

## ***5.0 RESPONSE TO COMMENTS***

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### **DEIS Comment Period**

The Draft Environmental Impact Statement (DEIS) was issued on October 15, 2004, with a Notice of Availability published in the Federal Register on October 22, 2004. A 75 day comment period was allowed. A public meeting was held on November 10, 2004. In response to comments on the DEIS, NIH decided to issue a Supplemental Draft EIS (SDEIS), which provided more information and more clearly displayed how scoping comments and comments on the DEIS were addressed.

### **SDEIS Comment Period**

The SDEIS was issued on April 1, 2005, with a Notice of Availability that appeared in the Federal Register. A 48 day comment period was allowed. Comments postmarked (or e-mailed or faxed) by May 18, 2005, appear in this chapter. Comments postmarked or received after May 18, 2005 were considered, but no formal response appears in this chapter. Comments contained in the late responses were similar to the comments included below. A public meeting was held on April 25, 2005, where oral comments were taken. Comment from the public meeting can be found in the Meeting Transcript following comment letter #115.

### **Response to Comments**

Each comment letter, email or fax submitted on the SDEIS was given a document number and electronically scanned. Substantive comments within the letters were marked with a bracket and assigned a number corresponding to a response found on the right side of the page.

Responses to individual comments reflect why no change was made or where changes have been made to address the comment. Many comments had already been addressed in the EIS and the responses to such comments point to the location in the FEIS where those comments were addressed.

Several comments were made that require no specific response but which will be considered by the NIH in its final decision. These comments generally show support for or opposition to the project, provide personal background information, or contain other information to which a response is not required.

A list of acronyms used in the response to comments may be found at the end of this chapter.

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Comments at SDEIS Hearing – April 25, 2005

Valerie Nottingham  
NIHB13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Ms. Nottingham,

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,



## LETTER 1

### S. Abbott

- 1.1 The SDEIS is an NIH document. The Council on Environmental Quality's regulations implementing the National Environmental Policy Act permit the preparation of EISs by contractors selected by the agency responsible for the EIS. 40 C.F.R. § 1506.5(c). The fact the private consultants participated in the preparation of the SDEIS does not render the EIS flawed. These consultants have no financial or other interest in the decision that the NIH will make in NIH's Record of Decision (ROD) or otherwise in the outcome of the proposed Boston-NBL project. The NIH will make an independent, objective decision on whether to proceed with the Proposed Action and report it in the NIH's ROD.
- 1.2 The proposed Boston-NBL is not expected to have an impact on housing prices. As noted in Section 4.2.1.1 of the FEIS, "With over 250,000 housing units in the City of Boston, the Project would have no adverse impact on housing stocks." However, the project would contribute approximately \$920,000 in non NIH funds for the creation of affordable housing.
- 1.3 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 with the input of concerned citizen advocates. The model was developed using the CDC report entitled *Public Health Assessment of Potential Biological Terrorism Agents* (U.S. DHHS 2002a); "weight of evidence" or WOE methodology; conservative estimates at each decision point; and was based on laboratory data generated in simulated "drop" studies. See Section 4.2.1.1 and Appendix 12 of the FEIS.
- 1.4 The worst case scenario recognizes the potential for human error and concludes that under the worst case an individual could be exposed to less than one *B. anthracis* spore. This dose of organisms is not infectious for normal or immuno-compromised individuals. Therefore, the risk, even assuming human error, is negligible. See

**LETTER 1**

**S. Abbott**

Section 4.2.1.1 "Community Safety and Risk – Worst-Case Release Scenario Risk Assessment" and Appendix 12 of the FEIS.

LETTER 2  
Albany LLC

ALBANY LLC  
P.O. Box 157  
Wayland, MA 01778

Ms. Valeric Nottingham  
Environmental Quality Branch  
Division of Environmental Protection  
National Institutes of Health, B13, Room 2W64  
9000 Rockville Pike  
Bethesda, MD 20892

RE: National Level 4 Emerging Infectious Disease Laboratory  
Albany Street, Boston, MA

Dear Ms. Nottingham,

I am writing to you in support of the Level 4 research laboratory proposed for the Biosquare site on Albany Street in Boston, Massachusetts. My business owns and manages a commercial building across the street from the site of the proposed laboratory. Over the past ten years, I have attended many meetings of the Biosquare Public Advisory Committee formed under the auspices of the Boston Redevelopment Authority and, since its inception last year, I have attended several meetings held by the B-LAG Advisory Group formed by the Boston University Medical Center. These groups have provided answers to many questions about the laboratory construction, security and operations as well as about the research planned to take place in the laboratory. Both of these advisory groups are expected to continue after the Level 4 lab is built.

While I continue to have many concerns about the site access, parking, and traffic patterns for the proposed development and about the positioning of other buildings within the security perimeter of the level 4 laboratory, I fully support the development of the level 4 laboratory on this site at this time. It is a tremendous opportunity for the City of Boston and New England to host this state of the art research facility. The nearby scientific talent that will be able to use this facility when it is completed will finally have the proper environment to do the necessary research to develop vaccines and treatments for dangerous diseases of the 21<sup>st</sup> century. I consider this use of the site to be fully compatible with the zoning of the site and with commercial uses that surround the site. We look forward to having the lab and its workers as neighbors.

If you have any questions, please do not hesitate to call me at (508) 358-4654.

Sincerely,

  
Bonnie L. Gossels, Manager

*Revd 5/16/05  
mme*

**LETTER 3**

**Alexander J. Allen**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab at BUMC.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,





2181 Washington Street, Suite 301 • Roxbury, MA 02119  
Tel 617-442-3343 • Fax 617-442-2425 • www.ace-ej.org

May 18, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Comment on the Supplemental Draft Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories, Boston, Massachusetts; EIS No. 040491

Dear Ms. Nottingham:

These are the comments of Alternatives for Community & Environment, Inc., (ACE) on the Supplemental Draft Environmental Impact Statement (SDEIS) for the National Emerging Infectious Diseases Laboratories (bioterrorism laboratory<sup>1</sup> or National Biocontainment Laboratory (NBL)) planned for Boston, Massachusetts.

ACE is part of the Stop the BU Bioterrorism Lab campaign, a coalition of many persons and groups, both within and outside Boston, that believe that the proposed laboratory, which would be owned by Boston University, presents too many environmental, health, and safety risks to be located safely on Albany Street in Boston's densely populated South End/Roxbury neighborhood.

We are disappointed that NIH choose not to list or discuss how the SDEIS differs from the Draft Environmental Impact Statement (DEIS), and to which DEIS comments the SDEIS responds, thus requiring all interested parties to take much additional time in review. It appears that the SDEIS responds to only a few of the comments we submitted on the DEIS. Thus, our comments on the SDEIS, with a few exceptions, are similar to our comments on the DEIS. We also request that our comments on the DEIS be considered comments on the SDEIS.

As we explain below, we believe that the SDEIS inadequately and incorrectly describes the potential impact of the proposed bioterrorism laboratory and fails to comply with requirements of the National Environmental Policy Act (NEPA). As an initial matter, we will repeat the point we made in our March 1, 2004, comments on the scope of the EIS and in our December 23,

<sup>1</sup> 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 toxic biological agents that cause 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.

## LETTER 4

### Alternatives for Community and Environment

2004, comments on the DEIS: the National Institutes of Health (NIH) has failed to complete an EIS of appropriate scope. We will then discuss the problems with the SDEIS as presented by NIH.

**I. A PROGRAMMATIC EIS IS REQUIRED**

NIH must withdraw its decision to place an NBL in Boston because it failed to complete an EIS of appropriate scope.

4.1

NEPA requires NIH to have completed a Programmatic EIS for its biodefense research agenda before initiating a program to fund the construction of new laboratory space for bioterrorism research at numerous locations throughout the country. That includes completing a Programmatic EIS to evaluate its laboratory agenda before publishing the Request for Proposals and Applications for a specific NBL. Regulations of the Council on Environmental Quality (CEQ) require preparation of a Programmatic EIS for "systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive." 40 CFR § 1508.18(b)(3). Furthermore, for federally assisted research such as that at issue here, a Programmatic EIS "shall be prepared...and shall be available before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives." 40 CFR § 1502.4(c)(3). NIAID's decision to fund 2 NBLs and 9 RBLs, pursuant to its Homeland Security-directed "biodefense research agenda," epitomizes a systematic and connected agency decision that has committed substantial funding that will restrict future alternatives. Thus, NIH should have created a Programmatic EIS before initiating the program under which it now intends to fund the construction of an NBL at BioSquare in the South End/Roxbury section of Boston.

4.2

In addition, NEPA requires NIH to have completed an EIS and the NEPA process before choosing Boston University (BU)'s proposal to construct an NBL in the South End/Roxbury section of Boston. NEPA unequivocally mandates as a prerequisite to such federal action that the agency undertake a rigorous environmental review before making any decision that could significantly impact the environment. NEPA, 42 U.S.C. § 4321 et seq., and its implementing regulations, 40 CFR § 1500 et seq. Because NIH's decision to grant \$127 million to construct an NBL could significantly impact Boston's environment through physical impacts such as increased traffic in the BioSquare area and airborne release of deadly pathogens, NEPA requires NIH to have completed an EIS prior to making the funding decision. NIH should have completed an EIS after it received the applications for NBL funding and before choosing which applicants to fund and the sites for the NBLs.

In promulgating NEPA in 1969, Congress intended that the EIS requirement fully and fairly inform decision makers of a project's potential adverse environmental impacts and reasonable alternatives before that body reached a decision. The Council on Environmental Quality's implementing regulations reflect this purpose by requiring that agencies abstain from committing resources that could prejudice the selection of alternatives until after making a final decision. 40 CFR § 1502.2(f). These regulations further state that "[e]nvironmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made." 40 CFR § 1502.2(g). Moreover, for a proposal initiated by a

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**Alternatives for Community and Environment**

4.1 A Programmatic Environmental Impact Statement is not necessary to assess the potential environmental impacts of the various biocontainment facilities proposed to be either constructed by the NIH itself or partly funded by the NIH. The various proposed biocontainment facility projects are not located in the same geographic region, and the proposed projects' potential impacts are neither synergistic nor cumulative. The various projects are not so interrelated or connected that their possible environmental impacts cannot be considered independently. Moreover, the NIH's approval of one project does not commit the agency to approve the other projects. As required by NEPA, the NIH is conducting an environmental review for the various biocontainment facilities.

Additionally, the regulation cited first in the comment, 40 C.F.R. § 1508.18(b)(3), says nothing about programmatic EISs; this regulation simply lists types of Federal actions. The other regulation cited in this comment, 40 C.F.R. § 1502.4(c)(3), is not applicable to the NIH's decision to prepare a separate EIS assessing the environmental impact of partially funding a National Biocontainment Laboratory at Boston University. The decision to fund the proposed Boston-NBL has not reached "a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives". 40 C.F.R. § 1502.4(c)(3). The NIH's decision to partly fund the proposed Boston-NBL remains subject to the completion of the NIH's NEPA review for the project and the selection of a course of action in the NIH's ROD.

4.2 Any decision by NIH to partly fund the proposed Boston-NBL remains subject to the completion of the NIH's NEPA review for the project and the selection of a course of action in the NIH's ROD.

private party, the CEQ regulations direct agencies to begin NEPA documents "no later than immediately after the application is received." 40 CFR § 1502.5(b). NIH did not immediately commence the NEPA process after receiving BU's application in February of 2003. Instead, NIH decided to fund NBL construction on a site in Boston, and chose BU to build the NBL on that site, before drafting an EIS. NIH failed to analyze the potential adverse environmental impacts and reasonable alternatives. Consequently, NIH's failure to draft an EIS violated NEPA, and the completion of NIH's current process would constitute a mere justification for having already committed funding for the laboratory construction.

4.3

A clear example of NIH's failure to follow NEPA requirements is its description in the SDEIS, at 1-9, that the proposed action is "to partially fund the construction of the Boston-NBL at the BioSquare Research Park in Boston, Massachusetts." The purpose of the SDEIS should have been to determine how to structure NIAID's program of grants to fund the construction of NBLs and RBLs around the country, and its funding of the so-called Regional Centers of Excellence, to minimize the potential environmental impacts and then to compare the environmental impacts of the potential NBL and RBL locations based on the acceptable applications it received. By limiting the SDEIS to a review of the BioSquare location, NIH fails to provide the NEPA mandated determinations and comparisons.

The SDEIS, at 1-9, incorrectly claims that NEPA does not require the preparation of a programmatic EIS for the overall NBL and RBL program because each project represents an independent undertaking located in geographically dispersed areas with no common cumulative impacts. Instead, the proposed laboratory in Boston is part of an integrated biodefense research agenda that includes two NBLs, more than one dozen Regional Biocontainment Laboratories (RBLs), numerous Regional Centers of Excellence (RCEs), an expansion NIH's own soon to be BSL4 laboratory in Hamilton, Montana, and a great increase in funding of research on select agents that could potentially be used in bioterrorism. The SDEIS states as much when it notes, at 2-40, that the NBL will support the research of the RCEs, and at 2-43, that those applying for funding for an NBL have linkages with the institutions applying for RCE grant awards.

4.4

Based on the above NEPA violations by NIH, we call upon NIH to retract its decision to fund BU to construct an NBL near Boston Medical Center. NIH should begin the NEPA process by drafting a Programmatic EIS for its biodefense research agenda.

**II. THE ENVIRONMENTAL JUSTICE ANALYSIS IS FLAWED AND DEFICIENT**

The Environmental Justice analysis in the SDEIS describes a larger geographic area than did the DEIS, but otherwise contains the same deficiencies found in the SDEIS. Thus, we begin by including our comments on the DEIS and then make some additional comments relating to the Environmental Justice analysis in the SDEIS.

4.5

The environmental justice analysis contained in the DEIS is flawed and deficient in several significant respects: (1) it substantially undercounts the minority population of the community surrounding the proposed lab; (2) it consistently understates the potential environmental impacts of the lab on the surrounding community; and (3) it fails to take account of the disproportionate health and

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4.3 The EIS for the proposed Boston-NBL addresses and analyzes fully the potential environmental impacts of any decision by the NIH to partially fund the construction of the building. The proposed Boston-NBL project is clearly an action distinct from the other proposed biocontainment facilities referenced in the comment. This comment appears to request the preparation of a Programmatic EIS for the various biocontainment projects being either partly funded by the NIH or considered for partial funding by the NIH. A Programmatic EIS for these facilities is not necessary to assess the potential environmental impacts of the various biocontainment facilities proposed to be either constructed by the NIH itself or partly funded by the NIH, including the proposed Boston-NBL. The various proposed biocontainment facility projects are not located in the same geographic region, and the proposed projects' potential impacts are neither synergistic nor cumulative. The various projects are not so interrelated or connected that their possible environmental impacts cannot be considered independently. Moreover, the NIH's approval of one project does not commit the agency to approve the other projects. As required by NEPA, the NIH is conducting an environmental review for the various biocontainment facilities. See Section 1.8 of the FEIS.

4.4 A Programmatic Environmental Impact Statement is not necessary to assess the potential environmental impacts of the various biocontainment facilities proposed to be either constructed by the NIH itself or partly funded by the NIH. The various proposed biocontainment facility projects are not located in the same geographic region, and the proposed projects' potential impacts are neither synergistic nor cumulative. The various projects are not so interrelated or connected that their possible environmental impacts cannot be considered independently. Moreover, the NIH's approval of one project does not commit the agency to approve the other projects. As required by NEPA, the NIH is conducting an environmental review for the various biocontainment facilities. The

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environmental reviews for several of these actions have already been completed, including those for a National Biocontainment Laboratory at the University of Texas Medical Branch in Galveston, Texas, and for two Integrated Research Facilities at which intramural NIH research will be conducted.

4.5 Information provided in the SDEIS was based on the most current, available US Census data on population and income. As described in Section 4.4.1.1, the SDEIS showed that the facility poses no significant environmental or public health impacts. There is no disproportionate impact on minorities due to the fact that the analysis of the potential effects indicates that the project is not a dangerous undertaking.

4.5



environmental burdens that are already being borne by the surrounding community.

While acknowledging in section 3.4 that the community surrounding the proposed lab meets federal criteria for an area of environmental justice concern, the DEIS significantly undercounts the minority population of that community. The DEIS defines the relevant community as consisting of two census tracts, numbered 711 and 712, which have minority populations of 31.5% and 42.5% respectively. A much more realistic assessment, that takes account of the significant minority neighborhood of Roxbury immediately to the south of the laboratory, would incorporate all the census tracts around tracts 711 and 712. This would include tracts 801, 804, and 805 to the south as well as tracts 704, 705 and 712 to the north and east. The total population of this larger area is 23,747, of which the minority population (not including Latinos/Hispanics) is 14,794 or 62.3%.

Moreover, the DEIS utilizes census data that does not include a category for Latinos/Hispanics, although such data is available from the Census Bureau. If Latinos/Hispanics are considered, the minority population of census tract 711 is 54.5% and the minority population of census tract 712 is 64.4%. Considering all of the surrounding census tracts, which as noted above is a far more accurate portrayal of the community's demographics, the minority population of the community surrounding the proposed lab is 68.4%.

The DEIS also significantly understates the environmental burdens posed by the proposed lab to the surrounding community. The DEIS bases its assessment of the environmental justice burden on a single worst-case scenario for the release of aerosolized anthrax spores, and then concludes that there is no burden. Putting aside the deficiencies in that analysis (discussed later in these comments), there are other obvious risks posed by bringing highly infectious substances into a densely populated area. These include the risks posed by other infectious agents (besides anthrax), some of which do not even exist today and whose risks to health and the environment are not known. There are also risks posed by the transportation of infectious agents to the proposed lab through densely populated neighborhood streets, and a potential escape of an infected animal or insect from the lab. While there may, to date, be no reported history of releases of infectious substances while they are being transported, there is a long history of accidental releases of conventional hazardous substances during the course of transportation and at least one recent incident of an escape of a laboratory animal. Environmental impact statements are expected to assume there *will* be such releases and to weigh the environmental effect of such releases on the surrounding community. The DEIS is deficient because it assumes there will be no such releases and then wishfully concludes that this assumption is all that must be considered.

The DEIS is also deficient because it fails to consider the disproportionate burden on health and the environment that is already being borne by the surrounding

community. Section 4.4.1 of the DEIS blithely states that “the neighborhood is not an area that currently has a disproportionate number of undesirable land uses.” That is simply untrue. Roxbury, the area immediately to the south of the proposed lab, has a disproportionate number of environmentally hazardous sites and facilities. According to a statewide study by Professors Daniel Faber and Eric Krieg, Roxbury is the eighth most intensively overburdened community in Massachusetts, when one takes account of the number of hazardous waste sites, trash transfer stations, polluting industrial facilities, power plants, and incinerators per square mile in the area. See D. Faber & E. Krieg, *Unequal Exposure to Ecological Hazards* 36 (Northeastern University 2001). Roxbury has ten times the average number of environmental burdens per square mile as the average Massachusetts community. *Id.* For example, according to current statistics maintained by the Massachusetts Department of Environmental Protection, the area has 269 listed hazardous waste sites.

Likewise, Roxbury already bears a disproportionate public health burden. According to data collected by the Boston Public Health Commission, Roxbury has the highest hospitalization rate of all the communities in Boston – 209.9 hospitalizations per 1,000 population, which is more than 50% more than the city as a whole. It has the highest rate of hospitalization for asthma in the city – 14.6 asthma hospitalizations per 1,000, which is 64% higher than the city as a whole and over four times the rate for several Boston neighborhoods. Roxbury also has the third highest number of emergency room visits – 10.3%, as compared to 2.0% for Charlestown and 2.7% for West Roxbury (both predominantly white communities). See [www.bphc.org/reports/pdfs/report\\_188](http://www.bphc.org/reports/pdfs/report_188).

All of these statistics are, regrettably, consistent with the disproportionate environmental and health burden borne by minorities in Massachusetts. Communities of color have more than four times the number of hazardous waste sites and nearly the five times the volume of industrial chemical emissions as predominantly white communities (communities that are over 95% white). See Faber & Krieg, at 25. Similarly, African Americans and Hispanics are far more likely than whites to suffer from health conditions such as diabetes, high blood pressure, hypertension or asthma. See Massachusetts Department of Public Health, *Minority Health Status Indicator Risk Ratios*, [www.mass.gov/dph/bhsre/resdep/hisp/99/hsi99.pdf](http://www.mass.gov/dph/bhsre/resdep/hisp/99/hsi99.pdf).

Despite Boston University’s aggressive public relations’ claims, the proposed lab would do nothing to address any of these public health problems. Instead, the lab would simply add to the disproportionate burdens already being borne by the predominantly minority community where it would be built. The DEIS does not consider these existing burdens at all; it falsely claims that they do not exist. The FEIS must contain a redone environmental justice analysis that is consistent with the actual composition of the surrounding community and that recognizes the additional burden that the laboratory will place on that community.

## LETTER 4

### Alternatives for Community and Environment

We have the following additional comments on the Environmental Justice analysis in the SDEIS:

Comparing the population of the South End to the City of Boston, as is done on many tables in the SDEIS, is the wrong comparison. The South End is an arbitrary neighborhood definition and does not reflect the whole neighborhood within reasonable proximity to the location of the proposed laboratory, as we noted in our comments on the DEIS. Further, the comparison should be to the Boston metropolitan area and to other proposed locations for the laboratory, not to the City of Boston.

### III. THE WORST CASE RELEASE SCENARIO IS FLAWED AND DEFICIENT

The SDEIS, at 4-3 to 4-7 contains a worst case release scenario that is somewhat different than the scenario presented in the DEIS, yet the scenario continues to be flawed and deficient in significant ways and does not present a true or accurate worst case scenario.

The SDEIS's purported worst-case release scenario is based on two reports entitled *Summary Report Hazard and Risk Assessment* (hereinafter, the "Summary Reports") prepared by RWDI West, Inc., and found in Appendix 9 of the SDEIS. One report is dated September 1, 2004; the other is dated March 23, 2005. Whether the SDEIS 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 in part on whether the Summary Reports are accurate and complete. As we discuss below, the Summary Reports are seriously flawed and deficient and do not present a worst-case release scenario. They are not a description of the potential environmental impact of the laboratory. They instead describe what may be considered best-case release scenarios.

Appendix 1 to these comments contains Professor Jeanne Guillemin's May 18, 2005, review of the March 23, 2005, Summary Report and October 24, 2004, review of the September 1, 2004, Summary Report. Dr. Guillemin has given us permission to include her reviews of the Summary Reports in our comments.<sup>2</sup> They should be considered a part of our comments.

Dr. Guillemin's conclusion upon her review of the Summary Reports is that:

... the two RWDI reports on Hazard and Risk Assessment fail to represent such threats as might exist to local communities by leaving out important medical and

<sup>2</sup> 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 recently published 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](http://www2.bc.edu/~guilleje/Homepage(Frames).html).

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4.6 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 with the input of concerned citizen advocates. The model was developed using information from the CDC report entitled *Public Health Assessment of Potential Biological Terrorism Agents*; utilizing "weight of evidence" or WOE methodology and conservative estimates at each decision point; and was based on laboratory data generated in simulated "drop" studies. The report containing the modeling data and results can be found in Appendix 12. The MPR model uses a highly conservative, aerosol-delivered dose to estimate risk to individuals who inhabit space, walk or reside in areas surrounding the proposed BU site. Based on work done by Brachman and co-workers (Brachman, et al. 1966) a conservative estimate of 500 spores over an 8-hr period was utilized as the pathogenic dose in the MPR model. The MPR model utilized 15 scenarios and was flexibly applied across the urban environment surrounding the site. In the MPR model, simplifying assumptions are made that are more unfavorable than analogous "credible" assumptions. The MPR model assumes that the spores, once released, disperse in simple but restrictive geometric patterns. In reality, spores released in the scenarios would disperse in a far more complex pattern (impacted by wind-speed, direction, environmental condition, etc.) resulting in significant dilution. The simple MPR model represents the concentrated eddy situation, thereby representing a maximized, though highly unlikely, risk. This approach makes calculations easier to understand by eliminating complex turbulence/dispersion models. It gives extra confidence that the actual risks to the community are less than the calculated risks presented in the analysis.

With regard to environmental contamination of soil, Turnbull and co-workers conducted tests for airborne movement of anthrax spores down wind from three heavily contaminated carcass sites (soil) under a variety of wind conditions (Turnbull 1998). Studies of the relationship between a contaminated site and the risks of humans or animals contracting pulmonary anthrax from that site show that even with highly

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contaminated soil sites, the risks are very low. The small number of spores released to the environment in highly conservative MPR modeling scenarios would remain airborne over long distances and times. The likelihood of significant soil contamination would be extremely small resulting in no human exposures at a pathogenic level (aerogenic or cutaneous).

epidemiological aspects of aerosol disease transmission. Their conclusion that no spores would be inhaled is based on a mechanistic model that ignores the complexities of disease transmission. Such complexities can be addressed by offering a flexible range in data input, which the RWDI authors appear reluctant to do.

In brief, Dr. Guillemín's conclusions about the March 23, 2005, Summary Report are that:

- Two important variables have been omitted from the Summary Report. That omission severely undermines the models used in the Report:
  - ▶ The Report ignores fundamental problems in calculating disease risks; and
  - ▶ The Report ignores significant epidemiological variables.

In brief, Dr. Guillemín's conclusions about the September 1, 2004, 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, including that:
  - ▶ The Summary Report used the wrong number of respirable anthrax spores per gram, estimating that 400,000 respirable spores per gram would be released and that no one would inhale even one spore of anthrax in a laboratory release. The correct number of respirable spores per gram is 40 BILLION, not four hundred thousand. If the Summary Report had used the correct number, it would have had to conclude that people would inhale anthrax spores resulting from a laboratory release. The study of the Sverdlovsk accidental release of anthrax in 1979 shows that those who died of anthrax inhaled as few as nine spores.
  - ▶ The Summary Report failed to consider the human dose response to anthrax spores (some people are more susceptible than others to contracting anthrax).
  - ▶ The Summary Report failed to consider the dispersal of anthrax spores in an urban environment and is not based on a site-specific analysis.
- 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, including from the release of biological pathogens expected to be in the laboratory that are more contagious than anthrax.
- 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.

The FEIS must correct the problems in the worst case scenarios identified by Dr. Guillemín.

In addition, the FEIS should analyze the potential environmental impact of the release of an infected insect or animal from the laboratory. We are aware of at least one instance in the past

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4.7 For security reasons, the specific routes to be utilized would not be identified. However, transportation of select agents to and from the Boston-NBL would be managed in accordance with all applicable local, state and federal regulations and guidelines and BUMC policy. These regulations and policies address appropriate notification, packaging, routing, and delivery protocols including delivery personnel screening, predetermination of routes, date and time of travel and delivery, and GPS monitoring to allow for vehicle tracking and response to incidents during travel time. See Appendix 7, High Hazard Material Management Policy. The requirements set forth for the proper packaging and shipping of select agents are inherently designed to make the shipment of these agents safe. After reviewing the DOT required packaging and the limited quantity of agent that would be shipped, it is expected that a vehicular accident would present a lesser potential exposure than that described in the worst-case scenario.

4.6

↑ two years in which a laboratory animal escaped into the community from an allegedly secure biological research laboratory in California. Boston University's application to NIH for funding of the laboratory recognizes the dangers inherent in an escape of an insect from the insectarium of the proposed laboratory.

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. An October 14, 2004, USA Today article reported 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 DEIS 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?"

↓ In addition, a December 15, 2000, memorandum obtained from NIH 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."

**IV. THE FEIS MUST 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**

4.7

↓ We repeat the comments we submitted on the DEIS; the comments are germane to the SDEIS:

The DEIS fails to contain any assessment of a release of a select agent when in transit to the laboratory. Instead, it discusses the protocols BU would use for

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4.8 A Threat and Vulnerability Analysis has been prepared for the proposed Boston-NBL facility. The document includes analysis and countermeasures, both overt and covert, to mitigate potential threats. Due to security concerns, this information will not be released to the public. However, an executive summary of the report can be found in Appendix 11.

shipment of biological materials. The FEIS must analyze the impact of the release of toxic biological agents into Boston while in shipment to the laboratory.

Two recent accidents that occurred during the shipment of infectious agents show that there is indeed a risk to the public from shipping and consequently the FEIS 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 additional federal rules are necessary to assure the safety of hazardous materials in transit. 67 Fed.Reg.157, p.53131 (August 14, 2002).

Further, the DEIS provides no information on designated transport routes. At a recent public hearing, a BU representative stated that the biological agents would not be transported on local streets. Yet, the Massachusetts Turnpike Authority prohibits the transport of hazardous materials (hazardous materials are those defined and listed in 49 CFR Chapter 1, Subchapter C, which include infectious 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, making transport on local streets likely. Because designated routes are not mentioned in the DEIS, it is unknown whether BU 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, and it is likely that local streets will need to be used, it is essential that the public, public health and emergency preparedness agencies, and regulatory agencies are fully aware and have the opportunity to comment during NEPA review on the routes of transport of select agents to the site. The FEIS must provide that information.

**V. THE FEIS MUST 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 COMMUNITY.**

We repeat the comments we submitted on the DEIS; the comments are germane to the SDEIS:

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4.8

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. Professor 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.

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 DEIS fails to analyze the threat of a terrorist attack or the consequences of a pathogen release caused by an attack. In public meetings, Boston University has claimed that any attack would destroy the stored pathogens, but that analysis must be provided for review and comment. Further, 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 DEIS contains no analysis of those risks. In addition the DEIS fails to analyze a release of select agents into the local community resulting from terrorist infiltration of the laboratory or nefarious actions by a laboratory researcher.

The risks to human life and the environment in the event of a terrorist infiltration of or attack on the laboratory are great because the laboratory will be located in a densely populated urban neighborhood, near residences, schools, and workplaces. An infiltration or attack that releases deadly pathogens will have a great likelihood of causing deaths due to the nearby population density; an attack that does not release deadly pathogens will nonetheless have the potential of causing damage to life and property because the laboratory is in close proximity to homes, schools, and workplaces. An appropriate DEIS would include an analysis of such threats and a comparison of how those threats and consequences would change if the laboratory were in another location.

The DEIS, at ES-4, notes that "[S]cenarios involving terrorist, intentionally destructive acts or other malevolent acts at the proposed Boston-NBI have been analyzed in an independent Threat and Risk Assessment (TRA)." Yet, NIH will not release the TRA, claiming it contains sensitive information. If the TRA contains security sensitive information related to how to secure the facility, NIH

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4.9 The SDEIS was a new document that incorporated the DEIS into it. All comments received during the DEIS comment period were used as scoping comments in the preparation of the SDEIS.

4.8

should delete that portion of the TRA and release a redacted TRA. NIH must release the TRA so that there can be public review and comment on the potential impact of malevolent acts on the laboratory and how that impact might be mitigated by changes in the design or location of the facility. For example, would siting the laboratory in a more secure location, not near a major thoroughfare, not on a highly used city street, and not near an area of helicopter overflights, make a terrorist strike less likely to occur or succeed? Would siting the laboratory in a less populated location mitigate the potential impact of a malevolent act? NIH's failure to release the TRA undermines the goal and requirement of NEPA that there be a full and fair review of the potential impacts of the laboratory.

**VI. THE FEIS MUST INCLUDE AN ANALYSIS OF ALTERNATIVE LOCATIONS FOR THE LABORATORY**

The SDEIS does not include a detailed analysis of alternative locations for the laboratory. Instead it briefly discusses and dismisses alternative locations owned by Boston University. Our comments on the DEIS were that NEPA requires a detailed analysis of various alternative locations, not only other locations owned by Boston University. The SDEIS does not consider or discuss any of the comments we made on the DEIS. Thus, we begin by including our comments on the DEIS; they are germane to the SDEIS. Then we make comments relating to the alternatives analysis discussion in the SDEIS.

4.9

Our comments on the DEIS were as follows:

The DEIS analyzed a no build alternative, but failed to analyze alternative locations outside of Massachusetts or in less densely populated areas within Massachusetts, including on current and former military bases. NIH notes that it failed to analyze other alternative locations because NIAID's objective is to fund construction of the laboratory at BioSquare and alternative locations would not meet that objective. NIH predicates its decision on its determination that the BioSquare location is a "unique setting."

NIH's rationale for not studying alternative locations for the laboratory is deeply flawed and inconsistent with NEPA. First, as we noted in Section I., above, NEPA mandates that NIH start the process with a programmatic EIS. NEPA does not allow NIH to choose a laboratory location and then limit its NEPA review to options for that location, based on the justification it used to choose the location.

Second, as we noted in Section V, above, the impact of a release due to terrorism or other malevolent acts might be mitigated or eliminated if the laboratory were located in a more secure or less densely populated location. It is incumbent on NIH to analyze other locations for the laboratory and to compare the impact of terrorism and other malevolent acts at each location.

Third, NIH must compare the Boston University proposal for the BioSquare location to each of the other NBL applications that it received. That analysis

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would include the ranking of each applicant, a discussion of the advantages and disadvantages of each location, and whether the potential environmental impacts differ from one location to another. The BioSquare location may be a "unique setting," with some specific advantages, but it also has significant disadvantages due to its urban location. Other applicants likely provide unique advantages and disadvantages also, and perhaps there would be less environmental impact at another location. To comply with NEPA, the FEIS must include such comparison.

Fourth, NIH should compare the Boston University proposal for the BioSquare location to an expansion of the laboratories at existing BSL4 locations as well as the Rocky Mountain Laboratories location. Each of those locations is also a "unique setting where established teams of researchers already work side-by-side on medical research." DEIS at 2-32. Thus, as similarly unique settings, a comparison of environmental impacts is appropriate and consistent with NIH's rationale for choosing the BioSquare location.

Fifth, locations within an hour's drive of Boston, including some current and former military bases, would meet NIH's rationale for choosing the BioSquare location and should be analyzed as alternative locations. Those locations are easily accessible to local teams of researchers. Some of those researchers live closer to those locations than they do to BioSquare. Those other locations have the advantages of higher levels of security and lower population densities than BioSquare. There may be less of an environmental impact and more economic benefit in locating the laboratory at one of those locations.<sup>3</sup>

Sixth, as discussed in Section VII, below, Boston regulations prohibit recombinant DNA use that requires BSL4 containment. NIH appears to have failed to determine the effect of the Boston regulation on the BioSquare location or to determine whether other locations would be more advantageous without such prohibition.

We have the following additional comments on the SDEIS discussion of alternative locations. The SDEIS states (ES-2) that the purpose

is to provide a highly contained and secure laboratory dedicated to studying emerging and re-emerging infectious diseases, many of which have potential as bioterrorism agents.

Section 1.3, entitled *Purpose and Need for Action*, does not define the purpose and need for the project (which is the construction of the NBL in Boston). Instead, it states that:

<sup>3</sup> The DEIS, at 2-33, claims that the worst case scenario shows that locating the laboratory in a lower density area would not reduce the risk to the public. As we explain in Section III, the worst case scenario is deeply flawed. A correct analysis would show that locating the laboratory in a lower density area would reduce the risk.

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4.10 As required under the NEPA regulations, the FEIS includes an analysis of alternatives to the Proposed Action, which is to partially fund the construction of the Boston-NBL facility at the BioSquare Research Park. The alternative analyzed is the No Action Alternative. As noted, Section 2.3 includes a summary of an alternative siting analysis undertaken by BUMC prior to making its decision to site the proposed NBL facility at the BioSquare site. As described in Section 2.3.2, the distance of the Tyngsborough and Peterborough sites from the City of Boston were not the only determining factors in their removal from the universe of sites for location of the facility. Other factors include lack of infrastructure and medical trauma facilities; increased costs and lack of efficiencies gained by ability to use existing BSL-2 and BSL-3 laboratories at the BioSquare Research Park; and inefficiencies in personnel costs.

The overall objective of NIAID's NBL construction program is to provide funding to design, construct and commission comprehensive, state-of-the-art Biosafety Laboratories (BSLs) including BSL-4, BSL-3 and BSL-2 laboratories, as well as associated research and administrative support space (see Appendix 1, "The Need for Biosafety Laboratory Facilities", prepared by NIAID, February 2004).

This Alternatives Analysis presented in the SDEIS does not support that purpose and need. Section 1.4.2 of the SDEIS states that "The NIH must consider three types of alternatives to determine the scope for analysis (40 CFR 1508.25(b)): no action, other reasonable courses of action and mitigation. Other reasonable courses of action include alternatives that meet the stated purpose and need."

This statement requires NIH to consider all reasonable courses of action that meet the purpose and need, to provide a laboratory. Therefore, the alternatives analysis must include all reasonable locations in the United States, and not just one in Boston. While this may make the DEIS unwieldy, it is precisely this reason that programmatic environmental impact statements are prepared as discussed elsewhere.

CEQ's Question 2a in the 40 FAQs<sup>4</sup> states that:

Section 1502.14 requires the EIS to examine all reasonable alternatives to the proposal. In determining the scope of alternatives to be considered, the emphasis is on what is "reasonable" rather than on whether the proponent or applicant likes or is itself capable of carrying out a particular alternative. Reasonable alternatives include those that are practical or feasible from the technical and economic standpoint and using common sense, rather than simply desirable from the standpoint of the applicant.

NIH has focused only on what is desirable in violation of Section 1502.14

An Alternatives Analysis in an EIS is guided by NEPA, 40 CFR 1508.25, the CEQ Regulations, CEQ's 40 FAQs, and on the lead agency's NEPA Compliance Procedures. The Alternatives Analysis framework presented in this SDEIS is inconsistent with all of these regulations and procedures in that alternatives that are selected for analysis are based on the following siting criteria (2-36):

"Sites for the proposed 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:

1. The site must be controlled (owned or currently leased) by Boston University (to remain within funding and timing constraints); and

<sup>4</sup> <http://ceq.eh.doe.gov/nepa/regs/40/40p3.htm>

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4.11 The EIS fully considers the reasonable alternatives to the proposed action and explains the reasons for eliminating other possible alternatives from further study. The preliminary site analysis performed by BU was similar to the analysis contained in the EIS. Section 2.3.2 of the EIS describes sites that were considered as alternative locations for the proposed NBL and the reasons for eliminating these sites from further study. The site analysis in section 2.3.2 of the EIS was prepared in order to determine whether any sites would be feasible for the proposed NBL. This analysis demonstrated that other sites considered were not feasible, and those sites were eliminated from further study. As described in Chapter 2, several factors were the basis for eliminating possible alternatives from further review, including the distance of the sites from the City of Boston, the lack of infrastructure and medical trauma facilities, increased costs and lack of efficiencies gained by ability to use existing BSL-2 and BSL-3 laboratories at the BioSquare Research Park, and inefficiencies in personnel costs. Additionally, a primary reason for rejecting other alternatives is that they failed to enable the NIH to satisfy the purpose and need of the proposed action.

2. The lot size must be sufficient to accommodate a minimum building size of 190,000 sf and at the same time meet federal security setback requirements (to meet federal safety criteria).

Siting Criteria 1 is in violation of NEPA. CEQ's Question 2b in the 40 FAQs states that:

An alternative that is outside the legal jurisdiction of the lead agency must still be analyzed in the EIS if it is reasonable.

By pre-determining that the site must be controlled by BU, the proponent is eliminating reasonable alternatives without even assessing them. While the introduction to Section 2.3.2 states that locations outside of Massachusetts or lower density areas outside of Boston were evaluated, the following section eliminates them immediately by requiring that BU control them. This is a good example of how the EIS is being tailored to the project without any respect for the EIS process or the law.

In addition, the SDEIS incorrectly implies that BU owned the entire BioSquare Phase II parcel, where it proposes to locate the NBL, when it applied for funding to construct the NBL. The truth is that BU was still assembling the parcel until late into 2003. It owned the land on which the laboratory building would be located, but needed additional land for the associated parking garage and to secure the location. BU could have acquired other property in various locations. That it chose not to do so does not allow a NEPA analysis based on the only location BU chose to acquire.

While the CEQ regulations do not specify how many alternatives are required in an EIS, they refer to a "range of alternatives" and CEQ's 40 FAQs state that this refers all reasonable alternatives, which must be rigorously explored and objectively evaluated. Reasonable alternatives are generally considered to be ones that meet the project's purpose and need and that are feasible and practicable.

In addition, the DHSS General Administrative Manual, Part 30 (environmental protection) states that:

All reasonable alternatives (including no action) are rigorously explored and objectively evaluated (30-50-60)

The SDEIS ignores NEPA and the DHSS's own Administrative Manual by referring to the No-Action Alternative as a "reasonable alternative" in Section 2.1.

While Section 2.3.2 states that BUMC undertook a comprehensive site analysis prior to 2002, this site analysis (including the sites considered and reasons for their elimination) is not presented in the SDEIS, therefore making it incomplete. Similarly, page 2-40 states that numerous sites were submitted in response to the BAA and that the Boston one was selected based on multiple factors including a review of environmental issues. These factors, the list of sites, and the environmental review must be presented in the EIS.

4.11

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4.12 The public scoping process identified “alternative locations outside Massachusetts or lower density areas outside of Boston” as an alternative to be considered. Section 2.3.2 addresses alternative sites owned by Boston University outside of Boston. As the Boston University Charles River Campus is located in the City of Boston and is a densely populated area, it was not addressed as an alternative to the proposed location.

The FEIS describes the criteria used to evaluate alternative locations and applies them to the relevant alternative sites in Section 2.3.2. As stated in Section 2.3.2.1 of the FEIS, alternative locations were dismissed as they did not meet one or more of the following: (1) the purpose and need for the project, (2) the programmatic criteria, (3) the minimum siting criteria, and/or (4) the second tier siting criteria.

4.12

The SDEIS lists three other locations that are owned by BU (primary siting criteria): Main BU Campus, Corporate Education Center in Tyngsborough MA, and Sargent Center in Peterborough NH. In what is clearly a very cursory attempt to eliminate other potential sites (in response to comments made on the DEIS and in scoping), the SDEIS makes several errors or omissions:

The SDEIS seems to rely on a letter from the Conservation Law Foundation (to BU dated October 7, 2004)<sup>5</sup> that lists these three other locations. No effort was made to disclose or investigate other properties such as the Boston University Tanglewood Institute (BUTI)<sup>6</sup> or other properties that BU may lease. Thus, the SDEIS fails to even define a range of alternatives that meet the primary siting criteria that it defines (page 2-36)

The SDEIS mentions (page 2-37) the Main BU campus. Yet, in the descriptions that follow the SDEIS omits to present a description of the campus (as it does for the other 2 alternatives in Tyngsborough and Peterborough). It does not even present a reason for eliminating it. The other 2 alternatives are eliminated because they do not:

- Incorporate existing BUMC institutional programs and objectives,
- Support the research of other institutions in the greater Boston area, and
- Be considered in proximity to the proposed Harvard University Medical School’s NIAID-Sponsored Regional Center of Excellence.

The main BU campus DOES meet these criteria and therefore cannot be eliminated. Yet the SDEIS did not describe or assess this location.

The SDEIS presents a second tier of site evaluation (page 2-36). These include

- Proximity to the proposed Harvard University Medical School’s NIAID-Sponsored Regional Center of Excellence
- Ease of access to and use of existing medical research institutions/research facilities, opportunities for efficient medical research collaboration and ability to function as a training center (see “Figure 2-5. Location of Nearby Research Facilities”).
- Proximity to a trained workforce
- Proximity to state of the art emergency response programs and facilities including police, fire, public health and medical trauma
- Proximity to interstate highway systems and a regional airport
- Presence of adequate public infrastructure including water and sewer
- Facility use and building dimensions allowed under local zoning
- Siting achieves Smart Growth objectives (locating new development near existing transit and utility infrastructure and redeveloping brownfield sites).

Nonetheless, the three reasons cited on page 2-43 under the section Rationale for Dismissing, are

<sup>5</sup>[http://www.clf.org/uploadedFiles/CLF/Programs/Smart\\_Growth/Policy\\_Reform/20041007\\_BioSquare\\_Letter.pdf](http://www.clf.org/uploadedFiles/CLF/Programs/Smart_Growth/Policy_Reform/20041007_BioSquare_Letter.pdf)

<sup>6</sup> <http://www.bu.edu/cfa/music/tanglewood/index.htm>

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4.13 The consideration of alternative locations for the Boston-NBL included a number of programmatic and siting criteria which were deemed necessary to achieve the purpose and need for the project. Among those criteria were trained workforce, transportation infrastructure and utility infrastructure. Remote, rural areas of lower population density areas were found to lack the transportation and utility infrastructure necessary to support the project. The trained workforce needed to undertake the project was found to exist in the City of Boston and surrounding municipalities in the Greater Boston area and not in more remote areas. Many of the new employees for the proposed Boston-NBL facility would be recruited internally at BUMC which has an existing highly skilled work force of medical research staff. See Section 2.3.2 of the FEIS.

- Incorporate existing BUMC institutional programs and objectives,
- Support the research of other institutions in the greater Boston area, and
- Be considered in proximity to the proposed Harvard University Medical School's NIAID-Sponsored Regional Center of Excellence.

Of these three reasons, only the last one is consistent with the second tier screening criteria presented on page 2-36. The SDEIS is deficient in that it applies undefined screening criteria in an attempt to brush away potential alternatives.

The SDEIS states that

Areas of lower density outside of Boston would not have the:

- Proximity to trained workforce,
- Proximity to interstate highway systems and a regional airport, or
- Presence of adequate public infrastructure including water and sewer.

There is not much to say about this gross inaccurate assumption. Does the statement in the SDEIS mean that everyone who lives outside of Boston has no highway or airport and no water and sewer systems? In addition, the SDEIS notes that 63% of the workforce of the laboratory is expected to reside outside Boston, further undermining the claim that only in Boston would the laboratory have proximity to a trained workforce.

The SDEIS (Page 2-43) states that "one of the program requirements of the BAA was that the Applicant must be "associated with or have planned linkages to one or more institutions or consortia that are applying for NIAID Regional Centers of Excellence (RCE), Biodefense and Emerging Infectious Diseases research grant awards" (U.S. DHHS 2002b)." Information on the Regional Centers for Excellence are presented below (they are absent from the SDEIS):

"In 2003, NIAID established eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs) throughout the United States.  
(<http://www2.niaid.nih.gov/Biodefense/Research/rce.htm>)

Region I: Harvard Medical School New England Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://nerce.med.harvard.edu>

Region II: New York State Department of Health Northeast Biodefense Center  
<http://www.nbc.columbia.edu/>

Region III: University of Maryland, Baltimore Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://marce.vbi.vt.edu>

Region IV: Duke University Southeast Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://www.serceb.org>

Region V: University of Chicago Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://www.glrce.org>

Region VI: University of Texas Medical Branch Western Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://rce.swmed.edu/>

Region VII: Washington University Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases <http://mrce.wustl.edu>

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- 4.14 As required under the NEPA regulations, the FEIS includes an analysis of reasonable alternatives to the Proposed Action, which is to partially fund the construction of the Boston NBL facility at the BioSquare Research Park. The alternative sites described in Section 2.3.2 were considered but eliminated from further study. NEPA does not require that an EIS include a full analysis of every possible alternative. As also described in Section 2.3.2, several factors were the basis for eliminating possible alternatives from further review, including the distance of the sites from the City of Boston, the lack of infrastructure and medical trauma facilities, increased costs and lack of efficiencies gained by ability to use existing BSL-2 and BSL-3 laboratories at the BioSquare Research Park, and inefficiencies in personnel costs.
- 4.15 As stated in Section 2.2.2.2 of the FEIS, any research that may be conducted in the proposed Boston-NBL would comply with all applicable federal, state and local laws, including laws governing the use of recombinant DNA (rDNA).

4.14

Region X: University of Washington WWAMI (WA, WY, AK, MT, ID) Regional Center of Excellence for Biodefense and Emerging Infectious Diseases  
<http://depts.washington.edu/wwamirce/>

While on one hand the SDEIS states that the NBL must be linked to one or more institutions that are part of the RCE, it on the other hand states that it has to be in Boston. That is surely a violation of the environmental review process. As evidence, the primary siting criteria (page 2-36) singles out Boston University and not any institution in an RCE.

Furthermore, the SDEIS fails to mention that there are a number of institutions that are already linked to the Harvard University RCE as listed on the RCE website (<http://nerce.med.harvard.edu/>). These are:  
Harvard Medical School, Boston, MA  
Boston Medical Center, Boston, MA  
Brigham and Women's Hospital, Boston, MA  
The CBR Institute for Biomedical Research, Boston, MA  
Dartmouth Medical School, Hanover, NH  
Massachusetts General Hospital, Boston, MA  
New England Regional Primate Research Center, Southborough, MA  
University of Massachusetts - Dartmouth, Dartmouth, MA  
University of Massachusetts Medical Center, Worcester, MA

Again, the SDEIS's elimination of all alternatives except Boston University is a violation of NEPA and the DHHS General Administrative Manual, Part 30 (environmental protection).

**VII. THE FEIS MUST DISCUSS HOW THE LABORATORY WILL OPERATE CONSIDERING THE BOSTON PROHIBITION ON RDNA USE REQUIRING BSL4 CONTAINMENT**

4.15

We repeat the comments we submitted on the DEIS for the comments are equally germane to the SDEIS:

The Recombinant DNA Technology: Use Regulations of the City of Boston contain the following prohibition at section 3.01:

RDNA use requiring containment defined by the Guidelines<sup>7</sup> as "BL4" shall not be permitted in the City of Boston.

The regulations contain no exception or limitation to the prohibition. It is an absolute prohibition.

<sup>7</sup> The Boston regulations define the Guidelines as the NIH Guidelines for Research Involving recombinant DNA molecules as published in the Federal Register of May 7, 1986, and later amendments, revisions, or substitutions to the NIH Guidelines.

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4.16 Compliance with the many environmental health and safety regulations and internal policies and procedures is a shared responsibility. The Principal Investigator, researchers, lab workers, OEHS staff, radiation protection staff, and occupational medicine staff are all involved in monitoring compliance. A variety of approaches are taken to monitor compliance. For example, regular lab inspections are conducted by professional safety experts from the Office of Environmental Health and Safety and the Radiation Protection Office. The Lab Safety Committee, Institutional Biosafety Committee and Radiation Safety Committee monitor compliance, review inspection results and address any issues identified. External government agencies provide additional monitoring of compliance. These local, state and federal agencies monitor compliance by conducting inspections, issuing permits, licenses and approvals and if necessary, issuing penalties or even closing down unsafe lab operations. See Table 1-4 of the FEIS for a listing of the relevant regulatory authorities.

4.15

The FEIS should explain how the laboratory would conduct research in the BSL4 component, considering the Boston prohibition. We expect that much of the research in the BSL4 would include rDNA use. Our concern in part is that the laboratory would try to find ways to avoid the prohibition, which might include doing research outside BSL4 containment that should be done with BSL4 containment, thereby increasing the risk of release and damage to human health and the environment.<sup>8</sup> Alternatively, the laboratory might have rDNA work done elsewhere. That would reduce the desirability of locating the laboratory in Boston and argues for comparing the Boston location to other locations for the laboratory. Having rDNA work done elsewhere would also result in more virulent organisms being shipped to the laboratory, thus increasing the risk of damage to human health and the environment in the event of a release during shipment of the organisms.

**VIII. THE FEIS MUST EXPLAIN WHO WILL MONITOR WHETHER BU COMPLIES WITH THE SAFETY STANDARDS AND PROCEDURES AND ENFORCE COMPLIANCE**

We repeat the comments we submitted on the DEIS for the comments are equally germane to the SDEIS:

4.16

The DEIS explains, at 1-5, that the "three elements of containment" in biological research laboratories are "laboratory practice and technique, safety equipment and facility design." It fails to provide information on which agencies have the statutory and regulatory to monitor whether BU and laboratory researchers are taking the necessary actions to minimize the potential for a release and which agencies have the authority to enforce compliance. Table 1-3 of the DEIS, which lists representative agencies with regulatory responsibilities, does not indicate which agency, if any, will monitor BU's laboratory practice and technique, safety equipment, and facility design, or have the authority to take action if BU or other researchers fail to meet acceptable standards. Who checks up on BU and the laboratory researchers? What enforcement may be taken if there is a problem? Because NIH claims that the laboratory will be safe due to laboratory practice and technique, safety equipment, and facility design, the FEIS must contain a discussion and analysis of inspection and enforcement mechanisms. It should also list each of the standards that must be met.

**IX. THE FEIS MUST PROVIDE INFORMATION TO SUPPORT MANY OF THE STATEMENTS MADE IN THE DEIS**

The SDEIS includes many statements for which it provides no support or insufficient information to allow for review and comment. It also provides incorrect and misleading information. The FEIS must include supporting documentation, more information, and correct

<sup>8</sup> For example, the prohibition would prevent using any rDNA-modified organism while working with animals or insects in BSL4 containment even though BU's application for federal funding indicated that its BSL4 containment area would include both insect and animal research.

and complete information for the statements so that there can be informed public review and comment. Those statements include:

SDEIS page number      SDEIS statement and our comment

- 4.17 ES-1: The SDEIS states that the facility would not conduct research to develop biological weapons. This statement is repeated many times in the SDEIS, such as on pages E-2 and 1-4. The FEIS should discuss how this would be enforced, considering that the distinctions between offensive and defensive applications of research on bioterrorism agents are difficult to establish at many stages of the research process, that the "dual-use dilemma" recognizes that some research can be used for both offensive and defensive purposes, and that there is no international mechanism to assure that research complies with the requirements of the Biological Weapons Convention.
- 4.18 ES-3: The DEIS states that there facility would generate approximately 1,300 construction jobs and that once the facility is open approximately 660 new positions would be created. The FEIS should list the construction jobs, including length of each. The FEIS should also list the 660 new positions that would be created.
- 4.19 ES-4: The FEIS should explain why the percentage or Boston residents employed at BUMC would be the same percentage employed in the bioterrorism lab.
- 4.20 ES-5: The DEIS states that the annual payroll associated with the facility is \$33,000,000 and using the current economic multiplier the economic activity generated would be \$72 million annually, including \$19.7 million with the City of Boston, and that the total economic impact would be \$130.5M annually. The FEIS should show how the payroll would be \$33M, provide details on the economic multiplier and how the percentage within the City of Boston was determined, and how the \$130.5M figure was derived.
- 4.21 ES-5: The DEIS claims that the bioterrorism laboratory is "similar in nature to other research buildings in the area..." The FEIS should describe those similar buildings, why they are similar, and what their environmental and economic impacts have been.
- 4.22 ES: In 1999, BU submitted plans for the area that would have included development of the site, not retaining an at-grade parking lot. The FEIS should compare the bioterrorism lab development of the site to the 1999 BU plans.
- 4.23 1-4: The SDEIS mentions NIH safety standards, including recently revised construction and design standards. The FEIS should provide a citation to or a copy of those standards and explain how NIH will assure that BU meets those standards.
- 4.24 1-4: The SDEIS claims that senior experienced investigators would serve as research mentors for junior faculty, postdoctoral fellows, and graduate students. The FEIS should list those senior experience investigators and describe each person's experiences working in a BSL4 laboratory and with select agents. It should also discuss when and under what

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- 4.17 As discussed in Section 1.1 of the FEIS, the facility would not develop offensive or defensive biological weapons, as this is forbidden by a national security directive and international law. President Nixon issued National Security Decision Memorandum in November 1969 which renounced the use of lethal methods of bacteriological/biological warfare and ordered the destruction of all stockpiled agents. In addition, the United States signed the Convention on the Prohibition of the Development, Production, Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, which became effective March 26, 1975 (signed by President Ford and ratified by Congress) and remains in effect today.
- 4.18 The estimate of construction jobs created includes all of the various building trades utilized for construction of the facility. No breakdown of jobs by trade is available at this time, but the estimate represents 1,300 construction jobs over the course of the facility construction period. The new 660 permanent jobs would include positions at all levels from janitorial and maintenance services to building security to lab technicians, scientific researchers and principal investigators.
- 4.19 As described in Section 4.3.1.1, many of the new employees for the proposed Boston-NBL facility would be recruited internally at BUMC which has an existing highly skilled work force of medical research staff. Hence the existing current employee profile at BUMC is believed to be representative of the likely employee profile of the new facility based on the types of positions to be created.
- 4.20 The projected annual direct payroll is based on an estimate of the amount of research to be conducted in the building on an annual basis. The multipliers used to create the total annual economic impact and the impact within the City of Boston are from the U.S. Bureau of Economic Analysis, Regional Input-Output Modeling System - RIMS II (U.S. Department of Commerce 1997). See Section 4.3.1.1.

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- 4.21 The project is proposed to be located in the BioSquare Research Park as part of the BioSquare Phase II development. The BioSquare Phase I project which was approved by the state and the City of Boston several years ago, includes an existing 1,000 car parking garage and three medical research buildings including the 160,000 square foot (sf) Evans Research Building, the 180,000 sf Center for Advanced Biomedical Research Building and the 160,000 sf 670 Albany Street Research building. There is a fourth, 180,000 sf medical research building planned for the site. These other BioSquare research buildings are not part of the proposed action by NIH and thus are outside the scope of the FEIS.
- 4.22 The Proposed Action is for NIH to partially fund the construction of the Boston-NBL facility and therefore, the No Action alternative is to not construct the Boston-NBL facility. If the NIH decides to choose the no-action alternative, that would be the end of NIH's participation in developing this particular site.
- 4.23 The standards include all applicable local, state, and federal standards, in addition to compliance with the NIH Design and Policy Guidelines (U.S. DHHS 2003b), the CDC / NIH Biosafety in Microbiological and Biomedical Laboratories standards is applicable (U.S. DHHS 1999). The NIH has set in place a group of professionals design experts to monitor BU's design documents for compliance with the above standards.
- 4.24 At this time, no senior investigators have been assigned to a specific duty at the laboratory and thus, they cannot be identified. As described in Section 2.2.5.1, all personnel would be required to demonstrate proficiency in performing experiments in the BSL-4 laboratory prior to initiating such work.

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- 4.25 BUMC provides annual laboratory training as a minimum standard and increases training frequencies depending upon the type of work being done in each specific laboratory. BUMC would determine the levels of training necessary to ensure that all employees are compliant with and fully knowledgeable of all regulations. Regulatory authorities would ask for training rosters and levels of competency and would interview employees to determine if training, education and knowledge are appropriate. See Section 2.2.5.1.
- 4.26 The BSL-4 laboratory would comprise approximately 16% of the total assignable space of the new facility. The concept of total assignable space allows for a visualization of each element of the facility independent from the other elements of the facility. Also, total assignable space allows for an easier understanding of the spatial relationship between the individual elements and the overall facility. The facility would be designed and built following all applicable federal, state and local regulations. Table 1-4 provides a list of the federal, state and local regulations that would apply to the facility.
- 4.27 As stated in Section 1.1, the Boston-NBL facility would be owned, operated and managed by BUMC. There was no intent to make a distinction between BUMC and BUMC personnel. A solicitation for a limited-competition cooperative agreement operations grant was issued by NIH during the summer of 2005.
- 4.28 In the winter of 2005, the Boston-NBL was adopted by charter as an Institute at Boston University. The National Emerging Infectious Diseases Laboratories Institute would be housed at the Boston University Medical Campus and headed by a Director. The governance structure for the facility would include several committees, including those that provide external scientific and community oversight of the operations at the lab. The Executive Committee would advise the Director of the Institute on the

- 4.24 circumstances junior faculty, post doctoral fellows, and graduate students will be performing research in the BSL4 laboratory.
- 4.25 1-4: The SDEIS claims that all trainees would undergo intensive safety training and certification before they might work in high containment facilities. The FEIS should discuss how and when researchers receive such training, the standards for such training, the certifying body, and whether refresher courses are required. The FEIS should also discuss who would determine whether the training and certification requirements are being met.
- 4.26 1-9: The SDEIS states that the BSL4 laboratory would comprise approximately 16% of the total assignable space in the building and would be designed and built in compliance with federal standards. It would be more accurate to state that the BSL4 laboratory would comprise approximately 31.5% of total laboratory space (see table 2-1). In addition, the FEIS should provide citations to the federal standards that apply to the building.
- 4.27 1-9: The SDEIS claims that the laboratory would be owned and operated by BUMC and managed by BUMC personnel. Why does it make a distinction between BUMC and BUMC personnel? Also, the Broad Agency Announcement under which BU applied for funding to construct the laboratory noted that there would be a separate process to choose an entity to operate the laboratory, yet the SDEIS states that BU will operate the lab and BUMC personnel will manage the lab. The FEIS should explain the apparent discrepancy between the SDEIS and BAA on this issue.
- 4.28 1-15: The SDEIS discusses a "charter for the Boston-NBL" but fails to provide the charter. A copy of the charter must be provided for review. It also notes the existence of three groups: an Executive Committee; a Community Liaison Committee; and an External Scientific Advisory Committee. The charter for each committee must be provided for review, as well as information showing the members of each committee, along with their affiliations and backgrounds.
- 4.29 2-5: Figure 2-3 shows the site plan safety features. The figure should also show the location of the no-scale fence. The FEIS should also explain how security will be maintained considering that the security perimeter encompasses not only the bioterrorism laboratory but also a future medical research building, about half of the Evans Biomedical Research Center, and about half of another future medical research building.
- 4.30 2-7: Table 2-1 shows that the BSL4 laboratory will occupy approximately 31.5 % of all laboratory space in the NBL (13,100 sq. ft. of 41, 700 sq. ft. total). The project proponent has erroneously stated that the BSL4 will be about 13% of the space. It should correct that misimpression.
- 4.31 2-7: The DEIS mentions clinical research and that those individuals needing acute medical care would be transferred to the Boston Medical Center (BMC). The FEIS should describe the security provisions that will be used for individuals, including laboratory workers, who are infected with select agents and hospitalized at BMC.

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scientific research and operational activities of the Boston-NBL. In addition, a Community Liaison Committee (CLC) comprised of six committee members who are not employed by Boston University or Boston Medical Center would review projects and activities of the Boston-NBL and assist the Director and other committees as needed to ensure effective communication on programs and activities involving the Boston-NBL and the community. BUMC would solicit nominations for membership on the CLC.

4.29 As described in Section 2.2.1, site security would be maintained by utilizing a 150 foot unchecked vehicle set back and a 100 foot unchecked pedestrian setback. Structures that are within these setbacks would be designed to comply with the setbacks by designing fire egress and loading facilities so that there is no impact and by undergoing risk assessments as building projects in the area are initiated. Figure 2-3 has been updated to indicate the location of the security fencing.

4.30 See Response to Comment 4.26.

4.31 Boston Medical Center has a number of protocols designed to address concerns surrounding patient confidentiality, patients with infectious conditions and patients who require isolated areas for both clinical and non-clinical reasons. These protocols are in place and would be utilized in the event that laboratory workers, or others, were exposed to infectious diseases and were determined to be in need of secure clinical facilities for treatment. Specific protocols are being developed to address the transport of infected individuals from the Boston-NBL facility to the existing isolation facilities at Boston Medical Center, should that be necessary.

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- 4.32 The proposed laboratory facility would be subject to many local, state and federal regulations. A list of agencies with regulatory responsibility may be found in Table 1-4. Compliance with these regulations would be ensured through proper personnel training and orientation measures, routine audit and oversight activities by supervisory personnel, and through routine testing and reporting of results. In addition, unannounced agency inspections may be conducted by many of these agencies including EPA, NIH, USDA, DEP, DPH, MWRA, BPHC, BWSC and the Boston Fire Department.
- 4.33 The NIH grant agreement for the Boston-NBL facility requires compliance with NIH design guidelines. The NIH guidelines on Backflow Prevention devices can be found at <http://orf.od.nih.gov/policy/volume4-plumbing.htm#h10>. BUMC would own and operate the lab and ensure compliance with all NIH guidelines during commissioning and operation of the building as described in Section 2.2.4.
- 4.34 Biological Safety Cabinets provide personnel, product, and environmental protection. To ensure proper function each cabinet must be certified at installation and annually thereafter. The recognized standard is the National Sanitation Foundation's Standard 49 (NSF-49). The NSF-49 certification method ensures that air balance is correct and filters leak free. NSF-49 consists of primary, secondary and adjustment/repair procedures. The complete standard can be purchased at <http://www.nsf.org>. BUMC would be responsible for the operation and maintenance of the laboratory. The Office of Environmental Health and Safety (OEHS) would be responsible for maintaining and servicing the HEPA filters in the facility.
- 4.35 BUMC requires annual recertification of Biosafety Cabinets, as well as additional certification for new cabinets or cabinets that have been relocated. This process of certifying cabinets is validated through

- 4.32 2-7: The SDEIS states that the research will comply with local, state, and federal regulations. The FEIS should list each such regulation that applies and how compliance will be assured.
- 4.33 2-8: The SDEIS mentions procedures for backflow preventers. The FEIS should provide a copy or citation to those procedures and discuss how NIH will determine if the procedures are followed and enforcement mechanisms if the procedures are not followed.
- 4.34 2-9: The SDEIS mentions National Sanitation Foundation Standard 49 procedures for HAPA filters. The FEIS should provide a copy or citation to those procedures and discuss how NIH will determine if the procedures are followed and enforcement mechanisms if the procedures are not followed.
- 4.35 2-10: The SDEIS mentions procedures for safety cabinets, including annual certifications and certifications whenever the cabinets are moved. The FEIS should explain who provides the certifications, provide a copy or citation to the procedures, and discuss how NIH will determine if the procedures are followed and enforcement mechanisms if the procedures are not followed.
- 4.36 2-17: The DEIS claimed that the building would be commissioned in accordance with the NIH standards and the Massachusetts State Building Code. The SDEIS mentions an "extensive commissioning process." The FEIS should provide a citation to the NIH standards that apply to BSL4 laboratories and explain whether the standards are legally enforceable or only guidelines. It should also provide a citation to any Massachusetts State Building Code specifically designed for biological containment facilities. For each, the FEIS should discuss which standards were written specifically for BSL3 and BSL4 laboratories. The FEIS should also discuss whether there would be third party commissioning.
- 4.37 2-19: The SDEIS places much reliance on BUMC OEHS staff to ensure building safety and security. The FEIS should discuss the qualifications required for BUMC OEHS staff and how NIH will determine if procedures are followed and enforcement mechanisms if procedures are not followed. The FEIS should explain why NIH has confidence in BUMC staff considering the large number of environmental health and safety violations at BUMC over the past four years (list attached to our earlier comments).
- 4.38 2-20: The SDEIS claims that BUMC will comply with all federal, state, and local regulations regarding rDNA use. Those regulations apply not only to BUMC, but also to the researchers in the laboratory. How will that be monitored? In addition, Boston regulations prohibit rDNA use in a BSL4 laboratory, yet rDNA use is prevalent in BSL4 laboratories. The FEIS must explain how BUMC and researchers will comply with the Boston prohibition considering the prevalent use of rDNA in BSL4 laboratories.
- 4.39 2-22: The SDEIS notes that BU will adhere to strict protocols for the shipment of biological agents. The FEIS should discuss which of the protocols are required by federal

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certified, trained, outside vendors in Biosafety and Laboratory Safety that have a long standing record with the university. These vendors follow all application regulations for the NSF-49. All Biosafety cabinets are inspected and enforcement of recertification is completed through general laboratory inspections, unannounced inspections, and Institutional Biosafety Committee review. See Section 2.2.4 and Appendix 6.

- 4.36 The building's commissioning plan is being developed specifically for this facility. A third party engineering firm would perform as the commissioning agent for the facility. The plan incorporates building components and systems and is not limited to the containment laboratory facilities. The NIH commissioning guidelines address issues directly related to laboratory facilities ([http://orf.od.nih.gov/commissioning\\_tool.htm](http://orf.od.nih.gov/commissioning_tool.htm)). The Massachusetts State Building Code addresses general building systems. Performance of the necessary inspections, operational testing to meet the building code and compliance with the required testing are legally enforceable, through, for example, the failure to issue an occupancy permit. The NIH is not an enforcement agency but can administratively enforce adherence to the NIH design guidelines, by stopping the funding to construct the facility (U. S. DHHS 2003b).
- 4.37 BUMC OEHS staff represents a number of specialized areas including industrial hygiene, health physics and biosafety. These specialized areas require specific credentials and certifications that may be checked by regulatory authorities at any time. BUMC has a staff of 23 such professionals in the Environmental Health and Safety Office who interface with regulatory agencies on a regular basis and attend multiple competency-based training programs annually.
- 4.38 In accordance with current policies and procedures, the Institutional Biosafety Committee (IBC) would review all proposed experiments for compliance with applicable DNA rules and regulations.

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Such approval would be required prior to initiating such experiments.

- 4.39 The High Hazard Material Management Policy, in Appendix 7, describes how BUMC plans to ensure strict compliance with all applicable federal shipping regulations. This includes specific roles and responsibilities of departments, including the Offices of General Services, Environmental Health and Safety, Mail Services, and Purchasing. The federal and international shipping protocols of the U.S. Department of Transportation and the International Air Transport Authority, along with any new standards for the transport of dangerous goods, will be strictly followed by BUMC. BUMC will ensure compliance through the Office of General Services audit and investigation responsibilities, including initiating, conducting, and/or participating in audits and investigations. The Office of Environmental Health and Safety will schedule all packages and initiate its own tracking methods. The DHHS has a role in regulating shipping of select agents under the Department of Health and Human Services Select Agent rule 42 CFR 73.0, part 73.16. Select agents must be properly shipped and are regulated by DHHS. See Response to Comment 4.32.
- 4.40 See Response to Comment 4.7.
- 4.41 Figure 3-1 has been changed to center the NBL site.
- 4.42 Based on recent groundwater chemical analyses results, it has been concluded that groundwater at the site contains low levels of contaminants below the applicable standards and poses no significant risk to human health, safety, public welfare or the environment. Thus, no remediation on groundwater is required. Based on the soil chemical analyses results and the completion of a Method I Risk Characterization, there is a condition of No Significant Risk of soil outside the footprint of the proposed Boston-NBL building. Soils excavated during construction would be handled and disposed of in

- 4.39 regulations, which additional protocols will be implemented by BU, and how NIH will determine if protocols are followed and enforcement mechanisms if protocols are not followed.
- 4.40 2-24: The SDEIS claims that there will be a designated route to and from the facility and access only by the local highway system. Residential streets would be avoided. Our response to that claim is set forth in Section IV, above.
- 4.41 3-3: Figure 3-1 has located the NBL site in the upper right quadrant of the depiction. By not centering the NBL in the depiction, the SDEIS fails to show the full extent of residences within a few city blocks of the NBL location. If it had located the NBL in the center of the depiction, a large public housing development, located only a few city blocks from the NBL location, would be shown, as would much more of the nearby residential neighborhood. The figure is thus misleading and should be corrected.
- 4.42 3-35: The SDEIS claims that there are only low levels of contamination typical of urban locations in the groundwater. The truth is that the site is contaminated with many toxic materials and that a site remediation plan is in development. The FEIS should provide information about that.
- 4.43 4-2: If the project will create 660 new jobs, why does the SDEIS estimate only 70 trips entering the site during evening and morning rush hour? If, as reported in the SDEIS, currently 48% of institution employees arrive in single occupancy vehicles, and some additional percentage carpools, why would be not expect approximately 330 trips entering the site during evening and morning rush hour (about 50% of the total new jobs)?
- 4.44 4-9: The SDEIS claims that BUMC has a "strong history of constructing and managing safe biomedical laboratories...." It also claims that BUMC has a good safety record, citing Appendix 4 of the SDEIS. The SDEIS ignores BUMC's very poor environmental health and safety record, which we provided with our comments to the DEIS. It also downplays the recent revelations that three BUMC researchers, in three separate incidents over a five-month period, became infected with tularemia in the laboratory and that two of the three required hospitalization. It also ignores that it took BUMC months to diagnose the laboratory-acquired infections as tularemia, that BUMC reported the infections to city public health officials later than required, did not report the infections to federal officials until later, and never informed the public. As you now know, the federal Occupational Safety and Health Administration has issued an \$8,1000 penalty to BU and BUMC for the incidents, terming each a "serious violation." It is amazing that NIH does not consider the incidents a serious problem. The FEIS should explain why NIH would not reconsider the award to BU/BUMC under these circumstances.
- 4.45 4-10: The SDEIS relies entirely on the assumption of an "excellent" safety record of three BSL4s around the world as compiled by Karl Johnson, MD (SDEIS Appendix 4). Dr. Johnson's research for his report is anecdotal, rather than fact based. It relies only on interviews with staff at the facilities. It is not a detailed review of all laboratory exposure

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accordance with a Release Abatement Measure (RAM) Plan filed with the state Department of Environmental Protection.

4.43 While a total of 660 new jobs would be created by the project, not all 660 persons would be working in the building at the same time, nor would all persons working in the building arrive or depart during the peak hour of traffic. The building would be occupied 24 hours a day, 7 days a week and most work shifts would begin and end outside the peak hours for traffic. The estimate of peak hour trips is based on the number of persons working in the building who are expected to arrive/depart via automobile during the peak hour only.

4.44 Appendix 4 of the EIS is a study specific to NIAID-supported laboratory facilities operating at BSL-3 and BSL-4 levels. As soon as confirmed cases of tularemia were identified, BUMC officials notified all appropriate authorities as required including the Boston Public Health Commission (BPHC), the Massachusetts Department of Public Health and the CDC. The BPHC's report on these exposures recommended that stronger procedures be put in place to monitor lab personnel and report suspected cases. BUMC concurred with these recommendations in its public Statement of Responsibility. BUMC has already implemented additional procedures including a mandatory notice to the Occupational Medicine Department after missing one day with any sickness and a medical alert card carried by all tularemia lab workers. BUMC has begun to implement the following procedures: 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; outside, expert review of BUMC research controls and procedures; and, working with the Boston Public Health Commission to improve the notification process.

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4.45 The portion of Dr. Johnson's report that addresses the exposure and clinical infection record of those three laboratories during the past 20 years is not anecdotal; it represents the facts, and particularly in the case of USAMRIID, it is based on written records from that Institute supplied to Dr. Johnson by the Principal Scientific Advisor to USAMRIID. Nobody working in the BSL-4 at USAMRIID suffered a clinical infection. The statement in Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (a)" in the FEIS is correct with just one caveat. BSL-4 containment did not exist as such until 1984 when the first edition of Biosafety in Microbiological and Biomedical Laboratories came out. That's why Dr. Johnson covered a 20 year period through most of 2003. No clinical infections occurred in BSL-4 work at USAMRIID in that 20 year interval.

4.46 All the agents listed in the published article referenced in the comment are either BSL-2 agents or BSL-3 agents. No clinical infections occurred in BSL-4 work at USAMRIID during the period of time in Dr. Johnson's study.

4.45



events at the three facilities, and should not be relied upon to make claims about the safety of BSL4 laboratories.

An especially incorrect statement in the SDEIS is that:

"With the longest running experience with a BSL-4 (33 years) Ft Detrick Maryland has an outstanding safety record....Previous documents exposures at Fort Detrick in their original lab facilities mention one laboratory-acquired infection between 1959-1969 and no clinical or other infections in the more recently constructed USAMRIID facility."

4.46



That statement, unfortunately, is incorrect and must be revised in the FEIS to reflect the true safety record of the facility. USAMRIID has had an extensive history of both exposures and laboratory-acquired infections over the last two decades. According to a study by USAMRIID researchers, published in the Journal of Occupational and Environmental Medicine in August 2004, 234 employees at USAMRIID were evaluated for exposure to 289 biological agents classified as "bioterrorist agents", resulting in 5 confirmed clinical infections between 1989-2002. The recorded infections were from exposures to glanders, Q fever, vaccinia, chikungunya, and Venezuelan equine encephalitis. There were also numerous exposures to anthrax, plague, Western and Eastern equine encephalitis, orthopoxviruses, yellow fever virus, and Rift Valley fever virus which did not lead to infections, but for which postexposure antibiotic prophylaxis was administered (when available). For some of these diseases, of course, there is no available treatment.

The report, (Rusnak, et al. 2002) thoroughly reviewed all exposure records, and paints a significantly different picture of the safety record at USAMRIID than Dr. Johnson's report, which implies that accidents are extraordinarily rare. In contrast data shows that there were an average of 16.7 persons evaluated per year for accidental exposures to bioterrorist agents. The authors of the study conclude:

In summary, we reviewed available medical and safety records at USAMRIID from 1989 to 2002 and reported on 234 evaluations of potential exposures and illnesses to bacterial, rickettsial, and viral disease agents. During this period, there were five confirmed infections. The large number of exposure incidents reported in this time period serves as a reminder that work in a laboratory of this type is inherently hazardous. (emphasis added)

This conclusion of this study must be included in this EIS in order to fully inform the public of the potential risks of such a facility.

Further, the authors also conclude:

Therefore, it is imperative for laboratories that elect to work with highly hazardous agents to be fully cognizant of the risk of occupationally

acquired illnesses and institute policies and proactive employee health procedures to evaluate potential exposures.

4.47

Nonetheless, the SDEIS does not address Boston University's policies or proactive employee health procedures to evaluate potential exposures. The FEIS must explain that these policies and procedures for preventing exposures and for detecting and evaluating exposures are crucial to the health of both the employees and the surrounding community. That must be included in the FEIS.

4.48

4-11: Why is the possibility of an escape of an infected insect discounted? There have been animal escapes from biological research facilities. Also, the NBL will be infecting fleas, ticks, and other insects. That should be analyzed and discussed in the FEIS.

4.49

4-13: The discussion of a terrorist threat assumes that no more than one select agent will be available to the terrorist. A terrorist, especially one that worked in the laboratory, or had contacts in the laboratory, would know where the select agents were located and could get and release more than the agents that were being worked on the laboratory at the time of the terrorist incursion.

4.50

4-15: The SDEIS claims that the mere presence of the NBL will attract bioscience related businesses to the area. The SDEIS supplies no evidence or information to support this assertion. The FEIS should review the area near the existing BSL4 labs to test the claim that BSL4 laboratories attract bioscience related businesses to their area.

In conclusion, we are disappointed that the SDEIS corrects none of the problems presented in the DEIS. Instead, the SDEIS contains the same problems presented in the DEIS and has added more problems and areas of noncompliance with NEPA.

Thank you for the opportunity to comment. For further information and to follow up, please contact Eugene B. Benson, Staff Attorney, ACE, at 617-442-3343 x 226 and [gene@ace.ej.org](mailto:gene@ace.ej.org)

Submitted by Alternatives for Community & Environment, Inc.

Eugene B. Benson

Eugene B. Benson  
Staff Attorney

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4.47 BUMC currently has policies and procedures in place to monitor and prevent worker exposure. These include a detailed medical surveillance training program, serum banking, and other procedures effective at prevention and monitoring of worker exposures. The Boston-NBL would have a comprehensive medical surveillance program which would be integrated into the current medical monitoring system. See Section 2.2.5.1 of the FEIS.

4.48 The proposed Boston-NBL facility and systems would be designed to significantly reduce the potential for possible vector-borne transmission through insects and rodents. The design of BSL-2, BSL-3, and BSL-4 containment laboratories and BSL-2, BSL-3, and BSL-4 animal containment laboratories would comply with recommendations and requirements of the *4th Edition Biosafety in Microbiological and Biomedical Laboratories* (U.S. DHHS 1999), *NIH Design Policy and Guidelines - Animal Research Facilities* (U.S. DHHS 2003c), and the current *Guide for the Care and Use of Laboratory Animals* (National Research Council 1996). The construction and operation of the Arthropod Containment Level laboratory would comply with the recommendations and requirements of the *Arthropod Containment Guidelines, Version 3.1* by the American Committee of Medical Entomology of the American Society of Tropical Medicine and Hygiene (ASTMH 2002). Infected arthropod work would be conducted in the innermost rooms under negative pressure conditions and all air supply and exhaust terminal devices would be screened to prevent arthropod escape. In insectary manipulation areas, cooler temperatures would be maintained to slow arthropod movement to reduce the potential for escape. Surfaces in all insectary spaces would be white to allow for quick identification of arthropods that escape primary containment. In addition, implementation of a pest management program would limit the potential for transmission of infectious agents from animals to humans. See Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (c)" in the FEIS.

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- 4.49 The safety and security systems in the building would include strict controls and audit requirements on all select agents at all times. These initiatives are directed at those working in the lab, who have already undergone a background check. The security protocols also require a series of checks and balances to access space and storage containers and require a minimum of two authorized persons being present at any time there is a risk involving a release.
- 4.50 The Boston-NBL is anticipated to foster additional bioscience research activity in the City and the region. Much as Cambridge and Boston have become a "cluster" center for the life sciences industry, the presence of a national biosafety research laboratory would attract researchers and businesses seeking to capitalize on the additional synergy create. Other BSL-4 research laboratories in San Antonio and Atlanta have similarly generated expanded interest in life sciences research activities. San Antonio is a growing biotech research location. Atlanta as the home of the U.S. Centers for Disease Control and Prevention has over 200 bioscience companies as well as multiple research universities.

APPENDIX I

Comments from Jeanne Guillemin  
Professor of Sociology, Boston College  
Senior Advisor, MIT Security Studies Program  
Author, *Anthrax: the Investigation of a Deadly Outbreak and Biological Weapons: From the  
Invention of State-Sponsored Programs to Contemporary Bioterrorism*

A good deal is known about the physical dispersion of aerosols but medical uncertainties still trouble attempts to predict risk with absolute conviction. This is especially so for outdoor emissions that cause disease on which, for obvious public health reasons, little research has been done and few events have been chronicled. For this reason, much importance has been attached to the 1992 study of the 1979 Sverdlovsk (USSR) epidemic in the USSR (Guillemin, 1999), which proved that an emission of spores from a military facility had killed some 70 local residents.

The emphasis in my comments is going to be on important variables that the RWDI West team *has left out* of its two reports (September 1, 2004 and March 23, 2005). These missing aspects severely undermine the credibility of their models. Sometimes people who are at ease with modeling the physical dispersal of particulates have difficulty with the complexities inherent in disease transmission and the general fact of medical uncertainty. Select agents can compound this problem because they rarely now cause epidemics and knowledge about them became esoteric. For example, we would all like to believe that we knew the dose response for anthrax spores, but human subjects are simply not available for research on such a dangerous disease as inhalation anthrax. The US Army spent years trying to determine dose response, in order to calculate munitions. The best it did was a study of a thousand monkeys conducted by Joseph Jemski in the 1960s, the details of which are lost to history, and some smaller, recent animal research. *If those composing models of dispersion are unfamiliar with medicine and epidemiology, they are likely to leave out or ignore important variables or strive for oversimplified, mechanistic results.*

I believe this unfamiliarity has undermined the several attempts that RWDI West Inc. has made to present credible models of the risk of anthrax to people in the area near the proposed BU NEIDL facility. Just as one example of medical ignorance, the authors of the 2005 summary report (Arulanadam et al.) assert on page 2 that the initial symptoms of anthrax infection resemble those of "a common cold." The initial symptoms for inhalational anthrax are actually flu-like, and can proceed to high fever and respiratory distress before terminal toxic shock. The difference is a crucial one from a medical screening point of view. Since the symptoms of anthrax are described in an article they cite (the 1994 *Science* article that I co-authored with Matthew Meselson), one becomes further convinced that the RWDI authors have insufficient medical knowledge to model disease risks from outdoor aerosol dispersion.

I. *Calculating Disease Risks: The Accident Scenarios*

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In the current RWDI rendition of worst case scenarios, choices were made to ignore fundamental problems in calculating disease risks.

1) A fundamental problem is what I would call the fallacy of the single vial scenario. Accidental spillage from a single vial of virulent anthrax spores is not at all the worst anthrax case scenario imaginable, although it could do real damage. A more credible worst-case scenario is the release of already aerosolized anthrax being used for tests of large non-human primates. In that event, the pathogenic quality of the emission would be at its maximum level and also invisible and scentless. To suggest that the worst that could happen in a major BSL-4 research facility is minor pathogen spillage misleads the public about the risks that advanced biodefense work entails. To test defenses against aerosolized germ weapons means creating germ aerosols. *Unless BUMC is willing to forego pathogenic aerosol experiments, the single vial scenario cannot be accepted as the basis for a worst case scenario.*

2) In previous comments on RWDI scenarios, I questioned the lack of a contagious disease model. Any of the contagious diseases represented by the select agent list (pneumonic plague, the hemorrhagic fevers) could be released through human or animal or even insect vectors, not just aerosols, with repercussions far beyond the current limited single vial spillage scenario presented in this report. *A worst-case model of a contagious disease accident should be constructed and presented to the Boston-area public for its assessment.*

3) Even if one accepts a lower-risk single spillage scenario, why leave out the higher range of numbers of respirable spores that might conceivably be released? The authors' rigid adherence to just 400,000 spores being released in a laboratory accident predetermines their no-risk conclusion. Since a single gram of anthrax can contain a trillion spores, the addition of a zero or two to the 400,000 spores would be realistic and it would also shift the risk of exposure from none towards some. *The higher ranges of spore numbers should be incorporated to produce more realistic models.*

4) The authors have represented a variety of atmospheric conditions that might affect release, but, in their fixation on 400,000 spores, they have bypassed one of the most important findings of the study of the 1979 anthrax epidemic, namely, that virulent anthrax spores can be deadly as far as 50 kilometers from the source of a release. *The long-range virulent impact of anthrax should be included in models.*

5) I mention above the uncertainties regarding human dose response for inhalational anthrax. In contrast, the dose response for tularemia was successfully researched by the US Army, in the famous Project Whitecoat project of the 1960s and early 1970s. Although less lethal than anthrax, tularemia bacteria are highly infective, which is why it was the preferred biological weapon at Fort Detrick during the days of the US offensive program. Since BUMC has a recent history with the agent for this disease, it should rank among the worst-case scenarios that the public and government officials review. *A model of an accidental dispersal of tularemia should be developed, using current dose response data.*  
*II. Including Epidemiological Variables*

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Computer models of outdoor pathogen release and disease transmission can be helpful only if they comprehend certain significant epidemiological variables and are open to a range of possibilities. The authors' limited understanding of disease transmission in an urban environment has led them to leave out important aspects that otherwise would have made their models more realistic and less dogmatic about their "no-risk" conclusion.

1) *Target aggregation and mobility.* The RWDI physical release models unrealistically presume that the select agent is mobile through space and over time and that the target population is both isolated as individuals and also stationary. It is only by presuming fixed individual immobility that a model would attempt to gauge the impact of anthrax pathogens on a single, immobilized person in the center of a plume, as if the release were in a wind tunnel. The reality is that collectivities of people make daily use of city space, indoors and outdoors.

The epidemiological reality of plume dispersal in an urban area was shown in the study of the 1979 Sverdlovsk epidemic. In that case, the victims were either aggregated at work (in a ceramics factory in particular) or they were in their homes or circulating in the affected neighborhood. A competent model of a potential aerosol release from the proposed BUMC facility would factor in at least nodes of aggregation (workers in present adjacent BU facilities, local hospitals, factories, schools, restaurants, bars, etc.) and, to be more refined, estimate patterns of sidewalk and street traffic, by day and night. My point here is that urban spaces have discernible patterns of aggregation and mobility that, in the case of a dangerous pathogen release, would be crucial to understanding health risks. If the disease were contagious, these patterns would be all the more important. *Realistic patterns of population aggregates and mobility should be included in any model of aerosol dispersion.*

2) *Medical Uncertainty.* The problem of human susceptibility to disease is also a challenge for computer models of outdoor release. In remarks made on an earlier RW draft, I suggested that consideration should be given to the demographics of the communities that might be downwind of an anthrax aerosol release. What we know about inhalational anthrax, for example, suggests that older people are more vulnerable than others. The focus on the individual in the RWDI models ignores this important fact. The people who would be exposed in an anthrax aerosol event do not come in standardized packages and it is misleading to suggest that a single standardized individual as opposed to a range credibly predicts outcome. For example, a breathing rate of 30 liters per minute is standard reckoning for an active young male of average build with normal lungs. What about other people with different profiles and vulnerabilities?

Regarding the different contagious diseases, the usual demographic factors would predict likely targets: children, especially those under two years of age, the elderly, pregnant women, and people already sick or with compromised immune systems. The Massachusetts Department of Public Health has most of the relevant statistics for the BUMC area. Calculating simply the number of elderly would have been helpful for the anthrax model and, of course, the demographic profiles of local communities would have been essential for the missing contagious disease model. *Demographic data should be included in any models of aerosol pathogen dispersal.*

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To summarize, the two RWDI reports on Hazard and Risk Assessment fail to represent such threats as might exist to local communities by leaving out important medical and epidemiological aspects of aerosol disease transmission. Their conclusion that no spores would be inhaled is based on a mechanistic model that ignores the complexities of disease transmission. Such complexities can be addressed by offering a flexible range in data input, which the RWDI authors appear reluctant to do.

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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 O'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

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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:

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- 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.

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*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.

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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.

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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)

**LETTER 4**

**Alternatives for Community and Environment**

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.

*References*

F. A. Abramova, L. M. Grinberg, O. V. Yampolskaya, and D. H. Walker, "Pathology of Inhalational Anthrax from the Sverdlovsk Outbreak in 1979," *Proceedings of the National Academy of Sciences* 1993 (90): 2291–2293.

John Bartlett, Luciana Borio, Lew Radonovich, Julie Samia Mair, et al., "Smallpox Vaccination in 2003: Key Information for Clinicians" *Clinical Infectious Diseases* 36 (2003): 883–902.

R. J. Blendon, C. M. Des Roches, J. M. Benson, M. J. Hermann, et al., "The Public and the Smallpox Threat" *New England Journal of Medicine* 2002, 348 (5): 426–432.

P. S. Brachman, "The Public Health Response to the Anthrax Epidemic," in Barry S. Levy and Victor W. Sidel, eds., *Terrorism and Public Health: A Balanced Approach to Strengthening Systems and Protecting People*. New York: Oxford University Press, 2003, 101–117.

LETTER 4

Alternatives for Community and Environment

H. W. Cohen, R. M. Gould, and V. W. Sidel "The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences" *American Journal of Public Health* 2004, 94 (10): 1667-1672.

T.C. Dixon, J. Guillemin, M. Meselson, and P. Hanna "Bacillus Anthracis: Infection Revisited" *New England Journal of Medicine* 1999; 1: 815-825.

DRES (Defence Research Establishment Suffield) *Risk Assessment of Anthrax Threat Letters*. Technical Report TR-2001-048, September 2001. Suffield, Canada.

R. Ganl and S. Leach, "Transmission Potential of Smallpox in Contemporary Populations" *Nature* 2003, 414 (13): 748-751.

J. Guillemin, *Anthrax: The Investigation of a Deadly Outbreak*. Berkeley, CA: University of California Press, 1999.

----- "Soldiers' Rights and Medical Risks: The Protest Against Universal Anthrax Vaccinations" *Human Rights Review* 2000, 1 (4): 124-139

----- "Medical Risks and the Volunteer Army" in Pamela R. Frese and Margaret C. Harrell, *Anthropology and the United States Military: Coming of Age in the Twenty-first Century*. New York: Palgrave, 2003a, 29-44.

----- "Bioterrorism and the Hazards of Secrecy: A History of Three Epidemic Cases," *Harvard Health Policy Review* 2003b, 4 (1): 36-50.

----- *Biological Weapons: From the Invention of State-sponsored Programs to Contemporary Bioterrorism*. New York: Columbia University Press, 2005.

E. Gursky, T.V. Inglesby, and T. O'Toole "Anthrax 2001: Observations on the Medical and Public Health Response" *Biosecurity and Bioterrorism* 2003, 1 (2): 97-110.

L. M. He and B.M. Tebo "Surface Charge Properties of and Cu(II) Adsorption by Spores of the Marine *Bacillus* sp. Strain SG-1" *Applied Environmental Microbiology* 64 (3): 1123-1129.

Institute of Medicine, *Anthrax Vaccine: Is It Safe? Does It Work?* Washington, DC: National Academy Press, 2002.

**LETTER 4**

**Alternatives for Community and Environment**

D. B. Jernigan, P. L. Raghunathan, B. P. Bell, R. Brechner, et al., "Investigation of Bioterrorism-Related Anthrax, United States. Epidemiologic Findings" *Emerging and Infectious Disease* 2002, 8 (10): 1019-1028.

B. S. Levy and V. W. Sidel, "Challenges that Terrorism Poses to Public Health," in *Terrorism and Public Health: A Balanced Approach to Strengthening Systems and Protecting People*. New York: Oxford University Press, 2003, 3-18

M. I. Meltzer, I. Damon, J. W. LeDuc, and J. D. Millar, "Modeling Potential Responses to Smallpox as a Bioterrorist Weapon," *Emerging Infectious Diseases* 2001, 7 (6): 959-969.

M. Meselson, "Note Regarding Source Strength" *ASA Newsletter*, 21 December 2001, 1, 10-11.

M. Meselson, J. Guillemin, M. Hugh-Jones, A. Langmuir, I. Popova, A. Shelokov, and O. Yampolskaya, "The Sverdlovsk Anthrax Outbreak of 1979" *Science* 1994, 266 (5188): 1202-1208.

J. Miller, S. Engelberg, and W. Broad, *Germs: Biological Weapons and America's Secret War*. New York: Simon & Schuster, 2001.

National Research Council, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, *Biotechnology in an Age of Terrorism: Confronting the Dual Use Dilemma*. Washington, DC: National Academy Press, 2003.

Victor Sidel, Meryl Nass, and Todd Ensign, "The Anthrax Dilemma," *Medicine and Global Security* 1998 2 (5): 97-104. US Army Munition Expenditure Panel, St. Jo Program. *Preliminary Discussion of Methods for Calculating Munition Expenditures, with Special Reference to the St. Jo Program*. Camp Detrick, Maryland, 1954.

World Health Organization. *Public Health Response to Biological and Chemical Weapons: WHO Guidance*. Geneva: World Health Organization, 2004.

S. Wright, "Introduction" in S. Wright, ed. *Biological Warfare and Disarmament. New Problems/New Perspectives*. 2002, 3-24.

**LETTER 5**  
**Caroline Alves**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

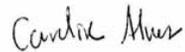
Dear Ms. Nottingham:

Our community needs projects like the proposed biosafety laboratory.

The biosafety lab will create jobs. Boston University Medical Center (BUMC) has said that 1300 construction jobs and 660 permanent jobs will be created. Our community needs these jobs.

In addition, BUMC has committed \$1 million to training Boston residents to be lab technicians. The training will be part of the City Lab program. After nine months, the graduates are able to find meaningful jobs at a laboratory at the medical center or in a similar laboratory in the City. This will be a great partnership and illustrates BUMC's strong commitment to our community.

I support the Biosafety Lab.





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

Telephone: 617-983-6400 Facsimile: 617-983-9081

May 2, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)**

Dear Ms. Nottingham:

I am writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC).

As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world. I am familiar with the design of the proposed laboratory at BUMC and believe that it is being designed and built using sophisticated and state-of-the-art safety and security systems. I firmly believe that BUMC has a deep commitment to ensuring the safety of the laboratory, the researchers and the community. Despite some discussion concerning its location, I believe this facility should be located in the greater Boston area, which functions as a hub for medical research activities due to a significant base of resident medical research scientists. By placing the facility in such close proximity to this rich research community, scientists are assured of their ability to share research and knowledge through direct collaboration with other institutions in the greater Boston area.

The Biosafety Level 4 Laboratories in North America have a very good safety record. With more than 77 years of combined operations, there has never been a community incident or an environmental release.

A BSL-4 laboratory will provide much needed capacity to study emerging infectious diseases and will be very beneficial for scientists and researchers throughout the region who are looking for cures and vaccines for some of the world's deadliest diseases. This laboratory will safely conduct research on infectious diseases that threaten the safety and security of our city, of the nation and indeed, of the world.

I support BUMC's research efforts and its plans to build the NEIDL.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Donna M. Ambrosino', is written over a light-colored background.

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

**LETTER 6**

**Donna M. Ambrosino, M.D.**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

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I support the Biosafety Lab.

*Dunia Andreadi*

LETTER 7

Dunia Andreadi

LETTER 8

Maria Andreadi

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

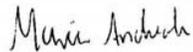
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I support the Biosafety Lab.





**CBEP** Center for Biodefense  
and Emerging Pathogens  
111 Brewster Street • Pawtucket, RI 02860 • 401-729-3857

3 May 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious  
Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

The Center for Biodefense and Emerging Pathogens (CBEP) is writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC). There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses, and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases, including those that may occur as the result of a bioterrorism attack. The mission of CBEP involves research, education, training and consultation in the arena of biodefense; our mission and that of other scientific groups invested in the public health would benefit greatly from the presence of the NEIDL in Boston.

Our organization would like to comment on two very important issues raised in the document - the appropriateness of the proposed location of the facility and the safety of the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed NEIDL facility at the BioSquare Research Park, Boston University undertook an alternatives siting analysis that evaluated existing sites under its control to determine the best location for the facility. The study concluded, and CBEP concurs, that the best location for this facility is exactly where it is proposed in the BioSquare Research Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical research park which contains medical research facilities including Biosafety Level 1, 2 and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare Research Park is also located directly across the street from the Boston University Medical Center campus which also houses hospital and medical research facilities and is the largest Level 1 Trauma Center in New England.

*Affiliated with Memorial Hospital of Rhode Island*

LETTER 9

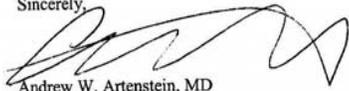
Andrew W. Artenstein, MD

While it is clear that some community members feel that such a facility should be located in a more rural location, CBEP feels strongly that the facility should be located in an urban area which functions as a hub for medical research activities and which has a significant base of resident medical research scientists. This would facilitate the use of shared research facilities and knowledge via direct collaboration among the various institutions located in the greater Boston area.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, CBEP believes that the facility will be safe. There are several federal and state programs which require the facility to be constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, we urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,



Andrew W. Artenstein, MD  
Director, Center for Biodefense and Emerging Pathogens  
Associate Professor of Medicine and Community Health,  
Brown Medical School

**LETTER 9**

**Andrew W. Artenstein, MD**



One Boston Medical Center Place  
Boston, MA 02114-2193  
Tel: 617-476-8900  
Fax: 617-476-3002  
www.bumc.org

May 4, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

RE: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I am writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC). There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases.

Our organization would like to comment on two very important issues raised in the document - the appropriateness of the proposed location of the facility and the safety of the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed NEIDL facility at the BioSquare Research Park, Boston University undertook an alternatives siting analysis that evaluated existing sites under its control to determine the best location for the facility. The study concluded, and our organization agrees, that the best location for this facility is exactly where it is proposed in the BioSquare Research Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical research park which contains medical research facilities including Biosafety Level 1, 2 and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare Research Park is also located directly across the street from the Boston University Medical Center campus which also houses hospital and medical research facilities and is the largest Level 1 Trauma Center in New England.

We understand that some community members feel that such a facility should be located in a more rural location. We feel strongly that the facility should be located in an urban area which functions as a hub for medical research activities and which has a significant base of resident medical research scientists. Siting the facility in this manner assures that efficiencies are reached in

**LETTER 10**

**Cheryl S. Barbanel, MD, MBA, MPH, FACOEM**

terms in the ability to share research facilities and knowledge through direct collaboration among the various institutions located in the greater Boston area. In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, our organization has no question that the facility will be safe. There are several federal and state programs which require the facility to be constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, we urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,



Cheryl S. Barbanel, MD, MBA, MPH, FACOEM  
Chief, Occupational & Environmental Medicine  
Boston Medical Center

**LETTER 10**

**Cheryl S. Barbanel, MD, MBA, MPH, FACOEM**

**LETTER 11**  
**Florintina Barbosa**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories**

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab at BUMC.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,

*Florintina Barbazz*

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

Our community needs projects like the proposed biosafety laboratory.

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In addition, BUMC has committed \$1 million to training Boston residents to be lab technicians. The training will be part of the City Lab program. After nine months, the graduates are able to find meaningful jobs at a laboratory at the medical center or in a similar laboratory in the City. This will be a great partnership and illustrates BUMC's strong commitment to our community.

I support the Biosafety Lab.

*Norma Barbosa*

**LETTER 12**

**Norma Barbosa**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
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Dear Ms. Nottingham:

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I support the Biosafety Lab.

*Broderick Bass*

**LETTER 13**  
**Broderick Bass**

LETTER 14

James M. Becker, M.D.

James M. Becker, M.D.

Boston Medical Center  
One Boston Medical Center Place/CS00  
Boston, MA 02118-2393  
Tel: 617 638-8600  
Fax: 617 638-8607



BOSTON UNIVERSITY  
SCHOOL OF MEDICINE  
James Utley Professor  
and Chairman  
Division of Surgery



Surgeon-in-Chief



May 4, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world.

I believe that the NEIDL at BUMC will be one of the safest laboratories in the world. I have been briefed on the systems and the design and am familiar with operations in biomedical research laboratories. I am impressed by the building's safety and security features and by the team BUMC has assembled to build this important project.

I should also note that there are some who have incorrectly raised the city of Boston's rDNA regulations, as a reason the laboratory should not be built. This is simply misinformation. rDNA research is conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions, BUMC authorities have stated that they will do all research in compliance with the Health Commission's guidelines.

This laboratory will be an important project for the research community and those interested in finding cures for emerging infectious diseases and I fully support it.

Sincerely,

A handwritten signature in cursive script, appearing to read "James M. Becker".

James M. Becker, M.D.  
James Utley Professor and Chairman of Surgery  
Surgeon-in-Chief

LETTER 15

Emelia J. Benjamin, M.D., Sc.M.

May 3, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

RE: Supplemental Draft Environmental Impact Statement-National Emerging Infectious  
Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

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As you are aware, biomedical research laboratories operate under strict procedures and protocols at  
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conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions,  
BUMC authorities have stated that they will do all research in compliance with the Health Commission's  
guidelines.

This laboratory will be an important project for the research community and those interested in finding  
cures for emerging infectious diseases and I fully support it.

Sincerely,

Emelia J. Benjamin, M.D., Sc.M.  
Professor of Medicine  
Boston University School of Medicine  
**The Framingham Heart Study**  
73 Mount Wayte Ave. Suite 2  
Framingham, MA 01702-5827

**Nottingham, Valerie (NIH/OD/ORF)**

**From:** Abenton1@aol.com  
**Sent:** Wednesday, May 11, 2005 1:24 PM  
**To:** NIH NEPA Comments  
**Subject:** Letter of support - BUMC BioSafety Lab - Boston Massachusetts

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories**

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab at BUMC.

I live in the community where the proposed lab is being built and I have the utmost confidence in BUMC. When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

I am further pleased that the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,

Adrienne Benton

5/11/2005

**LETTER 16**  
**Adrienne Benton**

Valerie Nottingham  
NIHB13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Ms. Nottingham,

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,

Laurie Berry  
164 Pleasant St.  
Cambridge, MA 02139

**LETTER 17**

**Laurie Berry**

17.1 See Response to Comment 1.1.

17.2 See Response to Comment 1.2.

17.3 See Response to Comment 1.3.

17.4 See Response to Comment 1.4.

17.1

17.2

17.3

17.4



NEW YORK UNIVERSITY SCHOOL OF MEDICINE

Martin J. Blaser, M.D.  
Frederick H. King Professor of Internal Medicine  
Chair, Department of Medicine  
Professor of Microbiology

550 First Avenue, OBV-A606, New York, NY 10016  
Telephone: (212) 263-6394  
Facsimile: (212) 263-3969  
Email: martin.blaser@med.nyu.edu

May 4, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious  
Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I am writing this letter to express support for the National Emerging Infectious Diseases  
Laboratories at Boston University.

The Biosafety Level 4 Laboratories in North America have an outstanding safety record.  
With more than 77 years of combined operations, there has never been a community incident or  
an environmental release.

I am familiar with the design of the proposed laboratory at Boston University. I believe that it is  
being designed and built using state-of-the-art safety and security systems. Boston University has  
a deep commitment to ensuring the safety of the laboratory, the researchers, and the community.  
In a world of risk, we must consider that the magnitude of risk from this lab to the community is  
extremely low.

A BSL-4 laboratory will provide much needed capacity to study emerging infectious diseases  
and will be highly beneficial for scientists and researchers throughout the region who are looking  
for treatments and vaccines for some of the world's deadliest diseases. This laboratory will  
safely conduct research on infectious diseases that threaten the security of Boston, of the nation  
and of the world.

I support Boston University's research efforts and its plans to build the NEIDL. It will be an  
asset to Boston and to the United States.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin J. Blaser".

Martin J. Blaser, M.D.



New York University  
A private university in the public service

LETTER 18

Martin J. Blaser, M.D.

Dolores Boogdian  
452 Park Drive #16  
Boston, MA 02215  
617-236-4627

May 18, 2005

National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Report on the  
Boston University Medical Center National Biocontainment Laboratory

Dear Sir or Madam:

I write to express my deep reservations and objections to the proposed Level 4 Biosafety Lab (BSL-4) at the Boston University Medical Center in Boston, Massachusetts. The proposed location is in a dense population center and seems clearly inappropriate in light of the substances that will be handled by the proposed facility. Studying "agents that pose a high risk of life-threatening disease for which no vaccine or therapy is available" (to quote your own website definition of a BSL-4 lab) should not be done in an urban center. This seems so clear that it boggles one's mind that this facility has been granted funding through your office, and that others in the country may be similarly sited. For that reason, I call upon you to justify your identification of this location as suitable for such a dangerous undertaking, and how this location was chosen over others that were proposed to NIH.

I also call upon you to describe and account for a situation where any of the biological agents that will be handled in the facility (including but not limited to anthrax) are released, so that the possible impacts on the surrounding community can be understood. The possibility and results of such a release should be described, not only those that arise due to inadvertence, and the casual dispersal and exposure of toxic substances that will ensue, but due to purposeful capture and intentional broadcast of these agents in an urban area. Such an analysis must be undertaken, not only because of the real possibility of criminal (or "terrorist") activities, but because the possibility must be made clear to the residents of Boston and those working within the City so that they can truly understand the environmental impacts of this laboratory and the consequences that may come from its existence in their city. Anything less is a subterfuge and brash cover-up of the nature of this facility.

## LETTER 19

### Dolores Boogdian

- 19.1 The Maximum Possible Risk (MPR) model scenarios found in Appendix 12 apply an extremely conservative modeling algorithm over the proposed Boston University site taking into consideration the urban nature of the site. The model evaluates risks at a variety of points across this urban setting. Results of release scenarios subjected to maximum possible risk modeling reveal that public health risk resulting from the proposed siting of the BU laboratory is negligible.
- 19.2 The analysis of the potential effects indicates that the project is not a dangerous undertaking. Section 2.3, particularly the Siting Criteria in Section 2.3.2, explains how Boston University decided this location was appropriate.
- 19.3 It is impossible to determine all of the agents that potentially may be worked with in the proposed BSL-4 facility over time because laboratory personnel will be engaged in emerging infectious disease research as well as civilian biodefense research. However, the Centers for Disease Control and Prevention has evaluated microbial agents for potential use as agents of bioterrorism (Rotz, et al. 2002). Since several characteristics of civilian populations differ from those of a military population including a wider range of age groups and health conditions, previous lists of military biological threats cannot be adopted for civilian use. Second to smallpox, the possession of which is limited by international agreement and therefore will not be worked with at the proposed BU site, *Bacillus anthracis* is the agent that poses the greatest real and perceived public health risk if used as a weapon or through an accidental release. Thus, anthrax spores were chosen as the "worst case" modeling agent.

**LETTER 19**

**Dolores Boogdanian**

19.4 See Response to Comment 4.7.

19.5 See Response to Comment 4.44.

19.6 As noted in the FEIS, any research that may be conducted in the proposed Boston-NBL would comply with all applicable Federal, state and local laws, including laws governing the use of recombinant DNA. See Section 2.2.5.1.

19.4

The analyses regarding the possibility and consequences of release must also include those that arise by virtue of the agents' transport to, from and within Boston on the streets and highways leading to and from the proposed laboratory.

19.5

It is essential that the analyses to be undertaken account for mistake, because mistakes occur. Boston University staff in a BSL-3 lab recently made a mistake, and the possibility of a release of tularemia occurred. Although the agent sickened the exposed workers, it was by sheer luck that the exposed workers did not cause others with whom they came in contact to sicken. That will not be the case if the agents to which workers are exposed at the proposed facility, and who may inadvertently expose others, are those typically handled in a BSL-4.

19.6

Lastly, the City of Boston has banned rDNA research. It must be revealed how the research that would be conducted at a BSL-4 will comply with this ban.

I urge you to ensure a thorough analysis of the impacts of a release of these agents in an urban setting, as is now suggested, so that you as well as the trusting public understand what the possible consequences are, and to truly understand whether they can ever be sufficiently mitigated or avoided.

Thank you for the opportunity to comment.

Signed:

Dolores Boogdanian

**LETTER 20**  
**Maria Bossa**

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

**Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab at BUMC.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,



**LETTER 21**

**Christopher Brayton**

Valerie Nottingham, Chief, Environmental Protection  
National Institutes of Health, B13 RM. 2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories

Dear Ms. Nottingham,

I write to you of the Biosafety Lab at BUMC.

I have attended most of the meeting held by BUMC in their efforts to tell us about the laboratory and to answer questions from the community covering our concerns. After attending the meeting and visiting University of Georgia in Atlanta and their level 4 lab.

I have reached the conclusion that this lab is important to find cures for infectious diseases. I believe there is a need for this facility to do this research. And from what I have heard I believe BUMC has put together a plan that will provide a safe and secure lab for this research.

I have a ¼ mile from the proposed site for this lab and I feel comfortable BUMC will operate will all the controls needed to insure our safety.

Sincerely,

Christopher Brayton  
3 Haven Street  
Boston, MA 02118

Bayha, Ryan (NIH/OD/ORS)

From: Nottingham, Valerie (NIH/OD/ORF)  
Sent: Tuesday, May 24, 2005 10:59 AM  
To: Bayha, Ryan (NIH/OD/ORS)  
Subject: FW: BU Level 4 Lab

-----Original Message-----  
From: Cat [mailto:cat.bryant@gmail.com]  
Sent: Tuesday, May 17, 2005 10:37 PM  
To: NIH NEPA Comments  
Subject: BU Level 4 Lab

22.1

I am in strong opposition to the proposed lab being built in Boston. It is often compared to the existing lab in San Antonio, but in fact, that lab is outside the confines of the city, whereas this proposed lab is not. Building a lab of this nature in a densely populated urban area is a recipe for disaster. I don't believe BU as an institution has proven that it is capable of policing itself according to the needs that such a lab would require.

22.2

I also don't believe that, should some of the research fall under the heading of Homeland Security, that we, as residents, would be informed as to what type of materials are being tested there.

22.3

In addition, I live 3 blocks from the Boston line and work in Boston, and don't think that, should disaster strike, there is a comprehensive plan for evacuation of such a densely populated area.

I urge you to join me in opposing the building of this type of facility in Boston. Thank you.

Sincerely,

Cat Bryant  
47 Florence St. #1  
Somerville, MA 02145

## LETTER 22

### Cat Bryant

- 22.1 The Southwest Foundation for Biomedical Research BSL-4 is located within the confines of northwest San Antonio, Texas, within the city limits. The risk assessment that appears in Section 4.2.1.1 "Community Safety and Risk" in the FEIS shows that the risk of the facility to the surrounding population is negligible. The risk would be negligible whether the facility was in an urban environment or a rural environment.
- 22.2 The purpose of the Boston-NBL is to provide a highly contained and secure laboratory dedicated to studying emerging and re-emerging infectious diseases, many of which have potential as bioterrorism agents. The laboratory would not develop offensive or defensive biological weapons, as this is forbidden by a national security directive and international law. The facility would be partially funded by the National Institutes of Health, a part of the Department of Health and Human Services. The laboratory would be owned and operated by Boston University. The Homeland Security Department is not involved with this project. There would be no classified research undertaken at the Boston-NBL facility. See Section 1.1.
- 22.3 In the event of an emergency, the decision to evacuate or contain and shelter in place is one that is made by the City of Boston emergency response agencies. BUMC has and would continue to fully cooperate with these public safety agencies in emergency response planning for unforeseen events.

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Boston University  
School of Medicine

Office of  
Student Affairs

715 Albany Street, L-109  
Boston, Massachusetts  
02118-2526  
Tel: 617 638-4166 or 4194  
Fax: 617 638-4491  
E-mail: [plcarr@bu.edu](mailto:plcarr@bu.edu)

Phyllis L. Carr, M.D.  
Associate Dean  
for Student Affairs

May 11, 2005

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world.

I believe that the NEIDL at BUMC will be one of the safest laboratories in the world. I have been briefed on the systems and the design and am familiar with operations in biomedical research laboratories. I am impressed by the building's safety and security features and by the team BUMC has assembled to build this important project.

I should also note that there are some who have incorrectly raised the city of Boston's rDNA regulations, as a reason the laboratory should not be built. This is simply misinformation. rDNA research is conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions, BUMC authorities have stated that they will do all research in compliance with the Health Commission's guidelines.

This laboratory will be an important project for the research community and those interested in finding cures for emerging infectious diseases and I fully support it.

Sincerely,

Handwritten signature of Phyllis L. Carr, MD.  
Phyllis L. Carr, MD  
Associate Dean for Student Affairs

LETTER 23

Phyllis L. Carr, MD

**Nottingham, Valerie (NIH/OD/ORF)**

**From:** subrata@bu.edu  
**Sent:** Tuesday, May 03, 2005 7:04 PM  
**To:** NIH NEPA Comments  
**Subject:** National Infectious Diseases Laboratory (NEIDL)

Ms. Valerie Nottingham  
NIH B13/2W64  
9000 Rockville Pike  
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging  
Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I am writing to express support for the National Emerging Infectious  
Diseases  
Laboratories at Boston University Medical Center (BUMC).

The Biosafety Level 4 Laboratories in North America have a very good  
safety  
record. With more than 77 years of combined operations, there has never  
been  
a community incident or an environmental release.

I am familiar with the design of the proposed laboratory at BUMC and  
believe  
that it is being designed and built using some of the most sophisticated  
and  
state-of-the-art safety and security systems. I firmly believe that BUMC  
has a  
deep commitment to ensuring the safety of the laboratory, the  
researchers and  
the community.

A BSL-4 laboratory will provide much needed capacity to study emerging  
infectious diseases and will be very beneficial for scientists and  
researchers  
throughout the region who are looking for cures and vaccines for some of  
the  
world's deadliest diseases. This laboratory will safely conduct  
research on  
infectious diseases that threaten the safety and security of our city,  
of the  
nation and indeed, of the world.

I support BUMC's research efforts and its plans to build the NEIDL.

Sincerely,

Subrata Chakrabarti, Ph.D  
Instructor in Medicine  
Boston University School of Medicine  
700 Albany Street  
CABR, Rm W533  
Boston, MA-02118  
Ph: (617)6384260  
Boston, MA

**LETTER 24**

**Subrata Chakrabarti, Ph.D**

**LETTER 25**  
**Sheila Cheimets**

**Nottingham, Valerie (NIH/OD/ORF)**

**From:** David Cheimets [dcheimets@excite.com]  
**Sent:** Friday, May 13, 2005 5:09 PM  
**To:** NIH NEPA Comments

Gentlemen:

This letter will make clear my strong and continuing support for the creation of a bio-safety laboratory on the campus of Boston Medical Center in Boston to initiate research on emerging and evolving diseases.

I, along with many others, have testified in support repeatedly at the many hearings and meetings held to discuss this issue. Each person's reasons differ: mine are as follows.

- corporate research will continue to focus on problems with huge economic pay-offs, diseases and conditions that will result in widely used and profitable medications
- diseases that primarily affect third-world populations will not in any foreseeable future fit that description and therefore will continue to be ignored by the private sector
- International air travel makes it impossible to contain diseases on any one continent; we are all at risk for all diseases
- Boston needs to re-create itself as an international bio research center to continue its crucial role as the economic engine of the whole New England area. Textile manufacturing left as did shoe manufacturing and computers; back room operations for money management is sliding away now.
- Boston keeps in the area a good percentage of those who graduate from our prestigious universities; this facility will not only keep scientists here but bring many from elsewhere, enriching our workforce again. The present economic world values and rewards only a highly educated workforce.

Those of us old enough to remember the frightening and destructive polio epidemics of the past must stand witness to the need for this facility. Neither baseless fear nor stubborn ignorance should be allowed to prevent this facility from providing the solutions, cures and preventions that the world needs.

Thank you for your interest.

Sincerely,

Sheila Cheimets  
540 Massachusetts Avenue  
Boston, Massachusetts 02118  
617-536-3281

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5/16/2005