

1.0 PURPOSE AND NEED

1.1 BACKGROUND AND PLANNING CONTEXT

Following the events of September 11, 2001, the focus on national security in the United States has greatly intensified. Through the National Institutes of Health (NIH), which includes the National Institute of Allergy and Infectious Diseases (NIAID), which support broad-based programs of basic and applied research to prevent, diagnose and treat infectious and immune-mediated diseases, the Department of Health and Human Services (DHHS) is advancing biomedical research. Integral to this mission is the responsibility to conduct biomedical research aimed at addressing naturally occurring, newly emerging and re-emerging infectious diseases. The specific mandate of the NIAID in the post-September 11 national security efforts is to support research that will ultimately lead to the development of medical countermeasures in the form of therapies, vaccines and diagnostic tools to protect the country from deliberate attacks with biologic agents (Hirschberg, et al. 2004).

A lack of available and adequate research facilities is a major impediment to the study of emerging infectious diseases. As a result, many important pathogens have received little attention recently, and many have not been examined using the tools of modern science. This research deficit becomes most apparent now when there has never been a greater demand for information on the pathogens and host responses to them. Information from basic research studies is critical to the development of effective vaccines and therapies to combat infectious diseases. Such products can be developed only through understanding the basic biology of disease-causing agents. Cutting-edge discoveries in infectious disease research have resulted from NIAID programs. This proposed facility will enhance the capability of NIAID to support basic research on important pathogens. These enhanced capabilities, once in place, would have an additional benefit to the American public in that they would strengthen the nation's ability to respond to outbreaks of naturally occurring diseases. Recent outbreaks of SARS and West Nile Fever underscore the need to have an extensive and flexible infrastructure to support infectious disease research to meet the challenge of emerging diseases.

In February of 2002, NIAID, in consultation with a blue ribbon panel, developed a strategic plan for biodefense research to accomplish short and long-term goals. The NIAID strategic plan emphasizes both basic research and the application of that basic research to the development of products. The plan identified a critical need to expand the availability of national resources for biodefense research and identified a serious shortage of high-level biocontainment laboratories.

NIAID has a history of research that has had global impacts on public health improvement. This research capability allows NIAID to address unknown, future health threats associated with emerging and re-emerging infectious disease. NIAID is comprised of both intramural and extramural research areas. The Division of Intramural Research (DIR) and the Vaccine Research Center conduct intramural research. DIR conducts research in virology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics, and supports clinical, patient-centered research in allergy, immunology, and infectious diseases at the NIH's Clinical Center (NIAID 2002a). NIAID supports extramural research, done by non-federal scientists in universities, medical schools, hospitals and research institutions through grants and contracts.

NIAID issued a Broad Agency Announcement (BAA) in the fall of 2002 to build national laboratories to expand the research capacity. Boston University Medical Center (BUMC), a consortium of Boston University and Boston Medical Center, submitted an application to NIAID in response to the BAA in February of 2003 and received a \$128 million dollar grant award in September of 2003 to construct a National Biocontainment Laboratory (NBL). The NBL facility would be called the National Emerging Infectious Diseases Laboratories (hereinafter referred to as "Boston-NBL" or the "Project"). The Project is one of two National Biocontainment Laboratories funded by NIAID in 2003. These facilities, as well as several Regional Biocontainment Laboratories (RBLs), are being funded to help achieve NIAID's research and development mission.

The proposed Boston-NBL facility would be constructed at the BioSquare Research Park on Albany Street in the South End neighborhood of Boston across the street from the BUMC campus (see "Figure 1-1, Project Location"). The BioSquare Research Park, which is the City of Boston's only research park devoted exclusively to the life sciences sector, is located on a 14-acre site with a capacity for 2.2 million square feet of medical research facilities.

The BioSquare Research Park is immediately adjacent to the BUMC and its extensive medical, clinical and research facilities. Construction of the facility would add to the growing life science industry in the region that is supported by both the Commonwealth of Massachusetts and the City of Boston.

The Boston-NBL facility would be owned, operated and managed by the BUMC. The entity holding legal title to the site is University Associates, a Massachusetts limited partnership, the general partners of which are Univer Development Foundation, Inc. (the sole member of which is Boston Medical Center Corporation, a Massachusetts non-profit corporation), and the Trustees of Boston University, a Massachusetts non-profit, educational corporation. The Boston-NBL facility would contain state-of-the-art laboratories designed to safely find treatments and vaccines for many emerging and re-emerging diseases.

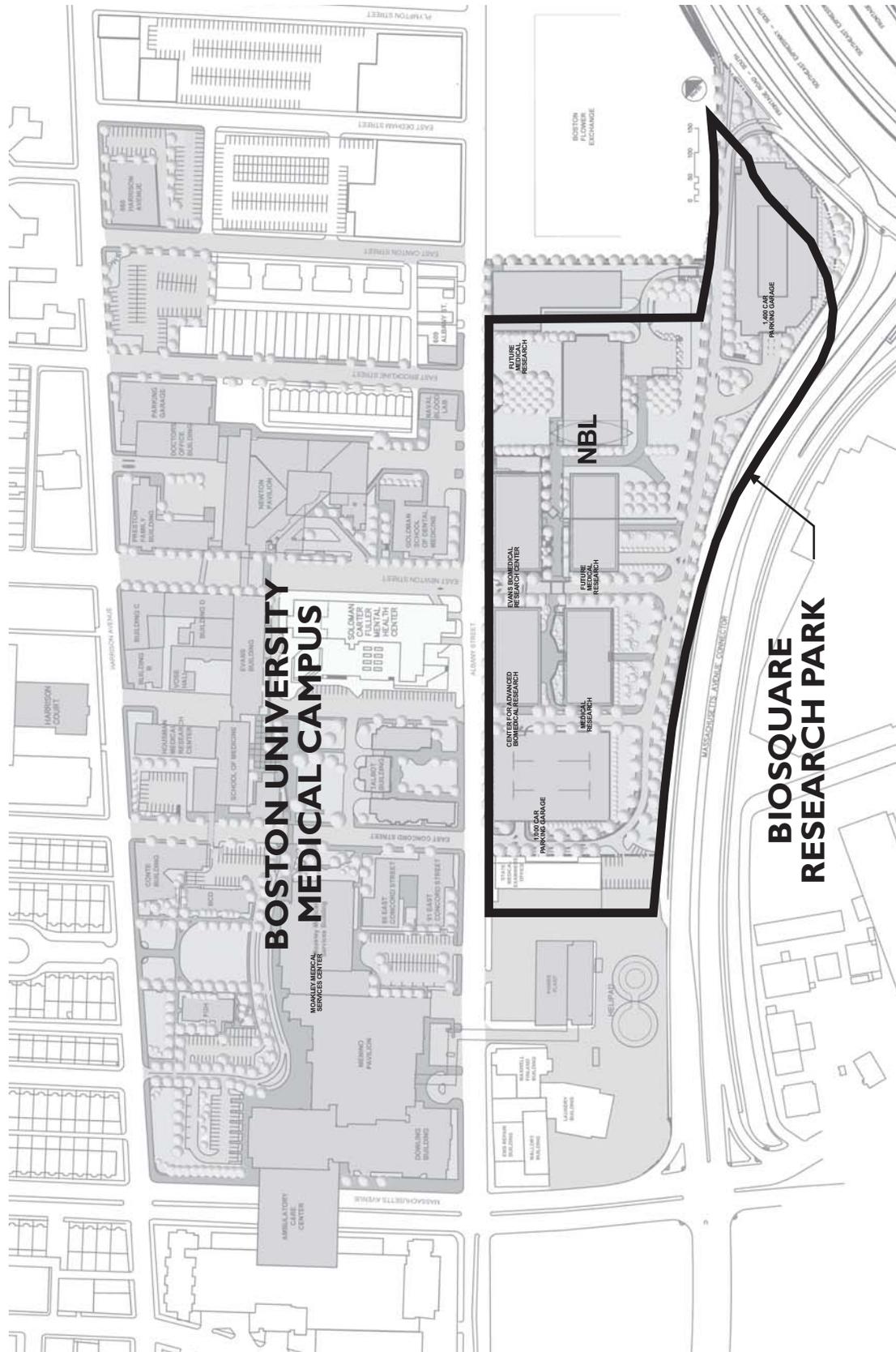


FIGURE 1-1
Project Location
source: Stubbins Associates, Fort Point Associates, Inc.

The facility would be approximately 194,000 gross square feet (sf) and constructed to the National Institute of Health's (NIH's) standards of safety. NIH safety standards include recently revised construction and design standards specific to high containment areas, redundant utility sources, extensive security and access control systems, and multiple site-specific safety, security and audit protocols that would be enforced by highly trained staff.

A major portion of the Boston-NBL would center on providing comprehensive core research facilities that would enable basic, translational and clinical research on emerging and re-emerging infectious diseases. The facility would contain core support laboratories with very sophisticated facilities including high power microscopes, Magnetic Resonance Imaging (MRI) machines, and tools to study new diagnostics, vaccines and drugs to treat infectious diseases.

As a national resource, these core research facilities at the Boston-NBL must anticipate the research needs of investigators over at least a 20-year time period and must complement existing and planned research facilities. To meet these needs, flexible core facilities devoted to a comprehensive array of research methodologies that contribute to the entire product development continuum from basic science to clinical research would be provided. The facility would support basic research to identify mechanisms of pathogenesis (origination and development of disease within body tissue) and potential targets for new diagnostics, vaccines, biologicals and therapeutics; translational research focused on identifying molecules/reagents/leads that might be useful as diagnostics, immunogens, biologicals or therapeutics; *in vivo* studies in small animals and non-human primates; and clinical studies.

Boston-NBL investigators would be able to utilize existing research space and Biological Safety Level (BSL)-2 and BSL-3 facilities located in the BioSquare Research Park. The Boston-NBL would also serve as a training facility, and would add to the region's and the nation's capacity to respond in the event of a bioterrorism threat/attack or an emerging infectious disease emergency, by providing facilities and support to first-line responders. As in all of the biomedical research facilities at BUMC, including the BioSquare Research Park, senior, experienced investigators would serve as research mentors for junior faculty, postdoctoral fellows (M.D.s and Ph.D.s) and graduate students in the biomedical sciences. All trainees would undergo intensive safety training, certification and background checks prior to their research work in the high level containment facilities.

The facility would not work on or develop biological weapons, as this is forbidden by a national security directive and international law. President Nixon, in 1969, agreed to a National Security Decision Memorandum, which renounced the use of lethal methods of bacteriological/biological warfare and ordered the destruction of all stockpiled agents. The United States signed the *Convention on the Prohibition of the Development, Production and 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. All research activities at the proposed facility will be carried out in strict compliance with federal, state and local regulations.

1.1.1 ORGANIZATION OF THE DOCUMENT

Chapter 1 – Purpose and Need. This chapter explains the purpose and need for the Proposed Action. It also includes a summary of public comments and issues raised during public scoping process.

Chapter 2 – Proposed Action and Alternatives. This chapter discusses and compares in more detail alternatives to the Proposed Action considered in the EIS.

Chapter 3 – Affected Environment. This chapter explains the current condition of resources that may be affected by the Proposed Action. Resources that would not be affected are identified and rationale provided as to why they will not be discussed further.

Chapter 4 – Environmental Consequences. This chapter discloses potential effects of the Proposed Action and alternatives, including direct, indirect and cumulative effects.

Chapter 5 - Response to Comments. This chapter provides copies of all comments received on the SDEIS and responses to those comments.

Literature Cited

List of Preparers

Acronyms and Glossary

Distribution List

Appendix 1 – Includes a NIAID publication that describes the need for biosafety laboratory facilities.

Appendix 2 – Identifies the characteristics of the diseases currently studied at BUMC and those which may be studied at the BUMC and Boston-NBL.

Appendix 3 – Provides a list of community meetings related to the proposed Project.

Appendix 4 – Contains information of the safety record of biocontainment laboratories.

Appendix 5 – Boston-NBL Security Program and Emergency Response

Appendix 6 – BUMC Standard Operating Procedures

Appendix 7 – High Hazard Material Management (HHMM) Policy

Appendix 8 – BUMC ICP Table of Contents

Appendix 9 – Risk Assessment Reports – September 1, 2004 and March 23, 2005

Appendix 10 – Supplemental Air Quality Analysis

Appendix 11 – Executive Summary Threat and Risk Assessment

Appendix 12 – BUMC/NEIDL Risk Assessment – September 2005

1.1.2 REQUIRED DISCLOSURES

Pursuant to the regulations that implement the National Environmental Policy Act (NEPA) found in 40 Code of Federal Regulations (CFR) 1502.16, the following are the required disclosures and where they are found in this document:

- Direct and indirect effects and their significance (Chapter 4)
- Potential conflicts between the Proposed Action and objectives of federal, state and local land use plans, policies and controls (Chapters 1 and 4)
- Potential environmental effects of alternatives (Chapter 4)
- Energy requirements and conservation, natural and depletable resource requirements and conservation and mitigation measures (Chapters 2 and 4)
- Urban quality and design and historic and cultural resources (Chapter 3 and Chapter 4)
- Mitigation to offset adverse environmental impacts (Chapters 4)

1.2 ELEMENTS OF BIOSAFETY CONTAINMENT

The three elements of containment in biosafety laboratories are laboratory practice and technique, safety equipment and facility design. The NIH and the DHHS Centers for Disease Control and Prevention (CDC) have defined four Biosafety Levels (BSL), which require different levels of containment and security based on the biological agents used and the types of research being conducted at the laboratories. While certain biological agents may require a given biosafety level, the recommended biosafety level may vary with the type of agent and type of research. The example discussed below for Hantaviruses illustrates this point.

According to the CDC, Hantaviruses are Category C biological agents (U.S. DHHS, 2002a). Category C agents are emerging pathogens that could be engineered for mass dissemination in the future because they are available, easy to produce and disseminate, and have potential for high mortality rates and major health impacts. Hantavirus pulmonary syndrome is an emerging disease. According to biosafety standards, BSL-2 practices and procedures are recommended for laboratory handling of sera with potential infections of Hantavirus pulmonary syndrome. Use of a certified biological safety cabinet is recommended for handling human body fluids when potential exists for spillage or aerosol. Potential infected tissue samples are handled in BSL-2 facilities following BSL-3 practices and procedures. Preparation and handling of viral concentrates is performed in BSL-4

containment facilities. Therefore, appropriate biosafety levels and the agent and type of research determine which procedures are to be used.

The proposed Boston-NBL facility would contain BSL-2, BSL-3 and BSL-4 labs, which, in addition to the BSL-1 designation, are discussed below and summarized in Table 1-1.

BSL-1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and which pose minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the building's general traffic patterns and work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment and/or facility design is not required. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or related science.

BSL-2

Biosafety Level 2 is similar to Biosafety Level 1 for work involving agents of moderate potential hazard to personnel and the environment. These types of laboratories have laboratory personnel with specific training in handling pathogenic agents and access to the laboratory is limited when work is being conducted. Within the facility, extreme precautions are taken with contaminated sharp items and biological safety cabinets or other physical containment equipment are used in certain procedures where aerosols or splashes may occur.

BSL-3

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

BSL-4

Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of laboratory infections and life-threatening disease and for which there is no vaccine and no cure. The laboratory staff has specific and thorough training in handling extremely hazardous infectious agents, the use and function of primary and secondary containment, and the standard laboratory practices and procedures. The laboratory director

Table 1-1: Biosafety Laboratory Levels

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
BSL-1	Agents not generally associated with disease in healthy people	Good microbiological practice; hand washing; and no eating, drinking or gum chewing in the laboratory	Pipeting devices-mouth pipeting is prohibited	Open bench-top sink for hand washing is required
BSL-2	Agents associated with human disease	Limited lab access; most work may be performed on a bench top; biohazard warning signs; "Sharps" precautions; and biosafety manual defining any needed waste decontamination or medical surveillance policies	Class I or II Biological Safety Cabinets (BSC) or other physical containment devices and lab coats, gloves and face protection, as needed	Open bench-top sink for hand washing is required and autoclave or another approved decontamination procedure is available
BSL-3	Agents associated with human disease and which cause illness by spreading through the air (aerosol), and agents that cause diseases that may have serious or lethal consequences	BSL-2 practice plus controlled access; decontamination of all wastes; and decontamination of lab clothing before laundering	Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices; protective lab clothing, gloves and respiratory protection as needed	BSL-2 plus physical separation from access corridors; self-closing, double-door access; no recirculation of exhaust air; negative airflow into laboratory and design includes back-up/redundant systems
BSL-4	Agents associated with human disease and which cause illness by spreading through the air (aerosol) or agents with an unknown cause of transmission and which also cause diseases that are usually life-threatening	BSL-3 practices plus clothing change before entering; shower on exit; and all material decontaminated on exit from facility	All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive-pressure personnel suit	BSL-3 plus separate building or isolated zone; dedicated supply and exhaust, vacuum, and decontamination systems; design includes back-up/redundant systems

Source: U.S. Department of Health and Human Services, 2004.

strictly controls access to the laboratory, which is either in a separate building or in a controlled secured area within a building completely isolated from all other building areas. A special training program for staff is required, including training on the personal protective equipment (positive pressure suit). A specific facility operations manual is prepared or adopted.

1.3 PURPOSE AND NEED FOR ACTION

The Proposed Action is to partially fund the construction of the Boston-NBL facility at the BioSquare Research Park in Boston, Massachusetts. The Boston-NBL facility would be a highly secure biocontainment laboratory that would support basic, translational and clinical research on vaccines and hazardous biological agents. The 194,000 sf facility would be located on the BUMC campus in Boston, MA and would house state-of-the-art BSL-4 biocontainment laboratories and the necessary associated BSL-2 and BSL-3 laboratories, animal facilities, insectary facilities, clinical facilities and research support space. The facility would serve as a national resource for conducting clinical and laboratory (in vitro and in vivo) research and testing on hazardous biological agents in support of the NIAID's biodefense agenda.

The NIAID is a component of the NIH, an operating division of the DHHS, and supports basic and applied research to prevent, diagnose and treat infectious and immune-mediated illnesses, including Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) and other sexually transmitted diseases, tuberculosis, malaria, autoimmune disorders, asthma and allergies. 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).

The Boston-NBL facility would include state-of-the-art BSL-2, BSL-3 and BSL-4 laboratories as well as associated research and administrative support space (see Appendix 2, Characteristics of Diseases studied at BUMC and which could be studied at BUMC and the Boston-NBL). The BSL-2 and BSL-3 laboratories would be similar to those already on the BUMC campus and the proposed BSL-4 laboratory, which would comprise approximately 16% of the total assignable space at the Boston-NBL, would be designed and built in compliance with federal standards. The BSL-4 laboratory would incorporate special engineering and design features to prevent microorganisms from being released into the environment, and safety and decontamination features would provide multiple layers of protection for the surrounding environment. The proposed laboratory would be owned and operated by BUMC, managed by BUMC personnel, and would meet the most stringent security and safety guidelines.

1.4 SCOPE

The scope of the Environmental Impact Statement (EIS) is established by the purpose and need for the Project and by DHHS procedures and authority. The scope consists of the range of actions, alternatives, environmental issues, impacts and mitigation measures to be considered and discussed in the EIS. The scope of this EIS complies with the NEPA regulations in 40 CFR 1508.25. The document evaluates the direct, indirect and cumulative effects of the Proposed Action on the existing environment (see Chapter 4, Environmental Consequences).

The document evaluates two alternatives – Proposed Action and No Action. Other alternatives, which were not considered feasible, are also described (see Chapter 2, Proposed Action and Alternatives).

1.4.1 IMPACTS

The regulations of the Council on Environmental Quality (CEQ) in 40 CFR 1508.25(c) require analysis of direct, indirect and cumulative impacts. Direct impacts are caused by the action and occur at the same time and place. Indirect impacts are caused by the action and occur later in time or farther removed in distance, but they are still reasonably foreseeable. Cumulative impacts result from incremental impact of the action when added to other past, present and reasonable foreseeable future actions.

1.4.2 ALTERNATIVES

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 measures. Other reasonable courses of action include alternatives that meet the stated purpose and need. Alternatives are discussed in Chapter 2. Impacts of the No Action Alternative, which would maintain the existing conditions, are also considered.

1.4.3 CONNECTED, CUMULATIVE, AND SIMILAR ACTIONS

The CEQ regulations at 40 CFR 1508.25 address the scope of analysis and elements to be considered in a Proposed Action. The regulations recognize that separate activities can combine and interact to create impacts that may be significantly beyond the effects of individual actions. These actions are considered cumulative and their additive effects must be addressed in the analysis.

Federal regulations also require a combined analysis of connected actions. Connected actions are closely related and 1) automatically trigger other actions, 2) could not or would not proceed unless other actions are taken previously or simultaneously and 3) are interdependent parts of a larger action and depend on the

larger action for their justification. The effects of connected actions are analyzed together. Similar actions are those that share a common timing or geography and are evaluated together.

The CEQ regulations implementing NEPA require consideration of environmental effects and prescribe mitigation where practical to limit those effects.

1.5 NEPA PUBLIC SCOPING AND ENVIRONMENTAL REVIEW PROCESS

This Environmental Impact Statement (EIS) has been prepared in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, regulations of the CEQ in 40 CFR 1500-1508, and the NEPA compliance procedures of the DHHS found in the General Administration Manual, Part 30 (Environmental Protection). The comments received on the Supplemental Draft EIS were used to scope the development of this Final EIS.

NEPA does not require preparation of a programmatic EIS for NIAID's overall NBL and RBL program, as each project represents an independent undertaking located in geographically dispersed areas with no common cumulative impacts. The NIAID grant award to BUMC for the Boston-NBL facility requires, and is contingent upon, compliance with NEPA. NEPA allows planning and design activities to proceed during the EIS preparation. This allows projects to be sufficiently well defined so that impacts can be assessed. The NIH will decide whether or not to partially fund the construction of the Boston-NBL Project based on the environmental analysis contained in this EIS and review and consideration of public comments.

On January 9, 2004, the NIH published its Notice of Intent to prepare an EIS on the proposed Boston-NBL in the Federal Register. Publication of the Public Notice initiated the NIH scoping activities. On February 9, 2004, the NIH published notice of a public scoping meeting and an extension of the comment period in the Federal Register. A Public Scoping Meeting was held at historic Fanueil Hall in Boston on Tuesday, February 17th from 7:00 PM to 10:00 PM.

Comments were provided during the extended public scoping period, which began on January 9, 2004 and ended on March 2, 2004. Of those comments, 52 members of the public provided oral testimony at the Scoping Meeting and 37 written comments were submitted. Commentors identified issues that are addressed in the EIS as discussed in Section 1.7 below. A summary of the issues raised during the scoping period is found in Table 1-2, Summary of Scoping, Draft EIS and Supplemental Draft EIS Comments.

The NIH filed a Draft EIS with the U.S. Environmental Protection Agency (EPA) on October 15, 2004. On October 22, 2004, the EPA published notice that the Draft EIS had been filed, was available for public review and comment and that a public meeting was scheduled for November 10, 2004. The public meeting was held at historic Fanueil Hall in Boston on Wednesday, November 10th, 2004 from 7:00 PM to 9:00 PM.

Comments were received during an extended 75 day public comment period, which began on October 22, 2004, and ended on January 3, 2005. Forty seven members of the public provided oral comments at the public meeting and 24 written comments were submitted. A summary of the Draft EIS comments is found in Table 1-2, Summary of Scoping, Draft EIS and Supplemental Draft EIS Comments.

NIH filed a Supplemental Draft EIS with the U.S. Environmental Protection Agency (EPA) on March 25, 2005. On April 1, 2005, the EPA published notice that the Supplemental Draft EIS had been filed, was available for public review and comment and that a public meeting was scheduled for April 25, 2005. The public meeting was held at historic Fanueil Hall in Boston on Monday, April 25th, 2005 from 7:00 PM to 9:00 PM.

Comments were received during an extended 48 day public comment period, which began on April 1, 2005 and ended on May 18, 2005. Fifty one members of the public provided oral comments at the public meeting, of which 29 were in favor of the project. One hundred and fifteen written comment letters were submitted, of which 68 were supportive of the project. Many commentors identified issues that were already addressed in the Draft and/or Supplemental Draft EIS. Others raised new comments, as discussed in Section 1.7 below. Additional information is included in the Final EIS based on comments on the Supplemental Draft EIS. A summary of the Supplemental Draft EIS comments is found on Table 1-2, Summary of Scoping, Draft EIS and Supplemental Draft EIS Comments.

To continue the Boston-NBL EIS process a 30 day waiting period will follow the publication of the Notice of Availability of the Final EIS (FEIS) in the Federal Register. The NIH will then consider all comments on the FEIS and prepare a Record of Decision approving or denying the Proposed Action.

A list of representative federal, state and local agencies with environmental regulatory responsibility for the project is found on Table 1-3, Representative Agencies with Regulatory Responsibilities, and a list of federal, state and local authorities with regulatory oversight responsibilities for the facility is found in Table 1-4, Existing Regulatory Oversight.

Table 1-2: Summary of Scoping, Draft EIS and Supplemental Draft EIS Comments

Comments	Issue Category	Ch. Addressed in FEIS
	COMMENTS FROM SCOPING	
44	Human Health and Safety (risk to public)	Ch. 4
35	Public Information	Ch. 1
32	Safety and emergency response	Ch. 2 & 4
31	Alternatives to Proposed Action	Ch. 2
27	Socio/Economic Issues	Ch. 3 & 4
26	Risk Assessment – Outside Threats	Ch. 4
20	Risk Assessment - Transportation	Ch. 4
18	Environmental Justice	Ch. 3 & 4
12	Regulatory Compliance	Ch. 1
4	Traffic and Transportation	Ch. 3 & 4
3	No Action Alternative	Ch. 2
2	Waste Management and Pollution Prevention	Ch. 2, 3 & 4
2	Historic / Cultural Resources	Ch. 3 & 4
1	Outside scope of EIS	Ch. 2
1	Air Quality	Ch. 3 & 4
1	Cost/Benefit Analysis	Ch. 3 & 4
	COMMENTS ON DRAFT EIS	
14	Cumulative Impacts	Ch. 4
5	Safety Record	Ch. 2 & 4
33	Risk Assessment model and assumptions	Ch. 4
8	Transportation of Agents	Ch. 3 & 4
16	Environmental Justice	Ch. 3 & 4
14	Community Relations	Ch. 1 & 4
21	Alternative Site Analysis	Ch.2
19	Emergency Response	Ch. 2 & 3
12	rDNA research	Ch. 2
10	Outside of Scope of EIS	Ch. 2
	COMMENTS ON DRAFT SUPPLEMENTAL EIS	
49	Safety, Security, and Emergency Response	Ch. 2 & 4
101	Risk Assessment	Ch. 4
12	Transportation of Agents	Ch. 3 & 4
9	Environmental Justice	Ch. 3 & 4
20	Community Relations	Ch. 1 & 4
32	Alternatives	Ch. 2
36	Socio/Economic Issues	Ch. 4
7	rDNA research	Ch. 2
15	Tularemia	Ch. 2 & 4
13	Waste Management and Pollution Prevention	Ch. 4

Table 1-2: Summary of Scoping, Draft EIS and Supplemental Draft EIS Comments (cont.)

Comments	Issue Category	Ch. Addressed in FEIS
1	Cumulative Impacts	Ch. 4
60	Regulatory Compliance	Ch. 1 & 3

Table 1-3: Representative Agencies with Regulatory Responsibilities

FEDERAL		Permit/Approval
Federal Aviation Administration		Notice of Air Hazard
Environmental Protection Agency	NPDES Construction Stormwater	General Permit
Environmental Protection Agency		NEPA Compliance
Department of Health and Human Services		NEPA Compliance
Council on Environmental Quality		NEPA Compliance
Occupational Safety and Health Administration		Construction Safety
Nuclear Regulatory Commission		Radioactive Materials License
STATE		
Massachusetts Environmental Policy Act Office		Environmental Impact Review
Massachusetts Historical Commission		Determination of No Adverse Effect
Massachusetts Water Resources Authority		Industrial Wastewater Discharge Permit
Department of Environmental Protection		Notification of Construction/Demolition
		Sewer Connection Permit
		Air Plan Approval Permit
		Massachusetts Contingency Plan
Massachusetts Highway Department		Highway Access Permit
LOCAL		
Boston Redevelopment Authority		Article 80 Large Project Review
		Cooperation Agreement
		Master Plan PDA Approval
Inspectional Services Department		Building Permit
Boston Civic Design Commission		Recommendation Pursuant to Article 80 Review
Boston Committee on Licenses		Flammable Storage Permit
Boston Department of Public Works		Street Occupancy and Sidewalk Permits
Boston Fire Department		Fire Safety Approvals
Boston Public Health Commission		RDNA Project Registration
South End Landmark Commission		Harrison/Albany Protection Area Design Approval
Boston Transportation Department		Transportation Access Plan Agreement
		Construction Management Plan
Boston Water and Sewer Commission		Site Plan Approval/Sewer Connection Permit
Public Improvements Commission		Various approvals for work in public ways

Table 1-4: Existing Regulatory Oversight

	Inspection	Close Lab or Operation	Permit or Approval	Design Construction Review	Penalty Authority	Siting
Federal						
Centers for Disease Control	●	●	●	●	●	
U.S. Department of Transportation	●	●	●		●	
Occupational Safety and Health Administration	●	●			●	
U.S. Environmental Protection Agency	●	●	●	●	●	
National Institutes of Health			●	●		●
Nuclear Regulatory Commission	●	●	●		●	
U.S. Department of Agriculture	●	●	●	●	●	
State						
Massachusetts Environmental Policy Act Office			●	●		●
Massachusetts Department of Public Health	●	●	●		●	
Massachusetts Department of Environmental Protection	●	●	●	●	●	
Massachusetts Water Resources Authority	●	●	●	●	●	
Local						
Boston Public Health Commission	●	●	●		●	
Boston Fire Department	●	●	●	●	●	
Boston Water and Sewer Commission	●	●	●	●	●	
Boston Redevelopment Authority			●	●		●
Boston Zoning Commission			●			●
Boston Inspectional Services	●	●	●	●	●	

1.6 PUBLIC PARTICIPATION

In addition to the required NEPA public review process described in Section 1.5 above, BUMC has made an institutional commitment to informing and educating the public about the proposed Boston-NBL facility. Comments from the community have indicated positive support as well as opposition to the Project. In 2004, BUMC established the Biosafety Laboratory Advisory Group (B-LAG) to serve as a forum for community input and feedback on the Boston-NBL facility. Comprised of 21 community members from the Dorchester (2), Roxbury (4), South End (13) and South Boston (2) neighborhoods, the B-LAG membership includes both supporters and opponents of the Project. Facilitated by the Director of Community Relations at BUMC, the group assists in identifying key topics of interest and concern for community stakeholders. The meeting discussions are based on member concerns and questions surrounding protocols and systems for biosafety laboratories in general. For example based on requests from the committee members, BUMC representatives hosted B-LAG members on a site visit of biosafety level 2 and biosafety level 3 laboratories located on the Boston Medical Center campus.

Community input on the development of the Boston-NBL facility has also been sought from the existing Project Advisory Committee (PAC). The Boston-NBL facility is proposed to be located within the BioSquare Research Park, an area that was designated by the Boston Redevelopment Authority for the development of medical research uses in the early 1990s. The PAC was established by the City of Boston in 1991 to strengthen community participation in the public process for the BioSquare Research Park. Its members are charged with advising the City, the Boston Redevelopment Authority and BUMC on activities proposed for the campus. The PAC is currently convened on an as needed basis by the Boston Redevelopment Authority at the City of Boston to discuss development projects and master planning efforts affecting the BioSquare and BUMC campuses. BUMC will continue to work with the PAC to discuss and identify issues for the proposed development of the Boston-NBL facility within the context of the BioSquare Research Park.

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 will be housed at the Boston University Medical Campus and headed by a Director. The governance structure for the facility includes several committees, including those that provide external scientific and community oversight of the operations at the lab. The Executive Committee advises the Director of the NEIDL Institute on the scientific research and operational activities of the Boston-NBL and includes one community member as an appointee. In addition, a Community Liaison Committee (CLC) comprised of six committee members who are not employed by Boston University or Boston Medical Center will 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. Going forward, the CLC will replace the B-LAG during construction and operation of the Boston-NBL. Finally, the External Scientific Advisory Committee, which will review all proposed research projects, will include a representative of the Boston Public Health Commission.

In all, more than 150 community meetings have been held in the Dorchester, Roxbury, and South End neighborhoods to provide factual information, answer questions and respond to concerns. These meetings have been supplemented by other forums, including briefings with federal officials, state legislators and agencies such as the Governors Office and Public Safety departments and representatives from the City of Boston including the City Council. Appendix 3 provides a list of some of the meetings held since filing the grant application for the Boston-NBL facility with the NIH in February of 2003.

A variety of other strategies and mediums have been employed to facilitate community exchange and input on the Boston-NBL. To ensure that interested residents understand the purpose, intent and programming for the facility, BUMC began supplementing the broad community-wide meetings. Breakfast Briefings were held to provide a basic orientation and overview of the research that will take place at the Boston-NBL and to provide opportunities to ask questions and get answers. Generally held on the Boston University Medical Campus, key researchers and safety and security personnel were made available to answer both general and more detailed questions in a small-group format. To date, more than 3,100 community residents have been invited to attend one of the more than twenty Breakfast Briefings held.

In addition to the Breakfast meetings, open Office Hours were hosted at different locations and times throughout the Dorchester, Roxbury, and South End neighborhoods. Held on a monthly or bi-monthly basis with representatives from BUMC's medical research and security staff, Office Hours provide community residents with one-on-one opportunities to learn more about the Boston-NBL. Upcoming Office Hours are advertised in local community newspapers. To date, three Office Hours have been held in the Roxbury neighborhood, three have been held in the South End, and one has been held in Dorchester.

Outreach efforts have gone beyond regular meetings to engage community residents in fact-finding activities that provide first-hand knowledge and understanding of research in biosafety laboratories and career opportunities in the biotechnology industry.

In addition to hosting community members on a tour of an Atlanta, Georgia, BSL-4, in January 2005 BUMC, Boston University and Boston Medical Center hosted the 1st Annual campus-wide job/training fair to showcase the diversity of employment opportunities available at the University's Medical and Charles River campus locations and at the medical center. Representatives from City Lab Academy, an entry-level training program for lab

technicians, were on hand to field questions about career opportunities and training in the biotechnology field.

In all, BUMC has conducted, and will continue to conduct a comprehensive public information program to facilitate access and understanding of the Boston-NBL. In addition to the activities above, Information Repositories were created to house Project materials and other relevant documents related to the development of the lab at easily accessible locations. Repositories are located at the Boston, Dudley, Roxbury and South End branches of the Boston Public Library and project overviews have been translated into Spanish and placed at each of the four local repositories.

The website for the Boston-NBL was redesigned with the goal of serving as a more useful and user-friendly tool for those interested in learning more about the project and providing feedback on the same. Between September and December of 2004, website announcement postcards and informational brochures were mailed to more than 3,100 households. Key project documents, including the Final Environmental Impact Statement prepared by the National Institutes of Health, will be made available for download electronically at www.bostonbiosafety.com.

Media and print advertising, particularly on public transit and in local community newspapers, television and radio, have been a key component of BUMC's outreach efforts as it relates to both the development of the Boston-NBL and the institution's presence as a good neighbor in the community. In the fall of 2004, BUMC launched "Health Matters", a weekly 15-minute radio show devoted to discussion of matters that affect and impact the community's health and showcasing the institutional resources that are available to address these. A few of the radio segments have dealt more directly with emerging and reemerging infectious diseases and the proposal to build the Boston-NBL facility.

In summary, input from the community outreach process revealed community concerns centered around five key areas: 1) transparency and access to information; 2) safety and security planning; 3) transportation of infectious agents; 4) emergency response; and 5) access to jobs and training. In response to these concerns, BUMC has expanded its public information process, enhanced and refined the safety and security operations for the Boston-NBL facility including updating its Emergency Response and High Hazard Materials Management Policy (see Appendix 7) and made significant community commitments to create jobs and sponsored job training initiatives. For example, resident concerns over transportation of infectious agents through residential streets led to a revised transportation policy that gives BUMC flexibility to hire dedicated drivers and carriers. In addition, BUMC has committed to invest \$1 million for job training scholarships in the biomedical research and biotechnology fields for 105 local City of Boston residents.

1.7 IDENTIFICATION OF ISSUES

As mentioned in Section 1.5 above, 52 comments on the EIS Scope were received orally at the public meeting and an additional 37 comments were submitted in writing. Forty-seven comments were received orally at the public meeting on the Draft EIS and an additional 24 comments were received in writing. Fifty-one comments were received orally at the public meeting on the Supplemental Draft EIS and an additional 115 comments letters were received. Several issues were raised during the Supplemental Draft EIS process, some of which were already raised during the Scoping and Draft EIS processes. The issues included: Project alternatives; safety, security, emergency response and risk assessment; transportation; socio-economic; environmental protection, including waste management and pollution prevention; environmental justice; regulatory compliance; and cumulative impacts as described below.

1.7.1 ALTERNATIVES

Many of the comments on the Scope and Draft EIS related to alternatives including: alternative locations outside of Massachusetts or in lower density areas outside of Boston; alternative locations for the BSL-4 laboratory component; and alternative locations at sites owned by Boston University. Chapter 2 discusses alternatives to the Proposed Action.

1.7.2 SAFETY/RISK ASSESSMENT/EMERGENCY RESPONSE

There were several comments relating to the modeling and assumptions used in the worst case analysis presented in the Draft EIS. Other comments were made regarding the accuracy of the BUMC and NIH safety records presented in Appendix 4 of the Draft EIS and questions regarding BUMCs emergency response program. Chapter 2 outlines the safety and security program for the Boston-NBL facility that ensures the facility would be operated in strict conformance with the governing federal safety regulations. Concerns over the safety of transporting agents to the facility were also raised, and are also addressed in Chapter 2. Chapter 4 includes a “worst case” analysis utilizing three different quantitative models to evaluate the risk from the loss of containment systems of the BSL-4 laboratory. Appendix 12 includes an additional risk assessment prepared by NIH.

1.7.3 TRANSPORTATION AND PARKING

Managing transportation impacts was a concern raised in the comment letters, including traffic generation, use of public transit and parking. Analysis of transportation impacts is provided in Chapter 4.

1.7.4 SOCIO ECONOMIC

Socio-economic issues mentioned include the Project's effect on the South End including both gentrification and adverse impact on property values, as well as quality of life issues. Additional discussion is provided in Chapter 4.

Finally, questions regarding the adequacy of the proposed community benefits were raised. Chapter 4 discusses the proposed community social and economic benefits.

1.7.5 ENVIRONMENTAL PROTECTION

Environmental Protection issues focused on waste disposal and pollution prevention, which is discussed in Chapter 2.

1.7.6 REGULATORY COMPLIANCE

Regulatory compliance issues focused on compliance with rDNA research regulations and a further understanding of laboratory safety issues surrounding the recent tularemia exposures at a research laboratory. Discussion of these issues may be found in Chapters 2, 4, and 5.

1.7.7 ENVIRONMENTAL JUSTICE

Several commenters also raised Environmental Justice as an issue, stating that the Project is proposed in an area with large minority populations. The federal government has a policy relating to environmental justice. Chapter 3 describes the criteria used to designate Environmental Justice neighborhoods and Chapter 4 describes the Project's environmental consequences on those neighborhoods.

The U.S. EPA comments on the Draft EIS suggested that the area defined for analysis of Environmental Justice issues should be expanded and that a description be provided of the public outreach efforts to date. The area of analysis for Environmental Justice issues has been expanded to include a one-mile radius, including all of the South End and portions of South Boston, Roxbury, Dorchester, Chinatown, Back Bay and Kenmore/Fenway. Baseline conditions are described in Chapter 3 and Project impacts are described in Chapter 4. As mentioned in Section 1.6 above, BUMC will continue to engage the entire community, including people of color and low-income members, through meetings, discussions and other forms of outreach and to respond to community needs and concerns.

1.7.8 CUMULATIVE IMPACTS

The U.S. Environmental Protection Agency requested that more information be provided on the cumulative impacts of the Project in combination with other projects currently being developed in the area. Chapter 4 addresses the cumulative impacts of the Proposed Action and other reasonably foreseeable actions.

1.8 ISSUES OR CONCERNS OUTSIDE THE SCOPE OF THE EIS

The following comments made during the initial scoping process and/or the comment period on the Draft EIS were determined to be outside the scope of the analysis as the issues are not relevant to the decision, affected by the proposed action, within the analysis area, or already decided by law or policy.

- Programmatic EIS for NIAID's proposed national NBL and RBL construction program. A Programmatic EIS is not necessary to assess the potential environmental impacts of the various biodefense facilities proposed to be either constructed by the NIH itself or partly funded by the NIH. The various proposed biodefense 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 biodefense facilities.
- Statements in support or in opposition to the Proposed Action. Such comments will be considered in the decision making process on this EIS.

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