B. Slack, E. Helmerhorst, C. Sulis, N. Bhadelia, R. Ingalls**

**Absent: K. Kirsch, K. Tuohey, E. Muhlberger, F. Gibson, J. Keeney, J. Barton**

**Staff: W. He, M. Hatton, K. Mellouk**

**Guest: S. Butler, A. Hartnett, S. Reno, Y. Petrofsky**

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## I. Review of July Minutes

Recommendation: Approved

For: 15

Against: 0

Abstained: 0

## II. New Business

### A. IBC Training Session: Vector Transmitted Infectious Disease Core

The director of the NEIDL Vector Core gave a presentation on the scientific aspects of research involving vector transmitted infectious disease.

### B. Chairperson Report

#### 1. Report on Viral Vectors policy

At the last IBC meeting, it was proposed to develop a formal policy to document and standardize the biosafety requirements for handling different viral vectors, such as AAV-based or replication incompetent lentiviral-based vectors, including those used in

animals. An ad-hoc group met to work on this issue, and the formal policy will be circulated to the IBC for review once complete.

## C. Technical Committees Report

### 1. Downgrade of HIV labs from BSL3 to BLS2+

OSHA and the CDC dictate the requirements for safe conduct of HIV research and mandate BSL-2 with special practices for most work, with BSL-3 requirements for research involving high titers. Due to the low-titer nature of the work in 2 of the HIV labs, the PIs and department chair have been involved, in conjunction with EHS and BPHC, in downgrading the facility from BSL-3 to BSL-2+; there has been no change in the protocols or practices, but this is simply a room downgrade (as newer BSL-3 facility requirements for recertification would require an HVAC upgrade). Any changes to the work in these labs would still be submitted to the IBC for evaluation. The IBC Vice Chair will be involved in reviewing these room-downgrade amendments for approval. It was suggested that the HIV labs at BU define a consensus for meaningful use of the term high-titer.

### 2. Approved Applications/Amendments:

***a) This month 9 applications and 22 amendments and renewals were approved.***

### 3. IBC Public Meeting:

The IBC public meeting will take place next month. A poll has been distributed, and IBC members should respond to determine the optimal meeting date/time.

## D. Biosafety Report:

### 1. Incidents Biosafety Report

There was a recent inspection by the CDC for recertification for select agents. A response was sent to address the CDC report, and they were satisfied with the responses given. Research Safety continues to work with the select agent researchers, especially those with the newly approved protocol.

# III. Protocol Review:

**Meeting is not closed**

## A. New Submissions

### 1. Protocol 1652

"Enterovirus 71 Models and Countermeasures"
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: 2
Brief Project Description: Hand-foot-and-mouth disease is a common illness of children. Although most children only develop mild disease following infection, in some cases, severe disease manifests with long-term consequences in the brain. The goal of our project is to evaluate a new potential vaccine for hand-foot-and-mouth disease in hopes of finding a way to prevent severe disease in children.
Reviewer Comments:
-This is a nicely detailed protocol, and they have addressed the initial concerns regarding how the cells are lysed, as this is a closed system, and clarified that ethanol is not used for enterovirus waste.
- As this is a novel agent for BU, it was mentioned that this should be evaluated for possible inclusion on the List of Agents with Potential to cause LAI. The standing subgroup committee will evaluate this for inclusion on the agent cards, and this is not an obstacle for IBC approval.
The PI needs to:
- Add sentence regarding safe handling practices for the bead beater system.
- Add sentence regarding training for LASC staff that may be in contact with animals infected with this biohazardous agent.

Recommendation: Approve Pending
For: 14
Against: 0
Abstain: 1

### 2. Protocol 1643

"Mechanisms of Autoimmune Disease."
Category: rDNA/ Bhz
Biosafety Level: 2
Animal Biosafety Level: 1
Brief Project Description: Our studies evaluate ways to interfere with T cells causing autoimmune diseases with an emphasis on type 1 diabetes. We study pathways and molecules that are important for the generation, function and survival of T cells that destroy the insulin-producing cells in the pancreas. These insights are then used to test whether blocking these novel pathways (for example with antibodies) in diabetic mice leads to therapeutic benefit. These studies will further our understanding of the mechanisms of autoimmune diseases and may result in the development of innovative therapies.

Reviewer Comments:
-This PI addressed many initial issues, and only a few minor issues remain. The PI needs to:
-On the "Materials Used in Research" page, uncheck "Synthetically derived nucleic acids".
-On the "Hazardous Biological Agents" page, where describing the live animal use of the murine retroviral vector, indicate the Animal Biosafety Levels as ABSL-1.
-On the "Public Health Commission" page, change "BSL-1" to "BSL-2".

Recommendation: Approve Pending
For: 15
Against: 0
Abstain: 0

**3. Protocol: 1645**

"Vitamin D and the innate immune responses to group A Streptococcus infection"
Category: rDNA/Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Brief Project Description: Group A Streptoccous (GAS) causes pharyngitis ("Strep throat") as well as more serious infections, like necrotizing fasciitis ("flesh-eating bacteria"). Healthy people may carry this bacterium in their throats, without any signs or symptoms of illness. My work proposes to examine how two types of cells in the throat sense and respond to this microbe, thereby offering insights into how these protections may fail to lead to true Strep infections.
Reviewer Comments:
-It was noted that the PI plans to conduct several experiments on an open bench in a shared lab space, and this agent has a history of LAI. There was a consensus for containment or additional practices to address this. In addition the reviewers, the IBC chair should review the PI's revision to address this point.
The PI needs to:
-In recognition of the proposed agent and the shared lab space, it is required that proper precautions are used for benchwork (including capping when vortexing) and a Biological Safety Cabinet is utilized for GAS and human cell experiments for aerosol protection. Describe this in the protocol. If a BSC absolutely cannot be used, describe the additional aerosol protection measures or practices that will be utilized.
-On the "Public Health Commission" page, answer the Host-Vector-Donor system question to include the same information entered on the Recombinant DNA page in terms of both Prokaryotic and Eukaryotic experiments.

Recommendation: Conditionally Approved
For: 15
Against: 0

Abstain: 0

4. **Protocol VA 003**

"Role of Th17 Pathway in Solid Tumors"
Category: rDNA/ Bhz
Biosafety Level: 2
Animal Biosafety Level: 1
Brief Project Description: We are studying a molecule that carries signals between cells (called CCL20) and the receptor for this molecule (called CCR6). These molecules are important for inflammation. We want to know if these molecules are involved in colorectal cancer. We want to ask this question by raising or lowering the amount of CCR6 or CCL20 in tumor cells. We will then see how fast these cells grow in mice. We will raise or lower the amount of CCR6 and CCL20 in cells using viruses. The viruses insert DNA into the cells that control the level of these molecules. These viruses do not cause disease in people. These viruses can be bought. They will be stored in locked laboratory space in locked freezers. The viruses will be given to cells in a hood, so people working with the viruses are not exposed. The viruses cannot make new viruses. We will then test the cells to see if the level of the molecules has been raised or lowered. When we have cells with the molecules raised or lowered, we will grow these cells. These cells will have the virus DNA but will not be able to infect other cells, animals or humans. The cells will be transported to the animal facility in leakproof and shatterproof containers. The cells will then be injected into mice. The mice will be injected and housed in a special facility so other people are not exposed to the animals or cells.
Reviewer Comments:
-The animal work in this protocol can be done at ABSL-1. They should include more information on the experiments investigating tumor growth in animals, and the Lay description should be reduced. Additional comments were noted by EHS during safety review.
The PI needs to:
- Provide more details on the lentiviral vectors, including vector names.
- Provide updated annual lab safety training for the PI, who was last trained 7/18/2011.
-Provide the name of the actual commercial sources for the lentivirus, where indicating "commercially available lentivirus".
-Correct language to indicate transductions, not transfections.
-Add 1-2 sentences to describe investigation of tumor growth in animals.
-Include the source of the viral vectors.
-Rewrite the lay terms description to be much shorter.
- Indicate the highest BSL as BSL-2/ABSL-1 (as only injecting stably transduced mouse cells into animals).
-Complete the Host-Vector-Donor system question (on BPHC form).
-Correct the BSL on BPHC form as BSL-2/ABSL-1.

Recommendation: Approved Pending
For: 15
Against: 0

Abstain: 0

**5. Protocol 1655**

"Abnormal Lysyl Oxidase Activity a Potential Therapeutic Target for Treatment of Diabetic Retinopathy"
Category: rDNA
Biosafety Level: 1
Animal Biosafety Level: ABSL-1
Brief Project Description: Diabetes can lead to several complications. A serious eye complication is known as diabetic retinopathy. In early stages of diabetic retinopathy, the retina slowly becomes dysfunctional because a serious abnormality related to retinal capillary function develops and this leads to blindness. In this project, we will attempt to prevent vision loss by normalizing disrupted retinal capillary function.
Reviewer Comments:
-There were still many things missing in the application, including a description of procedures used to evaluate research goals and more information on the animal work including any details on rDNA work. The Host-Vector-Donor information needs to be added to the BPHC form. It was noted as a BSL-1/ABSL-1 rDNA protocol, and there were additional minor notes from EHS, including removal of term "biohazards".
The PI needs to:
-Add to description of procedures used to evaluate research goals.
-Add to description of animal work, including any details on rDNA.
-Add the H-V-D to the BPHC form.
-Correct protocol as BSL-1/ABSL-1.
-Remove use of term "biohazards", as none are used in this protocol.

Recommendation: Conditionally Approved
For: 15
Against: 0
Abstain: 0

**6. Protocol 1640**

"Development of Novel Mycobacterium tuberculosis and Vibrio cholera; Therapeutics Using Systems Biology and Engineering Principles."
Category: Bhz
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Brief Project Description: The goal of this research project is to determine the biological responses of bacteria to treatment with antibiotics intended to stop cell growth, or to kill cells. Antibiotics are thought to achieve their effect on bacteria simply by interaction between the antibiotic molecule and its specific target in the bacterial cell, leading to cell death. As a result of our work, we intend to show that the ways in which a bacterial cell responds to the stress of an antibiotic actually plays a role in the ability of the antibiotic

to kill the bacteria. We expect that our work will highlight potential new targets for antibiotic design and lead to new therapies to fight infection.
Reviewer Comments:
-In addition to some minor points, such as adding the PI to the protocol, amending the start date, and stating exactly how waste is disposed of, there were some more in depth questions regarding the lack of precise details of experiments, lack of BSC use, and need for more specific agent training. Why is BSC not used, even if space is "isolated"?
The PI needs to:
-Add the P) to the list of personnel and answer the subsequent questions on training and experience.
-Provide additional detail on experiments to describe steps between harvesting of cultures and the rDNA work, including description of practices such as capping tubes to prevent spills and aerosol generation.
-Note that the work with these agents should be conducted in a Biological Safety Cabinet, particularly as Vibrio cholerae is a reportable infectious disease agent. Provide additional information on work in a BSC.
-Specify the agent-specific training that lab researchers will receive for work with these biohazardous agents.

Recommendation: Conditionally Approved
For: 15
Against: 0
Abstain: 0

**7. Protocol 1649**

"Receptor Trafficking in Health and Disease."
Category: rDNA/Bhz
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Brief Project Description: Changes in receptor protein sorting drive changes in cell behavior and function that can directly contribute to the development of diseases such as cancer and Alzheimer's disease. Yet, the molecular mechanisms controlling receptor sorting are far from understood. Our research is aimed at defining the sorting machinery at a molecular level and to understand how alterations in receptor sorting cause disease.
Reviewer Comments:
This protocol was initially well written, and the PI was completely responsive on all concerns prior to the meeting.

Recommendation: Approved
For: 15
Against: 0
Abstain: 0

## B. 3-year Resubmissions

### 8. Protocol 1019

"Cell movement during Xenopus development: a model for metastasis. The RHO GTPases in the control of cell movement. Apoptosis regulates notochord development."
Category: Bhz
Biosafety Level: 1
Animal Biosafety Level: 1
Brief Project Description: Our goal is to understand how specific molecules influence the development of embryos. To do this work, we use frog embryos because they are laid and fertilized outside of the mother, making them accessible during all stages of embryonic development, and most importantly because they share many developmental processes with other organisms including humans.
Reviewer Comments:
-It was noted that this protocol is BSL-1, and most issues were addressed, but a few minor points remain (such as personnel and sharps).
The PI needs to:
- Answer "State how many years of experience, when and where" for all personnel.

Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

### 9. Protocol 1035

"Relevance of transcription factor LSF to metastatic melanoma: initiation of translational studies; LSF: Roles in cell cycle progression, tumor growth and chemoresistance; Role of transcription factor LSF in cellular quiescence"
Category: rDNA/Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Brief Project Description: We are studying a pathway that is essential for cell growth and division. Recent findings indicate that this pathway can contribute to the progression of cancer. The present proposal seeks to understand the underlying basis for how this pathway controls cell growth. One goal is to determine whether or not this pathway is functioning correctly in certain types of human cancer, and whether it contributes to cancer progression. A second goal is to develop medical drugs that can inhibit the pathway. In the long term, findings from this research may allow doctors to distinguish among different types of tumors of a certain type, which will allow for the most appropriate treatment for each cancer patient.
Reviewer Comments:
-The application is missing a description of the assays and endpoints for the various lines. More details on the vectors, such as whether they are commercially available, is needed, and the BPHC must match the protocol.

The PI needs to:
-Include more details and description of the assays and endpoints for the various cell systems.
-Include a description of the viral vectors to include information on the vector backbone/components and the evidence from commercial or collaborator sources that these are replication incompetent.
-For all agents, provide specific names where indicate “source” companies or collaborators.
-Make the title on the BPHC form match the overall protocol title.

Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

**10. Protocol 874**

“Role of actin cytoskeleton regulator in neurodegeneration and neurodevelopment”
Category: rDNA/Bhz
Biosafety Level: 2
Animal Biosafety Level: 2
Brief Project Description: During the progression of Alzheimer's Disease (AD), human neurons show degenerative as well as regenerative changes, possibly influenced by certain genes. We hypothesize that the expression of these genes will correlate with the cognitive status of the examined subjects. The increased expression of these genes may alleviate abnormalities in mice carrying human genetic risk factor for late-onset AD. The proposed study aims to identify molecules that may promote neuronal regenerative potential in late-onset AD.
Reviewer Comments:
-The application needs more clarity with regards to procedures involving biohazards and precautions for human brain tissue use, including clarity of the nature of animal experiments. The samples are not fixed, so precautions for cryostat use should be included. The training and experience details are lacking
The PI needs to:
-Answer the questions regarding "role", lab safety training dates, "State how many years experience, when and where", and who is training for all personnel.
-Update the lab inspection dates for 3 rooms listed, as discussed with EHS, and other location details.
-Expand on the description of work with brain tissue. Include a sentence regarding the practices and precautions for handling this biohazard. Specifically indicate whether samples are fixed, and refer to the EHS SOP on safe cryostat use, stating that cut-resistant gloves are used when changing cryostat blades. Include the IRB approval number and expiration covering this work.

-Simplify the Layman's Terms to be less technical.
-Uncheck "Hazardous Biological Agents".

Recommendation: Conditionally Approved
For: 15
Against: 0
Abstain: 0

**11. Protocol 1043**

"Mechanisms of Oxidant Signaling in Post-MI Remodeling; Oxidative Stress in Myocardial Remodeling and Failure; Reactive Oxygen Species in Patients with Heart Failure"
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Brief Project Description: The project is to identify molecules in the blood that can be used as biological markers in heart failure patients. We predict that some of these markers may be used to assist diagnosis and treatment and improve prognosis.
Reviewer Comments:
-After a revision received this morning, the PI has addressed all application concerns. There are remaining individuals who need ROHP and LST.
The PI needs to:
-Have all lab members complete ROHP clearance and LST.

Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

# IV. Amendments

## A. Amendments for Committee Review:

**1. Protocol 894**

"1. Glycobiology of Giardia. 2. Beta-1,3-glucan and acid-fast lipids of oocyst walls. 3. Glycosylation and Glycosidases - Cell & Molecular Biology"
Category: rDNA/Bhz
Biosafety Level: 2
Animal Biosafety Level: 2

Brief Amendment Description: Add experiments that are also part of three IACUC protocols under review. With Toxoplasma, we plan to collect oocysts in stool of infected animals; grow exotic strains of Toxoplasma and infect animals; in the future, knock-out genes in conventional strains of Toxoplasma and then infect animals. With Eimeria we plan to vaccinate animals with recombinant oocyst wall proteins.
Reviewer Comments:
-There was a discussion of the Toxoplasma strains, including the exotic, which are not infectious to humans. The animal experiments involve handling precautions comparable to the lab setting. For infection of cats, there is possibility of creating infectious potential, but there is a 2 week window of non-infectious state, and this animals will only be used through 6-11 days.
The PI needs to:
- LASC staff potentially handling animals on this protocol must be trained in proper safe handling SOP for Toxoplasma gondii.

Recommendation: Approved
For: 15
Against: 0
Abstain: 0

## B. Approved Expedited Amendments:

### 1. Protocol 685

"Growth of laboratory adapted, vaccine and wild-type canine distemper virus and marine morbilliviruses and generation of recombinant laboratory-adapted, vaccine and wild-type canine distemper and marine morbilliviruses"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only) and agents

### 2. Protocol 1216

"Generation of mini-genomic cDNA clones of Crimean-Congo Hemorrhagic Fever Virus"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

### 3. Protocol 1454

"Growth of laboratory adapted and wild-type respiratory syncytial viruses and human metapneumoviruses and generation of recombinant laboratory-adapted and wild-type respiratory syncytial viruses and human metapneumoviruses"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

4. **Protocol 1453**
   "Use of vesicular stomatitis virus (VSV) as a vector for expression of foreign proteins and to generate viral pseudotype particles displaying foreign viral surface glycoproteins"
   Biosafety Level: BSL-2, N/A
   Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

5. **Protocol 729**
   "Generation of mini- and full-length genomic cDNA clones of Mapuera Virus."
   Biosafety Level: BSL-2, N/A
   Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

6. **Protocol 650**
   "Growth of laboratory adapted, vaccine and wild-type measles viruses and generation of recombinant laboratory-adapted, vaccine and wild-type measles viruses"
   Biosafety Level: BSL-2, N/A
   Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

7. **Protocol 1652**
   "Enterovirus 71 Models and Countermeasures"
   Biosafety Level: BSL-2, ABSL-2
   Expedited Change: Addition of lab space (NEIDL BSL 2 only)

8. **Protocol 540**
   "Dengue virus infection of African green monkeys; Flavivirus infection of rhesus macaques"
   Biosafety Level: BSL-2, ABSL-2
   Expedited Change: Addition of lab space (NEIDL BSL 2 only)

9. **Protocol 1409**
   "Replication and Transcription of Filoviruses; Early Host Immune Response in Protection against Filovirus Infection"
   Biosafety Level: BSL-2, N/A
   Expedited Change: Addition of lab space (NEIDL BSL 2 only)

10. **Protocol 678**
    "Regulation of HIV by T-Cell Signal Transduction; Regulation of HIV Transcriptional Elongation; Redox Regulation of HIV Transcription"
    Biosafety Level: BSL-2+, N/A
    Expedited Change: Downgrade of lab from BSL3 to BSL2+

11. **Protocol 1630**
    "HIV-1 transmission pathogenesis"
    Biosafety Level: BSL2+, N/A

Expedited Change: Downgrade of lab from BSL3 to BSL2+

12. **Protocol 618**
"A system biology approach to tuberculosis-Gene regulation in Mycobacterium tuberculosis"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of teaching project

13. **Protocol 1215**
"Growth of laboratory adapted, vaccine and wild-type mumps viruses and generation of recombinant laboratory-adapted, vaccine and wild-type mumps viruses"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition/removal of personnel, addition of lab space (NEIDL BSL 2 only)

14. **Protocol 1231**
"1- Infection-elicited oral bone loss: TLR2, ontogeny, and Porphromonas gingivalis; 2- Innate immunity, lipid signaling and chronic infection; 3- Interferon regulatory factors and periodontal disease; 4- Interactions of Porphyromonas gingivalis with adipocytes: pathogen-specific modeling of blood microbiome and inflammatory change in obesity"
Biosafety Level: BSL-2, ABSL-2
Expedited Change: Addition of personnel

15. **Protocol 824**
"Characterization of human hematopoietic and endodermal progenitors derived from iPS cells free of reprogramming transgenes; Determinants of Cell Fate and Differentiation in the Developing Lung; Hemangioblast Transplantation for Reconstitution of Lung Endothelium; Stem cell Reconstitution of the Lung Alveolus"
Biosafety Level: BSL-2, ABSL-2
Expedited Change: Addition of cell line and grant

16. **Protocol 1470**
"Mechanisms of metastatic melanoma phenotype development"
Biosafety Level: BSL-2, ABSL-2
Expedited Change: Addition of agent

17. **Protocol 756**
"The role of pheomelanin in melanoma development"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of agent

# V. Annual Renewals

## A. Annual Renewal of Protocols with Minor Changes

### 1. Protocol 615

"The use of non-transformed human colonic epithelial cells (NCM460) to investigate neurokinin 1 receptor signaling pathways"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of personnel, human cells, location

### 2. Protocol 887

"New vaccines to protect against hemorrhagic fever viruses"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of lab space.

### 3. Protocol 1260

"DEFINING THE ROLE OF POLARITY COMPLEXES IN THE HIPPO TUMOR SUPPRESSOR PATHWAY"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of funding source and personnel

### 4. Protocol 1203

"1) Anti-inflammatory regulation of beta-amyloidosis,; 2) In Vivo Reconstitution Models of Beta-Amyloidosis and NeuroAIDS; 3) Creation of TTBK-1 and TTBK-2 Conditional Knockout Mouse Strains; 4) Invention and Clinical Application of Protein Kinase Inhibitors"
Biosafety Level: BSL-2, ABSL-1
Expedited Change: Addition of personnel

### 5. Protocol 616

"Regulation of Cytokines"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of funding and personnel

### 6. Protocol

"MRNA EXPRESSION AND PATHOLOGY IN SCLERODERMA LUNG AND SKIN; FIBROBLAST AND IMMUNE CELL CULTURE FROM SKIN; IDENTIFICATION OF BIOMARKERS IN SKIN FOR DISEASE ACTIVITY AND PROGRESSION IN SCLERODERMA; BIOMARKER ASSAYS OF SCLERODERMA SKIN"
Biosafety Level: BSL-2, N/A
Expedited Change: Change in personnel

### 7. Protocol 1285

"Insulin regulation of cell nutrition; Secretion from adipose cells; Regulation of lipolysis"
Biosafety Level: BSL-2, N/A
Expedited Change: Change in personnel

8. **Protocol 1023**
"Tumor suppressor gene functions in development and cancer"
Biosafety Level: BSL-2, ABSL-1
Expedited Change: Addition of person and material

9. **Protocol 604**
"Transcranial Magnetic Stimulation in Major Depression with EEG and NIRS Monitoring"
Biosafety Level: BSL-2, N/A
Expedited Change: Change in personnel

10. **Protocol 1103**
"Hemodialysis Fistula Maturation Consortium Study"
Biosafety Level: BSL-2, N/A
Expedited Change: Change in personnel

11. **Protocol 896**
"Environmental PPAR Agonists Accelerate Aging of Bone and Impair Lymphopoiesis"
Biosafety Level: BSL-2, N/A
Expedited Change: Addition of personnel, location and material

## B. Annual Renewal of Protocols with no Proposed Changes

12. **Protocol 1007**
"Mitochondrial dynamics in beta cell function and dysfunction Metabolic Signal Transduction in Adipocytes"
Biosafety Level: BSL-2, N/A

13. **Protocol 1340**
"Neuromodulation and Cortical Memory Function"
Biosafety Level: BSL-2, N/A

14. **Protocol 877**
"Functional Studies of Granulocyte Membranes"
Biosafety Level: BSL-2, N/A

15. **Protocol 1503**
"Iodine Content of Vegans and Vegetarian Diets"
Biosafety Level: BSL-2, N/A

16. **Protocol 525**
"Isolation of DNA and RNA from cells, tissues, blood and saliva samples."
Biosafety Level: BSL-2, N/A

17. **Protocol**
"1- Infection-elicited oral bone loss: TLR2, ontogeny, and Porphromonas gingivalis; 2- Innate immunity, lipid signaling and chronic infection; 3- Interferon

regulatory factors and periodontal disease; 4- Interactions of Porphyromonas gingivalis with adipocytes: pathogen-specific modeling of blood microbiome and inflammatory change in obesity"
Biosafety Level: BSL-2, ABSL-2

18. **Protocol 1314**
"Cellular Imaging Core"
Biosafety Level: BSL-2, N/A

19. **Protocol 848**
"Molecular analysis of BRD2 signaling and B cell function; Biomarkers for lymphoma in a new transgenic mouse model; A novel, inducible nuclear kinase linked to leukemia; BRD2 signaling and B cell proliferation; B cell proliferation regulated through BRD2 signaling; Mechanisms of Brd2 immunoprotection from insulin resistance"
Biosafety Level: BSL-2, ABSL-1

20. **Protocol 1403**
"Interaction of vitamin D and fish oil on the prevention and treatment of prostate cancer"
Biosafety Level: BSL-2, N/A

21. **Protocol 698**
"1. Genetic determinants of hypertension susceptibility in humans; 2. Role of AVR, ADM and ANPEP in human essential hypertension; 3. Analysis of human tumor xenograft models"
Biosafety Level: BSL-2, N/A

22. **Protocol 598**
"Growth Factors and Gingival Fibrosis; The Lysyl Oxidase Propeptide and Bone Metastasis; Lysyl oxidase Isoforms in Oral Cancer; Inhibited Intramembranous Bone Healing in Diabetes; Lysyl Oxidase Propeptide: Breast Cancer Inhibitor"
Biosafety Level: BSL-2, N/A

23. **Protocol 1377**
"Biomarkers of early kidney damage among adolescents in Nicaragua"
Biosafety Level: BSL-2, N/A

24. **Protocol 1298**
"HAT HBO1 in epithelial cell cycle and kidney injury"
Biosafety Level: BSL-2, N/A

25. **Protocol 714**
"MYOKINES AND THE CARDIAC SECRETOME IN PATIENTS WITH HEART FAILURE (previously called ROS in heart failure patients)"
Biosafety Level: BSL-2, N/A

**26. Protocol 637**
"MRSA Colonization in the ICU"
Biosafety Level: BSL-2, N/A

**27. Protocol 756**
"The role of pheomelanin in melanoma development"
Biosafety Level: BSL-2, N/A

**28. Protocol 850**
"Transformation of Cells by the REL Oncogene (NIH); Sea Anemone NF-kB Signaling (NSF)"
Biosafety Level: BSL-2, ABSL-2

**29. Protocol 1309**
"Mechanisms of neural stem cell self-renewal and differentiation"
Biosafety Level: BSL-1, N/A

# Appendix 9

## RECORDS OF DECISION

21–654 was approved on November 10, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,477 (U.S. Patent No. 5,656,667), 1,413 (U.S. Patent No. 5,698,594), and 1,728 (U.S. Patent No. 5,502,077) days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 1, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E6–1365 Filed 2–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Emerging Infectious Diseases Laboratories Record of Decision

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (FEIS) and a thorough consideration of the public comments on the Draft EIS and Supplemental EIS, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final EIS. This action is to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), to be called the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Center (BUMC) Campus in Boston, Massachusetts.

**FOR FURTHER INFORMATION CONTACT:** Valerie Nottingham, Chief of the Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities Development and Operations, NIH, Building 13, Room 2W64, 9000 Rockville Pike, Bethesda, MD 20892, Fax 301–480–8056, e-mail *nihnepa@mail.nih.gov.*

**SUPPLEMENTARY INFORMATION:**

#### Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories (Final NEIDL EIS), and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

#### Selected Alternative

The NIH plans to partially fund the construction of a state-of the art National Biocontainment Laboratory, which will be known as the National Emerging Infectious Diseases Laboratories (NEIDL), on the Boston University Medical Center Campus in Boston, Massachusetts. The NIH will fund approximately $128 million dollars. The proposed NEIDL will enhance national security through the development and evaluation of improved diagnostics, therapeutics, and vaccines for the protection against naturally emerging and re-emerging diseases, including those that have the potential for bioterrorism. The proposed NEIDL will not conduct research to develop biological weapons.

The proposed NEIDL facility will be a new steel and reinforced concrete seven-story building that will be constructed within the BioSquare Research Park, with a total assignable area of 84,100 square feet, and will house Biosafety Level (BSL)–4, BSL–3, and BSL–2 facilities, BSL–4 and BSL–3 animal facilities, an Arthropod Containment Level (ACL)–3 insectary, offices, conference rooms, and support facilities including an effluent treatment room, secure loading dock, and dedicated mechanical floors to enhance containment features of the building.

The proposed NEIDL facility will be designed to safely support all the superimposed loads applied to the building and will be constructed to the requirements of Seismic Performance Category C, which assures that the building structure stays functional after a seismic event. In addition to standby generators to provide power in the event of a power outage, the NEIDL facility will have a distributed on-line uninterruptible power supply to power the BSL–4 laboratory biosafety cabinets, critical building control panels and alarms. The four biosafety levels have increasingly stringent design, security, and containment requirements. The safety levels are determined based on the biological materials used in research and the ways they affect the human population. BSL–1 facilities have no requirements for safety equipment, while BSL–4 facilities have extensive and multiple requirements for safety equipment and facility design such as isolation, buffer zones, airflow and pressure requirements, and high efficiency particulate air (HEPA) filtration.

The building also will be provided with an environmental monitoring system to assess room pressure differentials (to ensure negative pressure in the biocontainment areas), smoke detection, and the pressure drop condition HEPA filters. Visual indicators (such as pressure gauges) and audible or strobic alarms will alert NEIDL personnel in the event of an emergency or situation that requires corrective action or other response. The NEIDL will have fire protection systems that meet or exceed requirements specified by the National Fire Protection Association and all applicable local, state, Federal, and BUMC requirements.

The design of the proposed NEIDL facility's BSL–4, –3, and –2 laboratories will comply with the recommendations and requirements of the Centers for Disease Control (CDC) and the NIH joint publication addressing biosafety in laboratories, the current edition Biosafety in Microbiological and Biomedical Laboratories, as well as NIH's Design Policies and Guidelines for Biomedical Research Laboratories. The BSL–4, –3, –2 animal laboratories will further comply with the recommendations and requirements of the latest edition of Guide for Care and Use of Laboratory Animals, published by the National Research Council.

The BSL–4 laboratory environment employs the concept of a ''box-within-a-box'' principle, whereby the laboratory is built within a pressure-

controlled buffer. The BSL–4 laboratories will be physically and functionally independent from other laboratory functions. All penetrations in the walls, ceilings, and floor will be sealed. The control system for maintaining the required pressure differentials will be capable of being monitored inside and outside of the laboratory. The BSL–4 laboratories will utilize a series of airlocks for entry and exit, will have dedicated supply and exhaust ventilation, and workers in the BSL–4 laboratories will use positive pressure ventilation suits.

Workers will be required to take a chemical shower to decontaminate the surface of their suits before they can leave the area. Prior to emission through stacks on the building roof, exhaust air from the negatively pressurized BSL–4 laboratories will pass through dual HEPA filters mounted in series in a dedicated sealed exhaust system. The exhaust will also pass through isolation dampers that will close within seconds upon receipt of a containment isolation signal. In addition, each laboratory will be equipped with multiple Class II Biosafety Cabinets with their own HEPA exhaust system. Liquid waste will be sterilized in a biowaste cooker system before discharge. Solid waste will be sterilized in autoclaves prior to leaving containment areas.

The NEIDL BSL–3 laboratories, BSL–3 animal laboratories, and ACL–3 insectary will be separated by restricted traffic flow within the building and access to the laboratory will be restricted by the use of electronic recognition devices. A ventilated airlock will separate the common corridors from the containment facility. The airlock doors will be interlocked to prevent simultaneous opening of doors between the outside corridor and the containment areas. Directional airflow will be provided through the airlock with differential pressure monitoring.

Similar to the BSL–4 requirements, all electrical conduit, plumbing piping, supply and exhaust ducts and miscellaneous penetrations will be sealed at the point of penetration into the BSL–3 laboratory to ensure a tight structure. Tap water entering the BSL–3 laboratories through spigots in the sinks will have backflow preventors to protect the potable water distribution system from contamination. All BSL–3 laboratories will operate under negative air pressure. A dedicated, ducted HVAC system will draw air into the BSL–3 laboratories from the surrounding areas toward and through the BSL–3 laboratories with no recirculation from the laboratories to other areas of the building. This direction of airflow into the laboratories and the biosafety cabinets will be verifiable with appropriate visual and audible alarm systems to notify personnel of HVAC problems or system failure. All air will be discharged outside the building through HEPA filters. Each BSL–3 laboratory will be equipped with Class II biosafety cabinets. Each BSL–3 laboratory will be provided with shower-out facilities for researchers along with autoclaves for solid waste treatment prior to removal. Liquid waste will be chemically decontaminated prior to discharge and solid waste will be sterilized in autoclaves prior to leaving the laboratories.

Work with moderate-risk biological material will be conducted in BSL–2 laboratories. The air supply system will be designed to maintain negative air pressure in relationship to administrative space, offices, and corridors. There will be no HEPA filtration for BSL–2 exhaust. Liquid waste will be chemically decontaminated prior to discharge and solid waste will be sterilized in autoclaves prior to leaving the laboratories.

The design and construction of the NEIDL facility will address security concerns. Security measures are discussed below. Scenarios involving terrorist or intentionally destructive acts at the NEIDL have been analyzed in an independent Threat and Risk Assessment (TRA). The design as well as security plans and procedures of the NEIDL facility will address the TRA analysis and recommendations.

The NEIDL will be surrounded by a protective fencing system that allows for controlled access at staffed checkpoints for both vehicles and pedestrians and to create setbacks of approximately 100 feet from any location that could accommodate unscreened pedestrian traffic. Vehicular access would be strictly limited to BUMC vehicles and selected delivery and service vehicles. The service and loading area will be located on the south side of the facility within the secure perimeter. Pedestrian access to the building will be limited to a single entrance and security officers will be assigned to provide protective services at the site twenty-four hours a day, monitoring both the building and the grounds.

Access to the NEIDL facility will be strictly controlled by various measures. All employees will undergo background and security checks prior to being assigned to a laboratory area. Strict operational protocols, including specific training, would be imposed on laboratory personnel prior to working in the facility. Security officers will be on duty twenty-four hours a day to monitor controlled access. All employees will be required to wear security badges. Furthermore, security cameras will be in use, biometric access systems will be utilized, and all deliveries will be screened.

Access to the BSL–4 laboratory will be restricted to people whose presence is required and authorized. Air pressure resistant, lockable doors will be monitored and controlled by the security system. A log of persons entering and exiting the laboratory with name, time, date, and reason for entering the lab will be maintained and the log would be frequently audited by BUMC's Office of Environmental Health and Safety (OEHS).

**Alternatives Considered**

The NIH considered the two reasonable alternatives identified and considered in the Final EIS: (1) The Proposed Action Alternative (now the selected alternative) and (2) the No Action Alternative (not constructing the NEIDL). Previously, NIH examined several sites and various facility designs. Sites for the NBL were evaluated if there was a reasonable expectation that a facility could be constructed with the available funding, in a reasonable time, and while meeting federal safety criteria. To meet these constraints, two minimum siting criteria were established. These criteria included: (1) The site must be controlled (owned or currently leased) by Boston University (to remain within funding and timing constraints); and (2) The lot size must be sufficient to accommodate a minimum building size of 190,000 square feet (sf) and at the same time meet federal security setback requirements. Applying the above screening criteria reduced the potential sites for detailed evaluation to four locations and four designs, one of which became the Proposed Action. The three other alternatives considered were a site on the 210 acre BU Corporate Education Center in Tyngsborough, Massachusetts; a site at the BU Charles River Campus; and a site at the BU Sargent Center for Outdoor Education in Petersborough, New Hampshire. These other sites and designs were considered technically inferior, provided no environmental advantage compared to the Proposed Action, or would not meet the purpose and need as efficiently as the Proposed Action. Therefore, they were eliminated from detailed analysis in the EIS.

**Factors Involved in the Decision**

Several factors were involved in the NIH's decision to proceed with the Proposed Action. Based on analyses in

the Draft EIS, the Supplemental EIS and Final EIS, the Proposed Action best satisfies the stated Purpose and Need, which is to rectify the national shortage of biological containment facilities with laboratories and procedures for handling potentially lethal infectious agents. This national shortage of biological containment facilities represents a substantial impediment to conducting research on infectious diseases and is a national biodefense vulnerability. To be most effective, these facilities must be located where established teams of researchers are already working on related scientific problems. Additionally, the biological containment facilities should be located in an area with existing infrastructure critical to providing timely public health support in the case of a national, state, or local disease outbreak or bioterrorism emergency. Locating a new national biocontainment laboratory at the Boston University Medical Center campus takes advantage of BU's extensive expertise in biological medical research, and its infrastructure as a regional medical center.

*Resources Impacts*

The Final EIS describes potential environmental effects of the Selected Alternative. These potential effects are documented in Chapter 4 of the Final EIS. Any potential adverse environmental effects will be avoided or mitigated through design elements, procedures, and compliance with regulatory and NIH requirements. Potential impacts on air quality are all within government standards (federal, state, and local). NIH does not expect negative effects on the environment or on the citizens of Boston from construction and operation of the NEIDL.

*Summary of Impacts*

The following is a summary of potential impacts resulting from the Selected Action that the NIH considered when making its decision. No adverse cumulative effects have been identified during the NEPA process. Likewise, no unavoidable or adverse impacts from implementation of the Selected Action have been identified. The Selected Action will be beneficial to the long-term productivity of the national and world health communities. Biomedical research conducted at the NEIDL facility will have the potential to advance techniques in disease prevention, develop disease immunizations, and prepare defenses against naturally emerging and re-emerging diseases and against bioweapons. Additionally, the local community will benefit from increased employment, income and, government and public finance.

*Housing*

Temporary impacts during construction are expected to have a minimal effect on the existing residential neighborhoods. The Boston-NBL site is bounded by a regional commercial wholesale florist market on the east, a highway on the south, the Boston University Medical Center on the north, and the BioSquare Phase 1 Research Park on the west. Residential neighborhoods are found north of the site on two side streets off Albany Street and one block north of the site off of Harrison Avenue. Construction traffic will avoid residential areas and rely on Albany Street for access.

With over 250,000 housing units in the City of Boston, the Project would have no adverse impact on housing stock. As required by local ordinance, the Project would participate in the City of Boston's Affordable Housing Program through a contribution to the City's Neighborhood Housing Trust in the amount of approximately $920,000 to be used for the creation of new affordable housing. NIH funds would not be used for this contribution.

*Education*

The current public school capacity in the South End would be adequate to accommodate the expected minimal growth caused by the Boston-NBL facility.

*Transportation*

The results of a traffic analysis conducted for the BioSquare Phase II Final Environmental Impact Report/Project Impact Report (EIR/PIR) demonstrates that the transportation infrastructure is adequate to support the Project. The 70 trips entering and leaving the site during each of the a.m. and p.m. peak hours that are specifically attributed to the NBL represents only 15–16 percent of the additional peak hour traffic; they are not sufficient in and of themselves to change operations significantly at any of the study area locations. The potential introduction of new access to and from the regional highway system would remove existing and future vehicle trips from the congested corridors of Massachusetts Avenue and Albany Street. Traffic flow on the Massachusetts Avenue Connector (MAC) is limited by the signalized intersections at Massachusetts Avenue/Southampton Street/Melnea Cass Boulevard/MAC and Massachusetts Avenue/Albany Street, which are presently at capacity. By creating an access point to BioSquare from the highway system, the Project would reduce existing and future site generated traffic from these critical intersections.

*Community Safety and Risk*

Records from the past 21 years of accidents at NIAID laboratories indicate an outstanding record of safety showing that in more than 3 million hours of exposure, there have been only one clinical infection and four silent infections (no manifestation of disease symptoms). In this 21-year period, there has been no agent released from any of these laboratories to cause infection in the general population. Nationwide, there have been no clinical infections from working with BSL–4 agents during the past 31 years at NIAID supported laboratories and no documented cases of a laboratory worker's family members or the public acquiring a disease from NIAID laboratory operations.

Records of all reported laboratory accidents were reviewed from the past ten years by the BUMC Occupational and Environmental Medicine Department and it has been confirmed by that BUMC did not have any laboratory-acquired infections from research work at BSL–2 and BSL–3 with the exception of an incident in 2004 in which three research laboratory workers were accidentally infected with tularemia bacteria in their BSL–2 lab. Corrective actions already identified and implemented to prevent this type of accident from occurring again include increased safety training and procedures for lab workers; strengthened laboratory safety procedures; unannounced safety inspections of BUMC laboratories; applying additional tests and safeguards to infectious material sent to BUMC for research purposes; and working with the Boston Public Health Commission to improve the notification process.

With approximately 14 million hours of operating time in the laboratories during the ten year period described above there were nine incidents of animal bites; sixteen incidents of percutaneous penetration; and two incidents of eye splashes that occurred within BSL–2 laboratories. None of the exposures listed above, with the exception of the tularemia incident led to illness or evidence of serological exposure.

Operation of the NEIDL is expected to result in beneficial human health impacts. The NEIDL facility will allow the development of diagnostic tests, management strategies, and vaccines for a number of emerging viral diseases and agents that may be used to cause intentional harm. The NEIDL facility will also allow for the training of additional scientists in maximum

biocontainment conditions, and increase the laboratory space available for conducting experiments that require maximum containment in response to emerging and re-emerging infectious diseases.

To ensure that the project does not create any adverse public health impacts, an analysis was prepared to address the potential risk to the public of a ''worst case scenario'' involving loss of containment systems in the BSL–4 laboratory that coincides with a release within the facility. A quantitative risk assessment was performed with regard to a theoretical infectious agent release to the surrounding community from the Boston-NBL. The risk assessment examined a laboratory accident within the BSL–4 laboratory that coincided with potential catastrophic failure of containment equipment. The ''worst case scenario'' also included an analysis of a scenario depicting a laboratory acquired infection; a scenario depicting a release due to failure to decontaminate exhaust air; a scenario depicting the escape of an infected animal; a scenario depicting a biological material shipment; and a scenario depicting an unauthorized removal of biological material from containment area. The results of these studies showed the predicted maximum exposure to any member of the community from the ''worst case scenario'' is 0.29 spores over the entire duration of the event. As the exposure to a partial spore is not feasible, the risk of public harm is so minute that it may be described as negligible.

In order to address the concerns about community safety that were raised in public comments, the NIH prepared an additional risk assessment. An additional exposure modeling strategy was applied to the proposed Boston University site. The ''Maximum Possible Risk'' or MPR model was developed by the NIH in response to comments from the public. Fifteen different scenarios were subjected to analysis using the MPR model. The MPR model analysis included three scenarios depicting spills and work disruptions; one scenario depicting a spill on the floor with no HEPA filter in the HVAC system; one scenario depicting a spill on the floor during a power outage; two scenarios depicting physical removal of biological material; two scenarios depicting fire; and seven scenarios depicting explosions. The conclusions of the MPR model showed that all fifteen scenarios had no probability of public health harm.

In summary, twenty-one different risk scenarios, six in the original risk assessment and fifteen in the supplemental risk assessment, were examined in total. All twenty-one scenarios supported the conclusion that the facility poses negligible risk to the community.

*Employment*

The Boston-NBL facility will create approximately 1,300 temporary construction jobs and 660 new permanent positions. These new positions include all types and levels including environmental services, lab technicians, scientists, and administrative staff. The majority of positions would require skilled and experienced workers.

During construction, the project will comply with the City of Boston Jobs Policy through the creation of a Boston Residents Construction Plan, establishing goals for the recruitment of local residents for construction employment.

BUMC is committed to working with City agencies to ensure that Boston residents have the opportunity to benefit from the new employment generated by the facility. Toward this end, there would be opportunities for local residents to obtain training for various positions, such as laboratory staff, which would in turn benefit the local economy. The Boston-NBL facility will contribute approximately $185,000 to the City of Boston's Neighborhood Jobs Trust for training purposes.

*Income*

The Boston-NBL facility, like other BUMC facilities, would bring large infusions of outside money to the area to finance the laboratory's work. The NEIDL will have positive economic impact on the South End and surrounding neighborhoods throughout the construction and operation phases. The total direct wages to be paid per year at the Boston-NBL is projected to be $33,000,000, of which 21.4%, or a total of $7,062,000, is expected to go to Boston residents.

*Environmental Justice*

During the construction phase of the project, neighborhoods immediately abutting the Project site, including Environmental Justice communities (communities where 25% or more of the population is defined as a minority), may experience temporary impacts from construction because of their location and proximity. There will be no disproportionate effect on Environmental Justice communities. The project will develop a Construction Management Plan to minimize construction related transportation impacts.

The worst case scenario analysis shows that during operations of the laboratory there will be negligible risk to public health for the entire community. Therefore, there will be no disproportionate impact on Environmental Justice communities during operations.

*Visual Quality*

The project has been designed to complement the existing urban design context of the project area. The site plan and massing of the project would help to mend the irregular urban edge that now exists along Albany Street. The site design and building massing have been reviewed with the Boston Redevelopment Authority (BRA) urban design staff as part of the design review process to assure compliance with BRA guidelines and recommendations.

*Noise*

Construction of the project will result in a temporary increase in daytime sound levels near the site. The maximum $L_{10}$ (sound level exceeded 10% of the time) during construction is estimated to be 71 dBA, which complies with the City of Boston Noise Control Regulation that permits $L_{10}$ levels from construction operations to exceed 75 dBA. To reduce noise from construction the project would install high-grade mufflers on the diesel powered construction equipment and generators; combine noisy operations to occur for short durations during the same time periods; and perform construction activities only between the hours of 7 a.m. to 5 p.m.

*Air Quality*

The laboratory exhaust system will be designed to avoid any air quality impacts inside or outside the building under normal operations. The potential air quality effects from the laboratories will be minimized by: (1) Combining the exhaust vents from the internal laboratory hoods into groups before connecting to rooftop exhaust fans, thus providing enhanced dilution of any laboratory chemical emissions before they reach ambient air; (2) designing the rooftop stacks to have exit velocities of at least 3,000 feet per minute as a stack exit velocity of this magnitude would be sufficient to avoid stack tip downwash, a phenomenon in which the emissions from the stack are drawn downward as strong winds blow by the stack; (3) carefully controlling and limiting the storage of all chemicals within the building to minimize chemical emissions, liquid chemicals would not be left exposed to the air and would always be contained and transferred

within closed glassware; and (4) handling liquid chemicals in small quantities to reduce the potential air quality impacts in the event of an accidental spill.

The National Ambient Air Quality Standards (NAAQS) were established to protect public health and welfare, with a margin for safety. An air quality dispersion modeling analysis was performed for the generators, boilers and laboratory vents at the Boston-NBL in accordance with the U.S. EPA and state Department of Environmental Protection (DEP) modeling guidelines. The dispersion modeling results demonstrated that the maximum cumulative concentrations of criteria air pollutants from the boilers and generators, modeled with the existing interactive sources, and with background air pollutant concentrations added, will be safely in compliance with the NAAQS for all of the criteria air pollutants analyzed.

During the construction period, the project will comply with the state DEP Diesel Retrofit Program to reduce emissions from construction-related vehicle exhaust.

*Wastewater/Water Supply*

The daily sewage flows are estimated at 45,825 gallons per day (gpd) based on existing flows at similar BUMC labs. The project does not require improvements to existing sewage infrastructure. Sanitary sewage for the proposed project would be carried by the New Albany Street Interceptor, which is designed to carry a theoretical flow of 16 million gallons per day (mgd). This project anticipates a total new daily flow of 45,825 gpd, or approximately 0.29% of the theoretical capacity of the interceptor. The estimated peak sewage flow of 137,475 gpd would be approximately 0.86% of the system capacity. At the time the New Albany Street Interceptor was designed, much larger flows were expected from this area. Accordingly, there is more than sufficient capacity in the system to accommodate the additional flows from this project and the project will have no adverse effects on existing wastewater systems

The Boston-NBL will have a segregated plumbing system that will carry laboratory wastewater from every non-BSL–4 area to mixing tanks in the basement where pH adjustment and compliance sampling would occur prior to discharge to the sanitary system. The BSL–4 areas of the Boston-NBL building would feature a sterilization system designed to use heat to kill any biological agents that might exist in the wastewater from these BSL–4 areas. The sterilized effluent from the BSL–4 areas will be cooled and neutralized before discharge. The discharges from the facility will have no adverse effect on the wastewater treatment system.

Existing public water supply systems have been significantly upgraded in the past several years and has more than adequate capacity to service the Boston-NBL. The project will have no adverse effect on water supply.

*Historic Resources*

The proposed project will be sited in an area of large commercial, industrial and institutional uses near the South End Landmark District and National Register District. The Project is located within the South End Harrison/Albany Protection Area, which covers a transitional area adjacent to the above districts. The proposed Project meets the goals of the Protection Area and thus has no adverse effects on historic resources.

**Practicable Means To Avoid or Minimize Potential Environmental Harm From the Selected Alternative**

All practicable means to avoid or minimize adverse environmental effects from the Selected Action have been identified and incorporated into the action. The proposed NEIDL facility will be subject to the existing BUMC pollution prevention, waste management, and safety, security, and emergency response procedures as well as existing environmental permits. Best management practices, spill prevention and control, and stormwater management plans will be developed and followed to appropriately address the construction and operation of the NEIDL and comply with applicable regulatory and NIH requirements. No additional mitigation measures have been identified.

**Pollution Prevention**

Pollution prevention measures are described in Chapter 2 of the FEIS and reflect standard spill prevention procedures. Additional pollution from the NEIDL facility is not anticipated. Air quality permit standards will be met, as will all federal, state, and local requirements to protect the environment and public health. Additional pollution prevention methods will include:

Reducing construction waste by recycling materials wherever possible;

Water efficient landscaping; and

Adhering to current BUMC waste management practices.

**Monitoring and Enforcement Program for Mitigation Measures**

During the preparation of the FEIS, several potential environmental issues associated with implementation of the Selected Alternative were identified.

The local community is concerned about transportation impacts. Transportation of agents to and from the NEIDL is a concern for some. Strict rules and regulations govern how agents are packaged, labeled, handled, tracked, and transported. The transportation of agents will comply with all rules and regulations. According to the World Health Organization (WHO), worldwide, there have never been any cases of illness attributable to the release of infectious materials during transportation. There have been reports of damage to outer packaging. The risk to the community from the transport of infectious agents or other biologically-derived material is negligible.

Emergency planning was raised as a concern. BUMC has an existing Incident Command System and a detailed Disaster Operations Plan that is regularly reviewed and will be revised to include the operations of the NEIDL. Emergency responders in the area are confident that they will be capable of handling emergency situations.

In addition, possible adverse health and safety impacts on laboratory workers in the NEIDL and on nearby residents during the operational phase of the project were evaluated. The risks were deemed to be negligible and mitigable through adherence to guidelines outlined in the current edition of Biosafety in Microbiological and Biomedical Laboratories, a joint publication of the NIH and CDC, as well as other standards for safe operational practices.

**Conclusion**

Based upon review and careful consideration, the NIH has decided to implement the Selected Alternative to partially fund the construction of a state-of the-art national biocontainment laboratory, which will be known as the National Emerging Infectious Diseases Laboratories (NEIDL) on the Boston University Medical Campus (BUMC) in Boston, Massachusetts.

The decision was based upon review and careful consideration of the impacts identified in the Final EIS and public comments received throughout the NEPA process. The decision was also based on BUMC's extensive expertise in biological medical research, its experience in operating BSL–2, and –3 laboratories, and its infrastructure as a regional medical center being able to

fulfill the purpose and need to provide national biocontainment facilities. Other relevant factors included in the decision, such as NIAID's mandate to conduct and support research on agents of emerging and re-emerging infectious diseases, were carefully considered.

Dated: January 26, 2006.

**Juanita M. Mildenberg,**

*FAIA Acting Director, Office of Research Facilities Development and Operations, National Institutes of Health.*

[FR Doc. E6–1402 Filed 2–1–06; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice if hereby given of the ninth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 9 a.m. to 5 p.m. on March 27, 2006 and 9 a.m. to 5 p.m. on March 28, 2006 at the National Institutes of Health, Building 31, C Wing, Conference Room 6, 31 Center Drive, Bethesda, MD 20892. The meeting will be open to the public with attendance limited to space available. The meeting will be webcast.

The first day of the meeting will include sessions on pharmacogenomics and large population studies of genetic variation, the environment and common disease. The pharmacogenomics session will include a review of Federal efforts in pharmacogenomics and deliberation on draft recommendations in this area. The large population studies session will involve discussion of a draft report that identifies policy issues associated with mounting a large population study in the United States.

The second day will be devoted to sessions on genetic discrimination and patents and licensing issues. The genetic discrimination session will include an update on the status of Federal genetic non-discrimination legislation. The patents and licensing session will involve a presentation on the findings and conclusions of a National Academy of Sciences' report on intellectual property rights in genomic research and innovation, and a discussion on whether there are other issues in this arena that warrant SACGHS's further attention.

Time will be provided each day for public comments. The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112@nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

Dated: January 26, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06–979 Filed 2–1–06; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice is hereby given of the ninth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 9 a.m. to 5 p.m. on March 27, 2006 and 9 a.m. to 5 p.m. on March 28, 2006 at the National Institutes of Health, Building 31, C Wing, Conference Room 6, 31 Center Drive, Bethesda, MD 20892. The meeting will be open to the public with attendance limited to space available. The meeting will be webcast.

The first day of the meeting will include sessions on pharmacogenomics and large population studies of genetic variation, the environment and common disease. The pharmacogenomics session will include a review of Federal efforts in pharmacogenomics and deliberation on draft recommendations in this area. The large population studies session will involve discussion of a draft report that identifies policy issues associated with mounting a large population study in the United States.

The second day will be devoted to sessions on genetic discrimination and patents and licensing issues. The genetic discrimination session will include an update on the status of Federal genetic non-discrimination legislation. The patents and licensing session will involve a presentation on the findings and conclusions of a National Academy of Sciences report on intellectual property rights in genomic research and innovation, and a discussion of whether there are other issues in this area that warrant SACGHS's further attention.

Time will be provided each day for public comments. The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodation, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *sc112c@nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

Dated: January 26, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06–978 Filed 2–1–06; 8:45 am]

**BILLING CODE 4140–01–M**

*Name of Committee:* Cell Biology Integrated Review Group Cellular Signaling and Regulatory Systems Study Section.

*Date:* January 31–February 1, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

*Contact Person:* Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, s*mirnove@csr.nih.gov.*

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* January 31–February 1, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

*Contact Person:* Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov.*

*Name of Committee:* Oncology 1-Basic Translational Integrated Review Group Cancer Etiology Study Section.

*Date:* January 31, 2013.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Riverwalk, 420 W. Market Street, San Antonio, TX 78205.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Bioengineering Sciences and Technology.

*Date:* January 31, 2013.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, *pyonkh2@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 26, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012–31451 Filed 12–31–12; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Supplemental Record of Decision; Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories

*Responsible Official:* Daniel G. Wheeland, Director, Office of Research Facilities Development and Operations, National Institutes of Health.

**SUMMARY:** The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Supplementary Risk Assessment and a thorough consideration of public comments on the Draft and Final Supplementary Risk Assessment, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final Environmental Impact Statement (EIS). This action reaffirms the NIH's previous decision to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts.

**FOR FURTHER INFORMATION CONTACT:** *For further information on the Record of Decision:* Valerie Nottingham, Chief, Environmental Quality Branch, Office of Research Facilities, National Institutes of Health, 9000 Rockville Pike, Bld. 13/2S11, Bethesda, MD 20892 *nihnepa@mail.nih.gov.*

*For further information on the Supplementary Risk Assessment:* Kelly Fennington, Senior Health Policy Analyst, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838 *NIH_BRP@od.nih.gov.*

**SUPPLEMENTARY INFORMATION:** The National Institutes of Health (NIH), an operating division of the Department of Health and Human Services (HHS), has decided, after completion of a Final Supplementary Risk Assessment for the Boston University (BU) National Emerging Infectious Diseases Laboratories (NEIDL) and a thorough consideration of the public comments on the Draft and Final Supplementary Risk Assessments, that the NEIDL, in its current location in the BioSquare Research Park, poses minimal risk to the community surrounding the facility. The Final Supplementary Risk Assessment extensively evaluated scenarios involving the potential human health consequences of an exposure to laboratory workers and members of the general public as a result of unintentional or malevolent events. The Final Supplementary Risk Assessment also analyzed the potential human health impacts of siting the NEIDL at two alternate locations from the current site in Boston. The Final Supplementary Risk Assessment concluded that the risk to the public was generally low, regardless of where the facility was located. The analysis also showed there was no disproportionate impact to the residents living in the environmental justice communities adjacent to the NEIDL's current location or to any environmental justice communities at either of the two alternative locations analyzed. Based on the results of the Final Supplementary Risk Assessment, NIH is reaffirming its prior Record of Decision of January 26, 2006, published in the **Federal Register** on February 2, 2006.

On January 26, 2006, the NIH signed the Record of Decision (ROD) to partially fund the construction of a state-of the-art National Biocontainment Laboratory, which is now known as the NEIDL, on the Boston University Medical Campus in Boston, Massachusetts. The NEIDL is a research facility that was designed to include high- and maximum-containment laboratories for research on emerging and re-emerging infectious diseases. The ROD was posted in the **Federal Register** on February 2, 2006, and described the Proposed Action and alternatives considered in the NIH's Environmental Impact Statement for the NEIDL. The ROD also described many of the physical characteristics of the NEIDL and the safeguards that would be in place for research conducted in the building.

After the ROD was released, some members of the public continued to have concerns about the safety and environmental impact of the facility. Several citizens and public interest groups filed lawsuits in Federal court to stop the NIH's partial funding of the NEIDL's construction. Opponents also filed a lawsuit in Massachusetts state court challenging the state's approval of the project. Both lawsuits alleged failure to adequately assess the potential impacts of the NEIDL on public health in alternative locations. In the Federal court proceedings, questions were raised specifically about the potential risks of the biosafety level 4 (BSL–4) laboratory. To address the concerns raised in these lawsuits, NIH established an independent Blue Ribbon Panel to advise the agency on comprehensively responding to the concerns raised by members of the community and by the

courts. The Blue Ribbon Panel was established as a working group of the Advisory Committee to the NIH Director and was comprised of experts in infectious diseases, public health and epidemiology, risk assessment, environmental justice, risk communications, biosafety, and infectious disease modeling. At multiple points during the preparation of the Supplementary Risk Assessment, the NIH also consulted the National Research Council (NRC) Committee on Technical Input that had been critical of a previous draft NIH risk assessment for the NEIDL. With the technical and scientific guidance of the Blue Ribbon Panel and the NRC Committee on Technical Input as well as extensive public input, NIH prepared a Draft Supplementary Risk Assessment, which was published in the **Federal Register** on February 24, 2012. The publication of the Draft Supplementary Risk Assessment in the **Federal Register** began a 67-day public comment period. After a thorough consideration of comments received on the Draft Supplementary Risk Assessment, including those comments received during a public meeting held in Boston on April 19, 2012, NIH prepared a Final Supplementary Risk Assessment, notice of which was published in the **Federal Register** on July 6, 2012.

**Decision**

After careful consideration of the information and analyses presented in the Final Supplementary Risk Assessment, including the potential impacts on public health and safety arising from research involving infectious agents, as well as all public comments received during and after the assessment's preparation, the NIH has decided to reaffirm the decision reached in the agency's initial Record of Decision to implement the Selected Alternative, to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts described in the December 2005 Final EIS. The additional information provided from the Final Supplementary Risk Assessment results has reinforced the agency's original decision. The NIH's decision to reaffirm the ROD does not commit the NIH to support any specific research in the NEIDL in the future.

**Alternatives Considered**

The Final Supplementary Risk Assessment considered and compared the potential public health impacts of a biocontainment failure at three separate, proposed locations for the NEIDL. Those locations included an urban (the current BUMC site), a suburban (Tyngsborough, MA), and a rural (Peterborough, NH) setting. The results of the Supplementary Risk Assessment showed minimal differences in the risks of infections or fatalities to lab workers at the three different sites because the laboratory and its operations would be the same at all three sites. There are differences in the three sites with regard to population density and other features of the environment, such as availability of medical care. The possible effects of these differences on risks to the public were evaluated. The results show that no statistically significant differences can be concluded at the suburban and rural sites (Peterborough and Tyngsborough) compared to the urban site (Boston).

**Factors Involved in the Decision**

Throughout the course of the project, NIH engaged in extensive consultations with the Boston community. During the development of the Supplementary Risk Assessment for the NEIDL, public input was sought and considered multiple times before the report was finalized. In preparing its advice to the NIH for the Supplementary Risk Assessment, the Blue Ribbon Panel held multiple public meetings, including several in Boston at locations suggested by community members, to hear the concerns of the community and to solicit input on what scenarios and agents the community wished to see analyzed in the document. The approach taken to perform the Supplementary Risk Assessment, as well as the types of scenarios and agents studied in the Supplementary Risk Assessment, were thoroughly discussed and publicly vetted through the Blue Ribbon Panel and the NRC Committee on Technical Input. These two independent bodies provided technical advice that was then used to guide NIH through the risk assessment process. In order to help ensure that the Supplementary Risk Assessment was as comprehensive and technically and scientifically sound as possible, the NIH contracted with a leading consulting firm to perform the assessment. This firm engaged outside experts in infectious diseases and modeling to assist in preparing the assessment.

After extensive consultations with the Blue Ribbon Panel, the NRC Committee on Technical Input, and the public, the contractor preparing the Supplementary Risk Assessment identified and considered approximately 300 events that could potentially lead to loss of containment. The contractor grouped these 300 events initially into 30 categories of related events. Based on their likely risk, several of these events were selected to represent the overall group. The selected events include higher- and lower-risk events that occur in a variety of ways and expose different groups of people or the environment. Taking these factors into account, the possible events selected for detailed analysis in the Final Supplementary Risk Assessment were a needlestick accident, a centrifuge aerosol release, an earthquake, and transportation accidents.

To ensure examination of consequences with the most negative possible outcomes, mitigating features of the building systems, fully functional personal protective equipment, and standard operating procedures were not taken into account in the Supplementary Risk Assessment, which increased the risk by posing failures without taking into account mitigating features. For example, for purposes of the risk assessment, it was assumed that a needlestick would not be recognized and reported. Similarly, the risk assessment considered what would happen if a centrifuge release went undetected and unreported. In reality, lab personnel are trained to recognize and report such incidents, thus mitigating the consequences should such a lab accident occur.

The Final Supplementary Risk Assessment examined a variety of possible situations—including those that posed the maximum realistically expected risk that might expose laboratory workers and the general public to disease-causing microbes that will be studied in the NEIDL. While there is no such thing as ''no risk'', the results of the analysis showed that the risk of infections or fatalities resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. The risk assessment evaluated the NEIDL and proposed activities in its laboratories as well as the potential impacts to site-specific populations in the three alternative geographic locations.

**Practicable Means To Avoid or Minimize Potential Environmental Harm From the Selected Alternative**

All practicable means to avoid or minimize adverse environmental effects from the selected action have been identified and adopted. The NEIDL will be subject to oversight by numerous federal, state, and local entities including, but not limited to, the Centers for Disease Control (CDC) and

Prevention, the NIH, and the Boston Public Health Commission. The NEIDL will also be subject to federal, state, and local pollution prevention, waste management, and environmental regulations. This level of oversight and regulation, in addition to NEIDL-specific laboratory standard operating procedures and researcher training should greatly minimize any chance of a pathogen being released into the environment.

**Monitoring and Enforcement Program for Mitigation Measures**

Boston University has established policies and procedures to ensure that the NEIDL complies with all applicable Federal, state, and local regulations. In addition, trained biosafety staff at Boston University will perform periodic laboratory inspections to ensure safety standards are rigorously upheld. Laboratory inspections will also be performed by the Boston Public Health Commission. The CDC will also perform inspections for those laboratories performing research with Select Agents. Projects requiring the use of BSL–3 and BSL–4 containment must be reviewed and approved by the Boston University Institutional Biosafety Committee (IBC). The Boston University IBC includes at least two members from the public who are not affiliated with Boston University. The Boston Public Health Commission will also review and approve projects requiring BL3 or BL4 containment. Finally, as an NIH grantee, Boston University is required to comply with the grant terms and conditions. These terms and conditions require Boston University to file an annual progress report with NIH that describes the use of any highly pathogenic agents or Select Agents in the past year.

**Conclusion**

The Final Supplementary Risk Assessment examined a variety of possible scenarios, including those that posed the maximum realistic risk that might result in laboratory workers or the general public having primary or secondary infections resulting from release of pathogens that might be studied in the NEIDL. While there can be no such thing as ''no risk,'' the results of this analysis show that the risk of infections resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. This is largely due to the safeguards built into the facility, the low amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into everyday practice at the NEIDL and as well as due to oversight of the NEIDL by regulatory authorities, like the Boston Public Health Commission and the Centers for Disease Control and Prevention. The greatest risk posed by research in the NEIDL is to individuals conducting research in the building, not to the general public. The analysis did not show any statistically significant increase in risk to medically vulnerable populations when analyzed as a group or individually, as compared to what those risks would be at alternate sites. Based on these factors, NIH is reaffirming its prior Record of Decision, dated January 26, 2006, and concludes that high and maximum containment research could be conducted safely at the NEIDL based upon the current safeguards and engineering controls in place at the facility.

Dated: December 18, 2012.

**Daniel G. Wheeland,**

*Director, Office of Research Facilities Development and Operations, National Institutes of Health.*

[FR Doc. 2012–31509 Filed 12–31–12; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–HQ–IA–2012–N304; FXIA16710900000P5–123–FF09A30000]**

## Endangered Species; Receipt of Applications for Permit

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

**DATES:** We must receive comments or requests for documents on or before February 1, 2013.

**ADDRESSES:** Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov.*

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

**SUPPLEMENTARY INFORMATION:**

**I. Public Comment Procedures**

*A. How do I request copies of applications or comment on submitted applications?*

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

*B. May I review comments submitted by others?*

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**II. Background**

To help us carry out our conservation responsibilities for affected species, and

# Appendix 10

# NRC REPORT ON CONTINUING ASSISTANCE TO THE NIH

# Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 3

Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL

**Board on Life Sciences**
**Division on Earth and Life Studies**

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National Research Council
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Board on Life Sciences

500 Fifth Street, NW
Washington, DC 20001
Phone: 202 334 2187
Fax: 202 334 1289

December 6, 2011

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
Building 1
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

At your request, the National Research Council (NRC)[1] reconvened its Committee on Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory (NEIDL), Boston University[2] to provide you and your Blue Ribbon Panel with further technical input on the scope and design of any additional studies that may be needed to assess the risks associated with the siting and operation of the NEIDL.

In particular, you asked the NRC Committee to meet with the NIH Blue Ribbon Panel in public at key milestones in the development of the draft risk assessment. To this end, the NRC Committee met in open session with the Blue Ribbon Panel on November 2, 2011. The purpose of this meeting was to discuss the NRC Committee's comments and questions on a "90 percent" draft of the revised risk assessment. This Phase 3 letter report provides the NRC Committee's written comments in response to that November 2 meeting. The NRC Committee's full statement of task, as developed with your office, is provided in the main body of this report.

The Committee found that the "90 percent," or penultimate, draft of the risk assessment is a substantial improvement over past documents we have reviewed. What follows is intended to present some areas in which the Committee on Continuing Assistance to NIH sees elements that might be used to improve the version prepared for public comment.

We hope that the comments provided in this letter report will be helpful to you and the Blue Ribbon Panel as you consider how the remainder of the work to be performed is carried out. It is the Committee's consensus that the advice and assistance we have provided to NIH should

[1] The principal operating arm of the National Academy of Sciences and the National Academy of Engineering.
[2] The Committee is now known as the Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL. A list of Committee members and their biographies is included as Attachment A.

now be at an end. The Committee thanks NIH for seeking its input as it works to develop resources for advancing the national capacity to protect and improve health. The Committee hopes that its suggestions will be useful in this regard.

This report reflects the consensus of the Committee and has been reviewed in accordance with standard NRC procedures. The work was supported by Frances Sharples, Director of the NRC's Board on Life Sciences and Orin Luke of the Board on Life Sciences.

Sincerely,

John F. Ahearne, Chair
Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL

cc: Amy Patterson, M.D.

## ACKNOWLEDGMENTS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report:

**John S. Applegate**, University of Indiana School of Law, Bloomington, IN
**John C. Bailar, III** (Emeritus), University of Chicago, IL
**Kenneth I. Berns,** University of Florida, Gainesville, FL
**Charles N. Haas,** Drexel University, Philadelphia, PA
**Marc Lipsitch**, Harvard University School of Public Health, Boston, MA
**Stephen Ostroff,** Pennsylvania Department of Health, Harrisburg, PA
**Catherine Wilhelmsen,** U.S. Army Medical Research Institute for Infectious Diseases, Frederick, MD

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Edward B. Perrin, University of Washington, Seattle, WA. Appointed by the National Research Council, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring Committee and the institution.

## BACKGROUND AND INTRODUCTION

In 2003, the Boston University Medical Center (BUMC) was awarded a $128 million grant from the National Institutes of Health (NIH) to build one of two national maximum-containment laboratory facilities for pathogen research. The National Emerging Infectious Diseases Laboratories (NEIDL) are meant to support the National Institute of Allergy and Infectious Diseases' biodefense research agenda, conducting research to develop new approaches to treating, preventing, and diagnosing a variety of bacterial and viral diseases. Diseases and pathogens to be studied include viruses (e.g., Ebola, Marburg, dengue fever, Lassa fever, and highly pathogenic influenza) and bacteria (e.g., *Shigella* and plague) that occur naturally and cause infections or that could be used in deliberate attacks. The facility includes a biosafety level 4 (BSL-4) containment laboratory housed in a 192,000 square foot building. Although the NEIDL BSL-4 laboratory accounts for only 13 percent of the building's total space, it has been the source of virtually all of the community concern surrounding this project. The location of the facility on Albany Street in Boston's South End, which is an environmental justice community, (Boston Region Metropolitan Planning Organization, Journey to 2030; Loh, et al., 2002) has been controversial, and there have been numerous public meetings over the plans for the facility as well as three legal actions challenging the project. Construction of the laboratory building is now finished although commissioning of the laboratory facilities has not been completed. A remaining issue is whether the BSL-4 component will become operational.

The building, including the BSL-4 laboratory, is part of the BioSquare Phase II project. Under the Massachusetts Environmental Policy Act (MEPA), the Secretary of the Commonwealth of Massachusetts's Executive Office of Environmental Affairs issued a certificate stating that the BioSquare II project required the preparation of an Environmental Impact Report (EIR). Although the Massachusetts Secretary of Environmental Affairs in 2004 found that the final Environmental Impact Report adequately and properly complied with MEPA, this determination was challenged in court. In July 2006 the Superior Court of Massachusetts vacated Massachusetts' certification of the EIR and remanded the matter to the Secretary of Environmental Affairs.

NIH prepared a document, "Draft Supplementary Risk Assessment and Site Suitability Analyses" (DSRASSA), regarding the siting and operation of the NEIDL in response to comments from the federal court presiding over another lawsuit under the National Environmental Policy Act (NEPA) and to supplement NIH's previous assessments of the potential risks posed by the NEIDL at its current location in Boston.

At the request of the State of Massachusetts, in November 2007 the NRC Committee authoring the current report released the first in a series of letter reports assessing the DSRASSA.[3] The Committee's assessment was critical of the DSRASSA, finding that it was not sound and credible, did not adequately identify and thoroughly develop worst-case scenarios, and did not contain the appropriate level of information to compare the risks associated with alternative locations. The report also raised specific concerns about agent selection, scenario development, modeling methodology, environmental justice issues, and risk communication.

In March 2008, NIH established its Blue Ribbon Panel (BRP) to provide scientific and technical advice to the NIH Director through recommendations made to the Advisory Committee

[3] NRC. Technical Input on the National Institutes of Health's Draft Supplemental Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University: A Letter Report (2007). Available at: http://www.nap.edu/catalog/12073.html.

to the Director. The panel members were charged with providing ongoing, expert input to guide the development of any necessary additional risk assessment analyses. Also in 2008, the same NRC Committee reconvened at the request of NIH. The NRC Committee has been meeting with the BRP periodically as milestones were reached in the preparation of additional risk assessment materials. The NRC released its second letter report in April 2008.[4] The Committee restricted its comments in that report to suggestions based only on its previous review of the DSRASSA and improving the risk assessments presented therein as input to any additional studies that may be needed to assess risk associated with the siting and operation of the NEIDL. As noted in its 2007 report, the Committee acknowledged and emphasized the need for biocontainment laboratories, including BSL-4 laboratories. However, the Committee's view remained that the selection of sites for high-containment laboratories should be supported by detailed analyses and transparent communication of the available scientific information regarding possible risks.

In its 2008 report, the Committee refrained from prescribing specific methods and other details, electing instead to structure its suggestions to the NIH BRP around the following overarching questions that should be addressed in future reports about the risks associated with operating the NEIDL:

- What could go wrong?
  - — Release scenarios for infectious agents
  - — Agents to consider for risk assessment
- What are the probabilities that these scenarios will occur?
- What would be the consequences if they did occur?

The Committee also recommended that NIH make greater use of the accumulated wisdom in the published literature on how to achieve effective risk communication.

In 2009 NIH asked the NRC to convene the NRC Committee again to provide input at key milestones in the development of the supplementary risk assessment through a series of letter reports (see full Statement of Task, below). The first milestone for which input from the NRC was requested was the development of plans for the supplemental risk assessment. On March 19, 2010 at a joint meeting of the NIH BRP and the NRC Committee, the two contractor groups selected by NIH to complete the supplemental risk assessment—Tetra Tech and its subcontractors from the University of Utah—made presentations on the proposed plans for the supplemental risk assessment. At NIH's request, the NRC Committee focused its discussions of the proposed approaches on the following questions:

1. Is the range of agents being studied appropriate?
2. Is the approach to event sequence analysis appropriate?
   - — Will the method result in an adequate range of scenarios being considered and selected for analysis?
   - — Are the plans for analysis and expression of results appropriate?
3. Is the modeling approach appropriate?
   - — Is the approach to initial infection sound?
   - — Are the criteria for and selection of models sound?
   - — Are the uses of the hybrid branching-compartment models and the extreme values analysis sound?

[4] Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory, Boston University: A Letter Report (2008). Available at: http://www.nap.edu/catalog/12208.html.

On the basis of this meeting, in April 2010 the NRC Committee delivered its third letter report.[5] In that report, the Committee noted that it had heard about plans, but not yet results. In general, the NRC Committee found the proposed approaches to conducting the risk assessment suitable and well planned. The agents selected for analysis were appropriate and comprehensive, and the expertise available on and to the assessment team seemed strong. NIH and Tetra Tech appeared to recognize data limitations and the need for flexibility in study design. The Committee encouraged NIH and Tetra Tech to develop qualitative analyses (an explanation of the safety and risk profile) of all 13 pathogens on the list in a manner that is clear and accessible to the public. The Committee also suggested that the qualitative analyses in the body of the assessment be supplemented with results of quantitative modeling planned for five pathogens, with details provided in appendices. Further, the Committee encouraged NIH and Tetra Tech to rely on data that are available from existing case studies, public health surveillance of the surrounding communities, and release incidents, not only to support its models but also to provide a complete and understandable picture for the public. The NRC Committee again emphasized that the final risk assessment be able to serve as an effective risk communication tool.

On September 22, 2010, the NRC Committee again met in open session with the Blue Ribbon Panel to hear presentations by NIH's contractors on the approaches they were taking to conduct the risk assessment. After reviewing the material presented at the meeting, the NRC Committee concluded that it could not endorse as scientifically and technically sound the illustrative analyses presented. At that time, the NRC Committee found that the analyses presented did not represent a thorough assessment of the public health concerns raised by the Committee in its previous reports. The Committee noted that the analytical results discussed were incomplete, work on additional analyses was still ongoing, and expressed the hope that the comments provided in that letter report[6] would be helpful to NIH and the Blue Ribbon Panel as the remainder of the work to be performed was carried out.

In October of 2011, NIH provided a 1700 page "90 percent" draft of the revised risk assessment (RA) for the NEIDL to the NRC Committee for its review. (This is the penultimate draft of the document before it is released for public comment.) The Committee met in closed session on November 1, 2011 to compile its questions and comments for a discussion with the Blue Ribbon Panel and the NIH contractor team the following day, November 2. This letter report contains the NRC Committee's written comments in response to that November 2 meeting.

**Statement of Task for This Letter Report**

As with the Committee's previous two letter report of the same title, the statement of task for this letter report is as follows:

> The NIH will engage the Committee on Technical Input on the NIH's DSRASSA for the Boston University NEIDL at key milestones during the development of a

[5] Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 1: A Letter Report (2010)

[6] Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 2 (2010)

draft supplementary risk assessment. The NRC and the NIH Blue Ribbon Panel (BRP) will meet together in public to discuss the developing draft report. Information contained in the draft risk assessment may include data on agents, models, and scenarios; preliminary modeling results; and quantitative and qualitative assessments. Documents reviewed and discussed at these meetings will be made available to the public. Following each meeting with the BRP, the NRC Committee in closed session will prepare brief letter reports on the preliminary results of the supplementary risk analyses, focusing on whether the analyses are scientifically and technically sound in general and whether they address the public health concerns previously raised by the NRC in its review of the July 2007 DSRASSA. These letter reports will be made available to the public. The Committee will also provide written comments on the draft supplementary risk assessment when that document is made available for formal public comment. The Committee will submit its findings in the form of a final letter report that will also be made available to the public.

## COMMITTEE RESPONSE TO THE NOVEMBER 2, 2011 MEETING

### General comments

The 90 percent Risk Assessment draft is a substantial improvement over past documents the Committee has reviewed. Given the document's already substantial length, the Committee's comments are not meant to suggest that it would be desirable to add a great deal more text or analysis. Rather our comments are intended to present some areas in which the Committee on Continuing Assistance to NIH sees elements that might be used to improve the version that is ultimately prepared for public comment. Following a few general comments, the Committee will provide its thoughts on the individual chapters of the report.

1. This draft report is an extremely large and technically complex document. The Committee strongly recommends that both an Executive Summary written for the lay audience and a summary of Chapter 11 that synthesizes and interprets the major findings of the RA in plain language be developed to facilitate public understanding. Several of the other expansive chapters could also benefit from the addition of plain language summaries.

2. The document would be improved by including as one of its key messages a clear commitment by NIH and Boston University to encouraging and maintaining a culture of safety at the NEIDL. In addition, NIH or Boston University should periodically review the RA as new agents are introduced into the NEIDL or other significant changes are made in operating procedures. Of course the BU Institutional Biosafety Committee (IBC) and Institutional Animal Care and Use Committee (IACUC) will also review and oversee changes involving new organisms or toxins, procedures, or increased volumes of materials.

3. The Committee has reservations about the omission of a fomite "carry out" scenario in the quantitative modeling. The rationale for why this scenario is not included should, at the very least, be discussed and justified.

4. While the Committee recognizes that there are many areas for which there simply are no data to analyze for a number of the pathogens assessed, it is important that assumptions and conclusions that rely on "expert opinion" be distinguished from those that derive from data from the literature. The report would also benefit from being more transparent about what was done and for what reasons throughout.

5. The document is very difficult to navigate due to its structure and length as well as to inconsistencies in style and the use of terminology. It will be important to include many cross references so that conclusions presented in one section can be traced back to analytical discussions in previous chapters, etc.

**Chapter 1: Introduction**

Some of the statements included in Chapter 1 on "environmental justice" seem to imply that the major concern in this area is differences in population density among sites. It might be helpful to craft a paragraph for this chapter describing how environmental justice seeks to compare population characteristics, not just density. Other differences in environmental justice communities might include variations in host population susceptibilities to infectious agents and access to appropriate health care. The relevant factor is how much environmental justice communities differ in their ability to react if infection occurred.

**Chapter 2 and Appendices A and B: Facility Design, Operation, and Site Descriptions**

This chapter is readable for regulators as well as the general public. The illustrations help communicate the technology. The design as described is state-of-the-art by 2011 standards and construction appears to be compliant with all relevant standards and guidance, e.g., BMBL and Massachusetts State requirements. Oversight is described as being provided by the Institutional Biosafety Committee, which is standard. Additional oversight by the Institutional Animal Care and Use Committee, the NIH Office of Biotechnology Activities (RAC), and the NIH Office of Laboratory Animal Welfare should be mentioned, as these are important for animal and recombinant work.

Chapter 2 might be the right place for adding the recommended statement (see General Comments, above) on committing to a "culture of safety."

Training: Demonstration of competency should be instituted as a requirement for independent work in the BSL-3 or BSL-4 suites. In addition, periodic retraining and retraining after incidents such as accidents should be required. The BSL-4 simulator training is a positive aspect.

The fact that Boston University is working with the Boston Public Health Commission (BPHC, p. B-4) is a change for the better. Sustaining this partnership over the life of the facility would

be far preferable to relying on it only for establishing the ability to operate the BSL-3 and BSL-4 laboratories.

A positive note with regard to the NEIDL's current location is its affiliation with the Boston Medical Center, which has ample isolation space and provides an ability to bring point-of-care to the patient and minimize patient movement through the hospital.

Attachment B contains a number of editorial comments and minor questions from this chapter.

**Chapter 3 and Appendix C: Pathogen Characteristics**

This chapter and the lengthy Appendix C contain a wealth of valuable information on what is known about the pathogens assessed. But perhaps because of this great length (Appendix C is 300 pages) there is a certain lack of cohesion. The material would benefit from a clearer explanation of the state of the science and its relevance for the risk assessment. A brief introduction ("primer") to the chapter that explained the relevance of the major categories of information could be included for each pathogen. For example, an explanation of dose-response assessment that describes what is known about dose-response relationships relevant to predicting the likelihood and severity of human disease would be helpful. A common language description of principles and limitations of dose-response assessment could also help the less technically oriented reader understand the reason for the inclusion of this information in the chapter.

In addition, the epidemiological "case control" literature that refines our ideas about transmission routes and the likelihood and severity of resulting disease for some of the pathogens is not adequately incorporated into the analyses and referenced. This would enable "plausible inference" about routes of transmission rather than simply making statements such as "person to person transmission does not happen." In general, statements like this one occur throughout the document and should be softened to suggest that likelihood is small.

Again, in this chapter and throughout the document, it is important to distinguish carefully and clearly between what is based on expert opinion and what is based on data from animal models or other scientific evidence. It is also important to make clear where data do not exist and what assumptions have consequently been made and why. For example, on p. 3-71, lines 16-17, a statement is made that the RA will make probabilistic estimates of initial infection for those exposed to model-generated amounts of Tick-borne Encephalitis virus. However, there are no human dose response data for this virus, so an explanation of how such estimates can be made and what is assumed to make them is needed.

**Chapter 4 and Appendices D, E, and F: Event Sequence Analysis**

This chapter contains numerous tables of information about event and exposure scenarios. However, because the basis for assigning frequencies to the various exposure categories (e.g., Table 4-5 on pp. 4-10-4-11) is not clear, the Committee is not confident that we can agree with the values assigned. In several cases, the Committee definitely disagrees with the frequencies assigned. As noted above, the Committee would like to see the rationale for the exclusion of a

fomite "carry out" scenario, as this kind of event has been shown to be the source of significant problems at real labs.

Second, it is the Committee's view that real world experience would seem to indicate that the frequency of unreported punctures due to needle sticks may be much higher than the "low" category (once in 1 to 100 years) assigned (Table 4-5). Furthermore, because reporting of such an event is dependent on worker compliance, the Committee is concerned that the likelihood of a non-reporting lab worker spreading an infection may be somewhat underestimated. There is already a quote on page D-2 on why laboratory-related exposures may not be reported: "hampered by an indifference to and, frequently, an unwillingness to report these incidents" [in part] "due to fear of reprisal and the stigma associated with such events." Using a more realistic estimate of frequency and/or expansions of sensitivity analyses for this scenario could potentially strengthen this analysis.

Third, the assignment of frequency category C (1 in 10,000 to 1 million years) to the high consequence earthquake scenario, given the paucity of actual data on occurrences of large magnitude quakes on the eastern seaboard of the US, is a concern. (Note that a magnitude 5.8 quake occurred in 2011 in Virginia, where such earthquakes are conventionally thought to be highly unlikely.) The Committee recommends that the contractor at least investigate whether categorizing the latter frequency as a B (I in 100 to 10,000 years) makes a difference in the outcome.

Finally, the analysis of the probability that one or more infected animals might survive an earthquake and escape if the building collapses was not entirely convincing. This possibility is mentioned briefly at the bottom of page 4-31, and again on page 4-41 and in the appendices. Chapter 7 also suggests that infected animals could lead to pathogens becoming endemic in the local area. Could the probability that even if building containment fails catastrophically, all infected arthropods and lab animals will die rather than escape be discussed? At the very least, this and some of the other "highly unlikely" scenarios that are excluded from further consideration should at least receive attention in the form of sensitivity analyses.

**Chapter 5: Transportation and Appendix G**

The committee believes that the chapter on transportation is thorough and has no concerns with the content. The Committee is persuaded that following federal, state and local requirements should provide adequate means for addressing transportation issues if such should arise.

**Chapter 6: Threat Assessment**

The Committee is sympathetic to the difficulties of presenting a threat assessment but is concerned that this chapter will not alleviate public concern in its current form. It is frustrating to read because conclusions are not presented at the end. The chapter would benefit if it were to state clearly up front that the results of some calculations cannot be reported because of security concerns. This would at least spare the reader the frustration of finding no bottom line at the end of the chapter.

**Chapter 7 and Appendix H: Environmental Persistence**

The Committee agrees with the conclusions drawn about which pathogens have the potential to become established in the environment.

A "cleaned up" version of the Delphi report (Appendix H and attachments) would be valuable and should include explanations of how the information was used. Some of the data tables in the report (e.g., Attachment H-4, p.99) are not clearly labeled and their meaning is not apparent. As noted above, it is important that assumptions and conclusions that rely on "expert opinion" be distinguished from those based on data from the literature.

**Chapter 8 and Appendices I, J, and K: Health Effects Following Exposure**

Table 3-2B on p. 8-14: It is not clear whether the stated frequencies are for individual workers vs. workforce risk for needle stick. It appears that the risk of a needle stick event should go up with number of workers and perhaps with numbers of injections required.

The committee believes that the numbers presented in the table on p. I-10 (differential susceptibility) are optimistic and underestimate potential differences among vulnerable groups, particularly when categories are combined. For example, it is not unusual to find obesity and diabetes in the elderly, and the combination of these three factors in individual patients might dramatically change the estimates of increased vulnerability in some members of the population. It is also plausible that a pregnant woman could be both diabetic and HIV infected. Addressing the vulnerability factors one at a time may drastically underestimate susceptibility and co-morbidity. The Committee recognizes that data on such factors may be scarce. Given this, it is important that the document be completely transparent about how rigorous the estimates presented can be.

Some of the numbers in Table 5-2a on p. 8-23 are an example of false precision, e.g., $1.5X10^{-47}$, particularly when so many of the parameters have had to be estimated. Similarly, the dose response tables in appendix J (p. J-21) contain detail that may not be biologically meaningful.

**Chapter 9 and Appendix L: Secondary Transmission**

In general, the committee finds the modeling on secondary transmission to be satisfactory and the assumptions made in the chapter are transparent. There are, however, a number of editorial issues that it would help to address:

- There are about five different definitions of $R_0$ presented in this chapter and elsewhere; all are different and some are incorrect.
- The definition of "latency period" used in the document is usually what is referred to as "incubation period" elsewhere. These two parameters are not the same and only coincide when the onset of infectiousness coincides with the onset of symptoms.
- p. I-13, line 25: The assumptions that underpin the modeling methodology are clearly described. Some of these assumptions, though, are convenient approximations (e.g., the assumption that contact rates between medically vulnerable subpopulations and others are

directly and simply related to their abundance). The report would be improved if there were some discussion about how the approximations can be expected to alter (if at all) model conclusions.

- The equations in this chapter did not reproduce into the pdf version, and this must clearly be corrected before the document goes public.

**Chapter 10 and Appendix M: Environmental Justice**

The Committee believes that the RA team has made substantial progress in addressing environmental justice and Chapter 10 and Appendix M set out a credible and thoughtful approach to environmental justice based largely on federal and state environmental justice executive orders and policies. There is still, however, one significant short-coming in the environmental justice analysis, which is captured in lines 23 to 26 on page 10-22.

"If a member of the environmental justice community is exposed to a pathogen, there are no published data or guidance to inform the analysis of increased susceptibility to any of the 13 pathogens considered in the RA."

It is essential that the RA make a good faith effort to assess increased susceptibility to these pathogens. As noted earlier in this same chapter (page 10-19, lines 13 – 26), there is some evidence that minority communities have higher rates of hospitalization, morbidity and mortality from infectious diseases. Second, equal accessibility to health services and medical care – which would be available if the Massachusetts law is implemented – is not the same as equal utilization of health services and medical care. It is likely that environmental justice communities could have utilization barriers to medical care and health services. Third, the secondary transmission rate among environmental justice community members is a key question for community members. Citizens and the public are likely to ask about it. Questions of increased morbidity and mortality, accessibility and utilization of health services, and secondary transmission in minority communities should at least be explored in a philosophical discussion, even if current, hard data do not exist.

In the absence of data or guidance, the RA team should use the qualitative information that is available to it and, at a minimum, provide a discussion of the effects of health disparities and what these might mean in terms of transmission among, and impact to, the community. On such an important question, it is not enough to terminate all further examination in the way that lines 23 to 26 (page 10-22) now do.

**Chapter 11: Risk Characterization**

In general and as noted above, the Committee finds this chapter long on numerical information and short on explanations about what it all means. A summary written in plain language for the non-technical reader would improve the chapter and the report overall.

In keeping with comments made above in Chapters 4 and 8, the Committee is concerned that failure of protective equipment and failure to follow procedures on the part of personnel are underestimated in the analyses. For example, the categorization of various categories of human

error as "B" (one per 100 years or even less frequently) does not align with much of what we know about human error rates and the ability of human beings to defeat sophisticated engineering solutions. As another example, the Committee does not believe that the assumptions made about PAPR (powered air purifying respirator) failure rates on p. 11-8 are realistic. This could be addressed using a sensitivity analysis to see whether an increase has any effect on the overall assessment.

The statement on p. 11-9, lines 24-26 that an undetected needle stick would affect only one worker and is "estimated to be in frequency category B (one in 100 to 10,000 years)" is a strong statement that should be explained. (See also discussion under Chapters 4 and 8, above.) Similarly, on p. 11-27, line 31, the statement that there is "no risk of person-to-person transmission" is overly strong and in fact contradicts cases sited in chapter 3 of person to person transmission (e.g., for cutaneous anthrax). It would also be helpful to point readers to the source (in the report) of analysis and information on which conclusions about "operational information" are based (p. 11-29, line 5).

## SUMMARY

As noted earlier, the Committee finds that this penultimate draft of the RA is a substantial improvement over past documents we have reviewed. In the terms in which our Statement of Task is written, the RA is now closer to reaching its goal of being "scientifically and technically sound" and, in general, addresses the concerns raised in the original NRC review of the "DSRASSA" document in 2007. While there are many approaches to preparing a risk assessment and in some aspects the Committee would have used approaches other than those found in this draft, this is no reason to fault the document. It is clear that NIH and the Blue Ribbon Panel have gone to unprecedented lengths to improve the risk assessment for the NIEDL and have made substantial advances. It is the Committee's hope that the comments in this letter report will be taken as suggestions for improving the final draft report further. We wish NIH well as it moves into the next phases of this complex process and prepares for the solicitation of public comments on the final draft. It is the Committee's view that no further advice from this group would be useful nor should it be required.

## Attachment A: Committee Roster and Biographies

### Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL

**JOHN AHEARNE** *(Chair)*, The Scientific Research Society, Research Triangle Park, NC
**THOMAS ARMSTRONG**, TWA8HR Occupational Hygiene Consulting, LLC, Branchburg, NJ
**GERARDO CHOWELL**, Arizona State University, Tempe, AZ
**MARGARET COLEMAN**, Consultant, Cicero, NY
**GIGI KWIK GRONVALL**, University of Pittsburgh, Baltimore, MD
**ERIC HARVILL**, Pennsylvania State University, University Park, PA
**BARBARA JOHNSON**, Barbara Johnson & Associates, LLC, Herndon, VA
**PAUL LOCKE**, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
**WARNER NORTH**, NorthWorks, Inc., Belmont, CA
**JONATHAN RICHMOND**, Jonathan Richmond & Associates, Southport, NC
**GARY SMITH**, University of Pennsylvania School of Veterinary Medicine, Kenneth Square, PA

### Staff

**FRANCES SHARPLES**, Project Director
**ORIN LUKE,** Senior Program Assistant

### Committee Biographies

**John Ahearne** (chair) is Executive Director Emeritus of Sigma Xi, the Scientific Research Society, and Emeritus Director of the Sigma Xi Ethics Program. Prior to working at Sigma Xi, Dr. Ahearne served as Vice President and Senior Fellow at Resources for the Future and as Commissioner and Chair of the U.S. Nuclear Regulatory Commission. He worked in the White House Energy Office and as Deputy Assistant Secretary of Energy. He also worked on weapons systems analysis, force structure, and personnel policy as Deputy and Principal Deputy Assistant Secretary of Defense. Serving in the U.S. Air Force (USAF), he worked on nuclear weapons effects and taught at the USAF Academy. Dr. Ahearne's research interests include risk analysis, risk communication, energy analysis, reactor safety, radioactive waste, nuclear weapons, materials disposition, science policy, and environmental management. He was elected to the National Academy of Engineering in 1996 for his leadership in energy policy and the safety and regulation of nuclear power. Dr. Ahearne has served on many NRC Committees in the past twenty years, and has chaired a number of these, including the current Committee on Evaluation of Quantification of Margins and Uncertainty Methodology Applied to the Certification of the Nation's Nuclear Weapons Stockpile and the Committee on the Internationalization of the Civil Nuclear Fuel Cycle. He is a Fellow of the American Academy of Arts and Sciences, the

American Physical Society, the Society for Risk Analysis, and the AAAS. In 1966, Dr. Ahearne earned his Ph.D. in Physics from Princeton University.

**Thomas W. Armstrong** retired in 2008 from his position as Senior Scientific Associate in the Exposure Sciences Section of ExxonMobil Biomedical Sciences, Inc., where he worked since 1989. Dr. Armstrong also worked with the University of Colorado Health Sciences Center as the lead investigator on exposure assessment for epidemiological investigations of potentially benzene-related or other occupational exposure-related hematopoietic diseases in Shanghai, China. Dr. Armstrong also spent nine years working for the Linde Group, as both the manager of loss control in the gases division and as a manager of safety and industrial hygiene. Dr. Armstrong conducted research on quantitative risk assessment models for inhalation exposure to Legionella, and remains professionally active on that topic. He has recently contributed to publications on mathematical models to estimate exposures to hazardous materials, and methods for exposure reconstruction. He was a member of the Society for Risk Analysis and remains an active member of the American Industrial Hygiene Association. The American Board of Industrial Hygiene certifies him as an Industrial Hygienist. Dr. Armstrong has an M.S. in Environmental Health and a Ph.D. in Environmental Engineering from Drexel University.

**Gerardo Chowell** is an Assistant Professor at the School of Human Evolution and Social Change at Arizona State University. Prior to joining ASU, Dr. Chowell was a Director's postdoctoral fellow with the Mathematical Modeling and Analysis group (Theoretical Division) at the Los Alamos National Laboratory. He performs mathematical modeling of emergent and re-emergent infectious diseases (including SARS, influenza, Ebola, and Foot-and-Mouth Disease) with an emphasis in quantifying the effects of public health interventions. His research interests include agent-based modeling, model validation, and social network analysis. Dr. Chowell received his Ph.D. in Biometry from Cornell University and his engineering degree in telematics from the Universidad de Colima, Mexico.

**Margaret E. Coleman** is a medical microbiologist, risk analyst, and sole proprietor of Coleman Scientific Consulting. She serves as president of the Upstate NY Society for Risk Analysis (SRA) and in other leadership roles, including her appointment to the Editorial Board for the journal *Risk Analysis*. Also an active member of the American Society for Microbiology (ASM), she contributed an article to ASM's *Microbe* (*Microbial Risk Assessment Scenarios, Causality, and Uncertainty*). Ms. Coleman contributes to peer review processes for several journals, including SRA's journal *Risk Analysis*. She was selected as an invited expert at three recent workshops on microbial dose-response assessment and served as a reviewer for two NRC Reports (*Reopening Public Facilities After a Biological Attack; Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities)* and as a Committee member on the *Review of Testing and Evaluation Methodology for Biological Point Detectors*. Her recent consulting work includes qualitative and quantitative risk assessments for biothreat agents and related non-pathogenic species by inhalation, dermal, and oral exposure routes. Ms. Coleman earned her B.S. degree from the SUNY College of Environmental Science and Forestry/ Syracuse University and M.S. degrees from Utah State University and the University of Georgia in Biology/Biochemistry and Medical Microbiology.

**Gigi Kwik Gronvall** is a Senior Associate at the Center for Biosecurity of University of Pittsburgh Medical Center (UPMC) and Assistant Professor of Medicine at the University of Pittsburgh. An immunologist by training, Dr. Gronvall's work addresses how scientists can diminish the threat of biological weapons and how they can contribute to an effective response against a biological weapon or a natural epidemic. She is a term member of the Council on Foreign Relations and also serves on the American Association for the Advancement of Science (AAAS) Committee on Scientific Freedom and Responsibility. Dr. Gronvall is a founding member of the Center for Biosecurity of UPMC and, prior to joining the faculty in 2003, she worked at the Johns Hopkins University Center for Civilian Biodefense Strategies. From 2000-2001 she was a National Research Council Postdoctoral Associate at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland. Dr. Gronvall earned a Ph.D. from Johns Hopkins University for her work on T-cell receptor/MHC I interactions.

**Eric Harvill** is an Associate Professor of Microbiology and Infectious Diseases at the Pennsylvania State University. His primary research interest is in the interactions between bacterial pathogens and the host immune system, and his group investigates both bacterial virulence factors and host immune functions at the molecular level using the tools of bacterial genetics and mouse molecular immunology. These studies investigate the effects these molecular-level activities may have on the population-level behavior of infectious diseases. Dr. Harvill has served on several NRC Committees, including the Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis. He has reviewed for more than 20 scientific journals and serves on the Editorial Board for *Infection and Immunity*. Dr. Harvill has reviewed proposals for six different National Institutes of Health study sections, the U.S. Department of Agriculture and multiple international funding organizations. He has organized international and local meetings and chaired sessions at annual meetings of both the American Association of Immunologists and the American Society for Microbiology. He earned his Ph.D. at the University of California, Los Angeles.

**Barbara Johnson** has over 15 years of experience in the U.S. Government in the area of biosafety, biocontainment and biosecurity, and currently owns the consulting company Barbara Johnson & Associates, LLC. Dr. Johnson has managed the design, construction and commissioning of a BSL-3 Aerosol Pathogen Test Facility, and she launched the U.S. Government's first chemical and biological counterterrorism training facility. Research areas include biological risk assessment and mitigation, testing the efficiency of respiratory protective devices, and testing novel decontamination methods against biological threat agents. In the private sector she pioneered the development of the first joint biosafety and biosecurity programs between the United States and institutes in the former Soviet Union, and founded and directed a Center for Biosecurity in association with this work. She has served as the President of the American Biological Safety Association, and is the Co-editor of the journal Applied Biosafety.

**Paul A. Locke** is an Associate Professor in the Department of Environmental Health Sciences (EHS) at the Johns Hopkins Bloomberg School of Public Health. He is a public health scientist and attorney with expertise in risk assessment and risk management, radiation protection law and policy, and alternatives to animals in biomedical testing. Dr. Locke is a member of the Board of Directors of the National Council on Radiation Protection and Measurements (NCRP) and

chaired the NCRP's 2010 annual meeting program Committee. From 2004 until 2009 he was a member of the NRC Nuclear and Radiation Study Board, and has participated on two NRC Committees that evaluated the risks associated with the disposal of high-level radioactive waste. Dr. Locke has received several awards, including the Yale School of Public Health Alumni Service Award, and the American Public Health Association Environment Section Distinguished Service Award. He holds an M.P.H. from Yale University School of Medicine, a J.D. from Vanderbilt University School of Law, and a Dr.P.H .from the Johns Hopkins Bloomberg School of Public Health. He directs the EHS doctoral program in Public Health.

**Warner North** is President of NorthWorks, Inc., a consulting firm in Belmont, California. Dr. North is also a consulting professor in the Department of Management Science and Engineering at Stanford University. Over the past 40 years, Dr. North has carried out applications of decision analysis and risk analysis for electric utilities in the United States and Mexico for petroleum and chemical industries, and for government agencies with responsibility for energy and environmental protection. He has served as a member and consultant to the Science Advisory Board of the Environmental Protection Agency since 1978, and as a presidentially appointed member of the U.S. Nuclear Waste Technical Review Board. Dr. North has served as a member of the NRC's Panel on Public Participation in Environmental Assessment and Decision Making and on numerous NRC Boards and Committees, twice as Committee Chair. Dr. North is a past president of the International Society for Risk Analysis, a recipient of the Frank P. Ramsey Medal from the Decision Analysis Society for lifetime contributions to the field of decision analysis, and a recipient of the Outstanding Risk Practitioner Award from the Society for Risk Analysis.

**Jonathan Richmond** is CEO of Jonathan Richmond and Associates, a biosafety consulting firm with a global clientele. Prior to starting his own firm, Dr. Richmond was the director of the Office of Health and Safety at the Centers for Disease Control and Prevention in Atlanta, Georgia. He is an international authority on biosafety and laboratory containment design. Dr. Richmond was trained as a geneticist, worked for ten years as a research virologist, and has been involved in the field of biosafety for the past 25 years. He has authored many scientific publications in microbiology, chaired many national symposia, edited numerous books, and is an international consultant to ministries of health on laboratory safety and training. He served as President of the American Biological Safety Association.

**Gary Smith** is Chief of the Section of Epidemiology and Public Health in the School of Veterinary Medicine at University of Pennsylvania. He has a secondary appointment in the Department of Biostatistics and Epidemiology at the University of Pennsylvania's School of Medicine and is an Associate Scholar in the Center for Clinical Epidemiology and Biostatistics. He is also an affiliated faculty member of Penn's Institute for Strategic Threat Analysis and Response. His research deals with the epidemiology and population dynamics of infectious disease in humans as well as wild and domestic animal species. He has extensive experience of mathematical modeling in the context of infectious and parasitic disease control strategies (including the evolution of drug resistance) and has published case-control studies on a range of infectious diseases of animals and humans. Dr. Smith served on an FAO/WHO Expert Committee on the implementation of farm models in the developing world; he served on the Pennsylvania Food Quality Assurance Committee, and he was a member of a European Union

Expert Committee on Bovine Spongiform Encephalopathy risk. He has served on the editorial boards of *Parasitology Today*, *The International Journal of Parasitology*, *The Veterinary Quarterly*, and *Frontiers in Ecology and the Environment*. Dr. Smith earned Bachelors degrees in Zoology and Education from the Universities of Oxford and Cambridge respectively and a D.Phil. in Ecology from the University of York.

## Attachment B: List of Editorial Comments

### Chapter 1

p. 1-17, line 30: "Reasonableness" may not be the best descriptor; wouldn't "rigor" be a better term?

p. 1-20, line 15: Are the worker populations at the respective sites truly "equal"? Is there any intent to pursue local hiring in preference to other approaches?

### Chapter 2

p. 2-6, line 18: "*Biomolecule Production Core.* This operational service is responsible for developing SOPs for propagation and titration of all BSL-4 pathogens that will be used in the NEIDL."

Not clear why the Biomedical Production Core will develop SOPs for titration of BSL-4 pathogens. Is this not a normal practice for the researchers?

P.2-7, line 19: "*Specimen Processing Core.* This service supports NEIDL investigators in studying emerging infectious diseases by handling the collection and storage of animal specimens and cultures in the appropriate biocontainment setting (e.g., BSL-2, BSL-3)."

Who will be responsible for the storage of BSL-4 materials, and where will that be done?

p.2-8, line 11: "The BAS controls or monitors environmental and other 11 operational parameters (temperature, humidity, flow, and pressure values) for individual areas or 12 rooms, fire suppression, and liquid waste treatment."

Will the BAS also control the lighting in animal rooms?

P.2-10, line 7: "All electrical conduit, plumbing, piping, supply and exhaust ducts and miscellaneous 7 penetrations are sealed at the point of penetration into the high biocontainment laboratories (BSL-3 and BSL-4)."

"High containment" = BSL-3; "maximum containment" = BSL-4. This should be used throughout the report.

P.2-12, line 4: "In general, biological indicator vials are placed inside biocontainment bags containing the material to be processed in the autoclave. If the autoclave does not reach the programmed temperature, the spores will subsequently grow, and change the color of a pH-sensitive chemical in the growth medium."

Consider the following: In order to incubate the biological indicator, it has to be removed from the biohazard bag. If the spores should grow (indicating incomplete decontamination), then someone (plus the local area where the bag was opened outside of containment) will be

potentially contaminated. This is why the biological indicator is placed in "dummy" bags to mimic the contents of the biohazard bag.

p. 2-12, line 26: "A Class III BSC, is illustrated in Figure 2-4."

Figure 2-4 is a centrifuge; a Class III BSC is not shown. This figure is also referred to (appropriately) in the next section on centrifuges. The figure should be moved and a picture of a Class III BSC added at Figure 2-4.

P.2-14, line 10: "Ultra-low temperature freezers (Figure 2-5) provide long-term protection and storage for valuable samples of biohazardous materials."

An important feature (not mentioned in the draft report) is that such storage freezers need to be equipped with locks for biosecurity.

p. 2-16, line 29: "The IBC coordinates its application procedures with two other offices, Research Occupational Health Program (ROHP), to ensure that research personnel have adequate occupational health monitoring, training on safe work practices, exposure control emergencies, and use of PPE."

What is the second office? Only ROHP is listed.

p. 2-17, line 12: **2.1.4.3 Standard Operating Procedures and Training**

Generic question: Who reviews/approves SOPs?

p. 2-19, line 15: "Such materials are biological samples needing further analysis…"

What is the SOP for removing samples "for further analysis"? Where will that be done? Will they be irradiated? It would be helpful to describe this.

**Appendix A**

p. A-6, lines 4-8: Several of the items referenced are not "codes," but "guidelines" based on best practices and principles of biocontainment.

p. A-10, line 18: "… (e.g., an escape bottle air apparatus)."

Please describe.

p. A-18, line 8: "Work being performed within high-level biocontainment areas will be monitored by systems to ensure that at least two authorized persons are in each area at all times to ensure safety and minimize risk of an individual initiating a malevolent or unauthorized act."

Excellent procedure.

p. A-26, line11-12: “Gas decontamination will be considered for large pieces of equipment (e.g., penning, BSCs, carts) because gases pass between barriers of biocontainment.”

This does not make sense. Please clarify.

**Chapter 3**

p. 3-15, line 7- 8: “The disease occurs worldwide and in the US in animals. There are a significant number of naturally occurring cases reported in the US annually.”

The first sentence should be reworded as follows: “The disease occurs in animals worldwide and in the US.”

What does “significant” mean? Can a specific number or range be provided?

p. 3-17, line 24-25: “A vaccine was available for both military and civilian use that was offered to laboratory workers; however, currently, there are no FDA-approved vaccines available for *F. tularensis*.”

This sentence suggests that the vaccine for laboratory workers is no longer available, but this is not the case. A non-FDA approved tularemia vaccine is still available for lab workers from the special Immunizations Program at Fort Detrick, MD.

**Chapter 9**

Case fatality rate (CFR) should be used instead of mortality rate in the discussions in this chapter.