Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 1: BSL-4 INTRODUCTION

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National Emerging Infectious Diseases Laboratories

May 2013

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1.0 BACKGROUND

The National Emerging Infectious Diseases Laboratories (NEIDL) is part of a national network of laboratories that study infectious diseases – whether occurring naturally or introduced deliberately through bioterrorism. The facility is dedicated to the development of diagnostics, vaccines and therapeutics to combat emerging and re-emerging infectious diseases. The NEIDL includes Biological Safety Level 2 (BSL-2), Biological Safety Level 3 (BSL-3) and Biological Safety Level 4 (BSL-4) laboratories.

The NEIDL is owned and operated by Boston University and will only perform research that is approved upon review by the BU Institutional Biosafety Committee and other appropriate committees and regulatory agencies including the Boston Public Health Commission (BPHC). The minutes of the IBC are available to the public and posted at BU's IBC website at http://www.bu.edu/orccommittees/ibc/ibc-minutes/. The NEIDL, as part of the National Institutes of Allergy and Infectious Diseases (NIAID) network described above, may be called upon to support and serve, as needed, during a local, regional or national emergency to provide safe laboratories for the evaluation, identification and processing of materials that may cause harm to the community.

The NEIDL is one of two National Biocontainment Labs supported by NIAID and its research objective, as stated in the most recent Funding Opportunity Announcement is as follows:

The overall goal of the NBL Operations Support Program is to enable the NBLs to develop and maintain the research resources infrastructure and facilities required to conduct research that will facilitate the development of next generation therapeutics,

diagnostics and vaccines for infectious diseases. As part of the NIAID Biodefense Network, NBLs are expected to be a national resource and to provide maximum containment research facilities for NIAID funded investigators and other research, as appropriate. Additionally, the NBLs must be prepared and available to provide facilities and support to first-line responders in the event of a public health emergency.

Safety at the National Emerging Infectious Diseases Laboratories is of primary consideration and is integrated into every aspect of its design and operations. All systems within the NEIDL are built with both engineered and operational redundancies in place to assure safe operations at all levels. In addition, the NEIDL uses state-of-the-art technologies in its design and operations to ensure the safe conduct of research in secure environments. The laboratories emphasize comprehensive core research facilities that enable basic and translational research that may lead to the development of new vaccines, diagnostics and therapeutics related to emerging and re-emerging infectious diseases.

The NEIDL is committed to conduct its operations in a transparent manner and in accordance with city, state and national regulatory requirements and best practices. To achieve this goal, multiple levels of oversight and monitoring are in place and central to its operations and mission. This oversight includes:

- Environmental Health and Safety is dedicated to oversight of all personnel and environmental health and safety aspects of the facility as well as providing didactic and safety hands-on training.
- Institutional Biosafety Committee (IBC) is charged with peer and public review and approval of all research protocols, creation of policies and procedures, and review and investigation of all accidents and exposures.
- NEIDL Director and Associate Directors are charged with the overall oversight of the facility.
- The Internal Scientific Advisory Committee is charged with the review of research protocols at the earliest stages of development to verify their scientific merit and compatibility with the mission of NEIDL. The External Scientific Advisory Committee will be be formed in the future once all appovals for BSL-4 work are in place.
- Community Liaison Committee acts as a conduit to the community.

- Boston Public Health Commission (BPHC) is responsible for the oversight and enforcement of the city's Laboratory Regulations. BPHC also acts as the coordinating agency with all other City agencies including the Boston Fire Department, Boston Police Department, and the Office of Emergency Management.

- Centers for Disease Control and Prevention (CDC) is also responsible for the oversight and permitting of the possession, storage, use and disposal of Biological Select Agents and Toxins (BSAT).

The Biological Laboratory Safety Permit Application submitted to BPHC provides the information and basis for all aspects of the NEIDL operations, including: 1) the Biosafety and Chemical Hygiene programs; 2) commissioning and decommissioning procedures; 3) decontamination plans; 4) disease surveillance plans; 5) evacuation and emergency response procedures; 6) hazard evaluation and risk assessment program; 7) laboratory inspection program; 8) security plans; 9) management commitment and employee participation; 10) strain verification; and, 11) training programs.

These plans have been developed at a "concept of operations level" so that they are applicable to all work to be performed in BSL-4 laboratories. Specific projects will be submitted after having been reviewed and approved by the Boston University IBC. Each specific project that is submitted will include an overview of the standard operating procedures that are relevant to the research that is proposed.

Plans within the permit application are intended to complement each other and many have been developed with local city responders along with experienced consultants and under the guidance of the Boston Public Health Commission. These reviews have resulted in the development of plans involving access to documents, ongoing training programs and a comprehensive annual drill and exercise program with public partners.

Standard operating procedures that are developed will be available as part of the document review by the Boston Public Health Commission. This Section provides an overview of the NEIDL design and overall operational procedures.

2.0 COMMITMENT TO SAFETY AND COMPLIANCE

The leadership of Boston University (BU) and Boston Medical Center (BMC) has a longstanding commitment to protect human health and the environment, and to promote excellence in environmental stewardship that fully extends to the NEIDL. As part of this commitment, BU / BMC appointed an Associate Vice President for Research Compliance

responsible for ensuring compliance with federal, state, and local safety, health, and environmental requirements.

The NEIDL is located within the Biosquare development at the location of the Boston University School of Medicine (BUSM) and Boston Medical Center. The NEIDL is an Institute within BUSM that draws its faculty from various departments within BUSM and other Schools at Boston University. BUSM is one of the 16 colleges of Boston University; with the Dean of the Medical School reporting to the President of the University.

Boston Medical Center is a separate institution. However, Boston Medical Center and Boston University School of Medicine are closely aligned with BMC being a major affiliated hospital (with a formal affiliation agreement). Clinical department chairs within BUSM are simultaneously BMC chiefs. While BMC is no longer involved in the NEIDL project they provide support by having available the requisite infectious disease isolation units with its negative pressure rooms to appropriately house patients who present with certain infectious diseases. So, while the Boston University School of Medicine and Boston Medical Center are separate institutions, their goals are aligned and they have extensive collaborations.

As described in the Biological Laboratory Safety Permit Application, every aspect of the NEIDL's plans and operations are designed and developed to be fully compliant with all federal, state and local regulations as well as national and international guidelines and recommendations for best practices.

These plans were developed with the goals of:

- Incorporating safety into every aspect of the operations and facility design.
- Minimizing hazards of each experiment by reviewing all protocols and procedures and mitigating potential hazards as appropriate.
- Providing all employees with extensive training and awareness programs.
- Establishing a comprehensive oversight program.
- Continuously improving safety, health, and environmental protection practices.
- Maintaining transparency and informing the community of its activities through communications with the Community Liaison Committee (CLC) through monthly meetings addressing operations, scientific direction and safety. For more details on CLC please see http://www.bu.edu/neidl/community/clc/. Additionally:

- Two community representatives are members of the Institutional Biosafety Committee of which at least one is a member of the CLC.
- BU publishes the minutes of the monthly IBC meetings on its website (http://www.bu.edu/orccommittees/ibc/ibc-minutes/). The minutes provide details of IBC deliberations, summary of the projects discussed and the disposition of each.
- BU has published its various safety plan on the website for public information (http://www.bu.edu/neidl/safety/safety-plans/)

The plans clearly define the roles and responsibilities of each individual and group working in support of the NEIDL's mission, and describe their roles and responsibilities in carrying out BU's commitment to conduct research of the highest standards while maintaining an exemplary commitment to safety.

3.0 COMMUNITY BENEFIT

The NEIDL is unique in that it includes BSL-4 laboratory suites and the community benefit that has been, and continues to be, associated with that development compliments a long standing legacy of service to the community provided by Boston University (BU). The addition of the NEIDL to the BU Medical Campus has brought with it new opportunities and benefits for the community, including local infrastructure improvements, grant funding to local community organizations, and new opportunities to engage students in STEM education. In addition to the on-going community benefits listed in this section and those provided as part of the original construction of the NEIDL and BioSquare development, Boston University recognizes the obligation to contribute additional community benefits as part of the permitting process. As was done with the BU Fitwell program at Blackstone Community center, BU will work with the City to develop a plan that solicits community opinions, assesses needs and creates a benefit package that meets those needs as defined by the City of Boston and the BPHC. Additionally BU will file an annual report with BPHC detailing the accomplishments of the NEIDL Community Benefits Program. Community benefits will be negotiated with the city of Boston.

3.1 SPECIFIC COMMUNITY BENEFITS GOALS & ACTIVITIES

In addition to the ongoing community benefits and services described in this section, the NEIDL has contributed more than $3.3M in support of local infrastructure improvement projects and community funds in the City of Boston as part of the NEIDL's development and construction. To date, the NEIDL contributed approximately $807,000 to the Boston

Neighborhood Housing Trust, which funds the creation and preservation of affordable housing units throughout Boston; approximately $255,000 to the Boston Neighborhood Jobs Trust, which provides adult education, English as a Second Language and job training services to Boston residents; approximately $312,000 to the South End Community Improvements Fund; and $192,300 in support of the Cortes Street Housing Project. Boston University also funded a $1 million expansion of its City Lab Academy biotechnology and biomedical certificate training program. The expansion program ("City Lab Academy) provided full tuition scholarships for over 100 community residents over a period of 4 years.

Through the construction of the NEIDL and BioSquare development, BU provided several significant infrastructure improvements to the community: upgrading the East Newton and Albany Street intersection to operate as a four-way intersection; the construction of a portion of the South Bay Harbor Trail on BioSquare; the creation of internal campus roadways to South Bound Frontage Road and the ability to connect to the Massachusetts Avenue Connector via the East Concord Street extension; a decrease in storm water infiltration and inflow into the sanitary system; and the addition of a public "pocket" park on Albany Street.

Additionally, the economic impact of the NEIDL construction included 1,572 direct construction jobs and 1,534 indirect jobs. The impact of the NEIDL, once fully operational is expected to be 297 research related jobs and another 380 indirect jobs.

3.2 COMMUNITY OUTREACH & ENGAGEMENT

3.3 The NEIDL's Community Liaison Committee

The NEIDL's Community Liaison Committee (CLC), a group comprised of community stakeholders in the development of the NEIDL, provides valuable input on BUMC's community engagement efforts and helps to ensure that the University's resources are directed to the appropriate community members and organizations. In addition to ensuring two-way communication between the NEIDL and neighboring communities, CLC members serve in an advisory capacity to the NEIDL leadership and staff, and play a central role in ensuring transparency and openness in the operations and activities of the NEIDL.

3.4 Community Relations Team

To maintain a strong community presence and gather community input on the BU Medical Campus and NEIDL operations, the BU Office of Government & Community Affairs employs a BUMC community relations team tasked with planning, implementing, and overseeing community relations activities between BUMC and the residents, business owners, and neighborhood associations near that campus, on which the NEIDL is located. In addition to serving as the primary point of contact for any inquiries lodged by community stakeholders, the BUMC community relations team strives to maintain a strong presence within the community through regular attendance and participation at local business and community meetings and events.

Community Relations is actively involved in educating community members about the University's community programming and NEIDL activities and operations. Community Relations also meets one-on-one with individual community leaders, residents and local housing safety task force committees to discuss NEIDL and community issues.

In addition to administering the Community Grants Program, the BUMC Community Relations office also provides regular financial and in-kind contributions to community groups and organizations in the South End and neighboring Roxbury, Dorchester, and South Boston in support of their community development activities and programs. Boston University regularly provides the community with opportunities to participate in the University's athletic and cultural events through the donation of tickets to sports events like hockey and basketball games and to performances at the Huntington Theater.

3.5 Responsiveness to Community Needs

In addition to existing programs and services, BU Medical Campus has provided substantial information and education to the community directly related to the operation of the NEIDL in the form of tours, training and educational forums as well as the funding of scholarships. Building tours and informational sessions regularly occur for groups including community members, students, regulatory agencies and others. To date, more than 800 people have toured the NEIDL including residents, community leaders, elected officials, first responders, and members of the business community. Training sessions for first responders are developed and delivered in the NEIDL, emergency response programs are developed with the agencies that may respond and are exercised with those groups on a regular basis.

Community needs are frequently discussed with the NEIDL Community Liaison Committee and the BU Medical Campus has recently undertaken several new initiatives, including BU Fitwell at BCYF-Blackstone, summer athletic camp scholarships, and the BioScience Academy to address specific needs identified within the community. Our partnership with the City of Boston, Boston Public Health Commission, and the Boston Center for Youth Families to create the BU Fitwell at BCYF-Blackstone serves as the model for assessing community needs and we will continue to work with the city to develop a plan for future benefits related to BSL-4 permitting.

BU Fitwell at BCYF-Blackstone

In response to a community needs assessment conducted by the Boston Centers for Youth & Families (BCYF) and the Boston Public Health Commission and in support of Boston Moves for Health, an ambitious initiative launched by former Mayor Thomas M. Menino to increase access to free and low-cost physical activities and healthy living resources, Boston University partnered with the BCYF Blackstone Community Center to create the Boston University Fitness & Wellness Center at BCYF Blackstone, known as BU Fitwell. The program is staffed exclusively by BU Fitness personnel, and the fitness and wellness programming is directed and guided by experts from the University's College of Health & Rehabilitation Sciences: Sargent College, and the Schools of Medicine, Public Health, and Social Work. Through Fitwell, BCYF Blackstone Community Center members ages 14 and older, have access to quality fitness training, nutrition counseling, and wellness programing in a state-of-the-art fitness facility designed and renovated by Boston University.

Athletic Camp Scholarships

To provide local students and families with additional access to free and low-cost physical activities and healthy living resources to local residents, Boston University awards 100 summer athletic camps scholarships to City of Boston youth. Since summer 2012, every year, 100 local youth will receive coaching and training from Boston University athletic coaches in basketball, hockey, wrestling, softball, lacrosse, and sailing and rowing.

BioScience Academy

BU Medical Campus was also recently selected by the City of Boston as one of three local partners to implement a biotechnology workforce training program known as the BioScience Academy, which launched in fall 2012. The BioScience Academy is a workforce development program that provides biotechnology training to unemployed and underemployed Boston area residents. Program funding stems from the Metro Boston Skilled Careers in Life Sciences (SCILS) initiative, a four-year $5 million grant that the City of Boston received from the U.S. Department of Labor to grow and maintain the area's life sciences workforce. Boston University was selected as one of three training partners to implement the biotechnology training program, for which Boston University contributes half of participants' tuition. Students receive professional development training and a Certificate in Applied Biotechnology upon completion of twelve course credits through the School of Medicine and Metropolitan College.

Scholarship Aid

These newer community initiatives were added alongside the University's signature community benefit, its longstanding scholarship programs. In the 1970's Boston University established a substantial scholarship program, which it has continued to invest in and expand in an effort to increase access to higher education for local students. In FY2012 alone, the University committed a total of $13.7 million in scholarship funding to local students. $11.4 million of that funding was in support of the Boston Scholars Program, which has helped secure a higher education for Boston Public School students since 1973. In 2012 Boston University awarded 22 full scholarships and met the full calculated financial eligibility of 41 Boston Public School graduates.

Community Grants Program

In late 2011, in response to drastic budget cuts undertaken by community organizations across the city in the wake of the Great Recession, Boston University's Government & Community Affairs office implemented a community grants program. The $2,500 community grants are awarded to programs and services that benefit residents of Boston University's host community, with special consideration for programs and services that benefit local youth. Grant funding is intended to supplement the existing budgets of established organizations and agencies.

In 2012, Boston University doubled its commitment to the communities of Roxbury and South End, awarding not one but two $2,500 grants in support of the extraordinary efforts undertaken by local community organizations working to make a difference in the lives of the young people of Boston. Recently, Boston University awarded $2,500 to Discover Roxbury's ArtRox! series, which highlights and promotes Roxbury's art and culture and bring new art resources to the Roxbury community, and $2,500 to the Franklin Park Coalition's Back to Nature in Franklin Park program, which bring up to 1,000 youth, ages 5-18, from neighborhoods bordering Franklin Park (particularly Roxbury)to the park for energetic outdoor activities in a natural setting.

Support of STEM Education

Between 2007 and 2010, the NEIDL contributed $1 million to the sponsorship of 105 students in the City Lab Academy program, a biomedical research and biotechnology job training to Boston residents. City Lab Academy, prepares students for laboratory jobs in the biomedical sector, and serves as a transition year for students wishing to pursue a bachelor's degree in science while providing the foundation and hands-on experience necessary to join the research workforce. The BU Medical Campus demonstrated its continued support for City Lab's job training initiative, by contributing an additional $72,360 to the program in 2011.

In 2013, Boston University also awarded 6 full-time scholarships to students from the South End, Roxbury, Dorchester, and South Boston for SummerLab, a one-week program from students grade 10 through freshman year of college, which provides hands on lab experience through participation on a research team and use of state-of-the-art equipment to perform experiments of their own design.

In further support of the STEM disciplines, the NEIDL also provides tours of its unique, state-of-the-art facility to groups of students, in an effort to impress upon students the value of scientific research and get them excited about science.

4.0 CULTURE OF SAFETY AND RESPONSIBILITY

Boston University has established a safety model that is a core value integrated into the fabric of the institution. This culture of safety and responsibility is guided by the following principles:

4.1 Leadership and Oversight

- Leadership recognition and support of a culture of safety at every level within the institution.
- Demonstrated commitment and reinforcement on a regular basis though the consideration of safety issues at meetings, in the defining of jobs and in the evaluation of faculty, staff and programs across the institution.

4.2 Organizational Practices

- Organizational commitment at every level to recognizing that research and other activities present a potential risk, and to ensuring that these operations are conducted safely and in a responsible manner.
- Incorporating safety as an integral aspect of the institution's operations (e.g., experimental design, facility construction, equipment specifications).
- Creating an environment of collaboration among all stakeholders (i.e., researchers, Laboratory Managers, Department Safety Advisors [DSAs], students, staff, facilities management staff, public safety staff) to identify safety issues and to find solutions.
- Organizational learning is not only expected, but is also embraced.

4.3 Institutional Structure

- Creating an environment in which each individual understands their role in the research enterprise and conducts their activities in a responsible manner.
- Creating an environment where individuals are empowered to recognize and to report errors or near misses without fear of reprimand or punishment.
- Continuous review and examination of the infrastructure that provides support for safety practices and procedures.

4.4 Shared Core Values and Beliefs

- Empowering all members of the research community to accept their critical role in protecting their own safety as well as that of others.
- Emphasizing personal responsibility to safety and ethical conduct of research.

4.5 Management Systems Responsibility

- Investigating incidents or near misses, identifying "lessons learned," and modifying programs, as appropriate, to incorporate any enhancements identified during the investigation.
- Empowering individuals to report safety concerns and committing resources to address safety concerns.

5.0 FACILITY DESIGN

The National Emerging Infectious Diseases Laboratories Institute (NEIDL Institute) is a research laboratory located at the Boston University Medical Campus in the area commonly referred to as Biosquare. Safety and security are major factors in the building's design, which incorporates state-of-the-art systems.

The following is a brief summary of the key features of the facility.

5.1 Design Team

The design team, known as the "Team Alliance," was made up of CUH2A, Smith Carter, and Hemisphere Engineering (CUH2A Smith Carter Hemisphere). Collectively as an Alliance, they have been involved in many of the BSL-4 projects designed and constructed in North America, including:

- NIH, NIAID, Rocky Mountain Laboratories, Hamilton, Montana
- Centers for Disease Control and Prevention, Emerging Infectious Diseases Laboratory
- NIH, NIAID, Integrated Research Facility (Building 18), Fort Detrick, Maryland
- USAMRIID, Fort Detrick, Maryland

- Canadian Science Center for Human and Animal Health

5.2 Code Compliance

The overall facility design and construction is in conformance with the applicable codes, including:

- The NIH Design Policy and Guidelines; November 2003 Edition
- The U.S. Department of Health and Human Services, CDC/NIH, *Biosafety In Microbiological and Biomedical Laboratories* (BMBL); 5th Edition
- The Massachusetts State Building Code (780 CMR); 6th Edition

5.3 Design and Construction

The Quality Assurance and Quality Control (QA and QC) process for the building has been a primary element of the construction oversight. The following is a brief summary of the oversight.

a. During the construction document development process, there was continual peer review with the architecture and engineering disciplines within the Alliance.

b. Third party independent reviews by architectural and engineering professionals under the direct oversight of NIH were conducted at specific milestones (schematic 35%, design/development 70%, and construction document at 95% and 100%). The third party professionals performed additional reviews at other times during the construction document development process.

c. Similarly, during the construction phase, there was continual on-site QA and QC by the Alliance design professionals and full time, on-site presence of two engineering representatives from the Alliance.

d. During the construction phase, there were monthly site visits by the third party independent reviewers of the architectural and engineering disciplines under the direct oversight of NIH.

e. Turner/McCarthy, the construction manager, as a component of their construction administration, provided a full time on-site QA and QC division to oversee and assure that the construction was in full conformance and compliance with the approved construction documents. A subdivision of the Turner/McCarthy QC

division oversaw the BSL-4 maximum containment concrete and mechanical, engineering, and plumbing installation.

f. BU provided four full-time staff members on-site as a construction administration team to also oversee, validate, and support the QA and QC initiatives (one mechanical engineer, two field engineers, and a compliance administrator).

g. For security, the NEIDL has a 100-foot set-back and is designed to the standards of protection afforded to United States Embassies abroad to resist various potential threat scenarios, including explosions in the exterior of the building's perimeter.

h. The NEIDL is designed according to Massachusetts Building Codes for Seismic Category D.

i. The BSL-4 suites are structurally separated from the adjoining floors. This structural separation allows for movement in the event of an earthquake, while maintaining structural integrity of the BSL-4 suites.

j. BSL-4 suites have 12-inch thick reinforced concrete walls with special epoxy covering that acts as a sealant.

k. All fixtures for the BSL-4 suite designed specifically for the facility, and are Underwriters Laboratories (UL) tested, to ensure the facility retains its air pressurization.

5.4 Building Profile

The NEIDL has approximately 192,000 gross square feet of space. The space utilization of the NEIDL designed to support infectious diseases research requiring BSL-4 containment represents approximately 15% of the gross square feet of the NEIDL

5.5 Building Systems

The BSL-4 suite is designed as a series of suites each of which may be isolated from the other should there be need to shut off ventilation to a particular suite. This feature is important for routine maintenance, quality control shut downs, and for ease of decontamination.

The building is designed and constructed based on N+1 redundancy; that is, for each system, there is an additional unit in place to offer an extra level of protection and/or redundancy. For example, the facility has three effluent sterilization tanks--one for routine

operation, one for use when the first tank is under active sterilization mode, and one for back up. Critical utilities that support the building can be generated onsite in addition to being delivered from external sources. The design allows for continued operation with the loss of externally delivered utilities and such losses are addressed in emergency plans, tested in drills and exercise and available for review with and by internal and external responders and the BPHC. Additionally, the automation system is fully integrated with both on-site monitoring as well as feeds to the main control (staffed 24/7) at the BUMC Power Plant, located at 650 Albany Street.

5.5.1 Plumbing Water Supply

Domestic Water Supply

a. Loop water service, providing feeds from different directions, provides redundancy in the event of a water service interruption.

b. Water for fire protection is on the same loop system but with a separate, dedicated connection.

Plumbing Lab - Sanitary Waste

BSL-4 liquid waste is double-walled heavy gauge stainless steel pipe with an integral leak detection system which goes directly to an Effluent Decontamination system consisting of three 1,500-gallon steam sterilization tanks. The double-walled pipe also includes leak detection system that activates an alarm in the unlikely event of a leakage in the primary pipe. The sterilized effluent material will be released into the sanitary waste system after each susccessful sterilization run of the EDS at 121 degrees centigrade for 60 minutes. EHS reviews the print out report of each EDS sterilization run at the start of each day. The EDS is validated using biological indicators quarterly by EHS. .

Storm runoff flows to a separate storm water system.

5.5.1 Mechanical Systems

The Heating, Ventilating, and Air Conditioning (HVAC) systems are designed to ensure safe operating conditions under normal operations and during various potential emergency scenarios.

a. BSL-4 suites are all supplied with HEPA-filtered air. All suite exhaust air is treated by a *double* HEPA filter system before discharge to the environment. The HEPA filter banks are located immediately above the suites and are hard-connected to the suite rooms below using stainless steel ducts that are embedded into the concrete to minimize the potential for duct related issues. Each filter system is equipped with a damper system at the outlet designed to fail-safe--that is to close--in the event of an emergency, isolating the airflow path to and from the laboratory.
b. Cooling water systems are designed based on N+1 for the building and are on the Level 2 backup power.

5.5.2 Electrical System

Standard Supply

The building receives its primary electricity from N-Star through the building's Network vault, with 8,000 KVA (kilovolt-Amperes) capacities. Four separate feeders from the electrical grid enter into the building, each one at 13.8 KV to supply the electricity designed to allow for maintenance of individual feeds without impact on service. Dependent on the time of year, the building could run on one or two feeders, thus leaving minimally two feeder lines as backup in addition to generator power in the event of loss of all electrically fed power.

Emergency / Backup Generators

In addition to the redundant feeder lines, the building has two 1,500 KVA emergency power generators that run in parallel to supply emergency power and act as additional redundant systems should primary power be interrupted. These generators provide adequate power for the continued safe operation of the building and the facility stores enough fuel on site for 24 hours at 3,000 KVA; with safe shut down of laboratory operations, the fuel adequacy may be extended. Areas, equipment and systems supported by emergency power are included with the documents available to internal and external responders and the BPHC.

5.6 Fire Protection

The fire protection was designed to meet the special features of the building's high containment areas.

- BLS-3 office and support spaces are supported by a traditional wet sprinkler.

- BSL-4 suites are designed with a Water Mist suppression system. The system is backed up by a manually initiated dry sprinkler system.

- A fire pump is connected to the emergency generator.

5.7 Steam

The building utilizes steam for both its heating needs and for sterilizers used to neutralize biological agents prior to disposal.

- Primary steam is provided by Veolia at both low and high pressure.

- NEIDL boilers powered by natural gas provide secondary steam.

5.8 Building Automation System

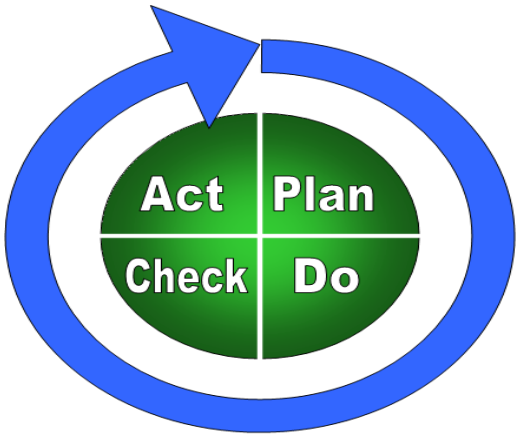
All critical building systems are fully integrated and are automated for monitoring and control. The building automation system monitors, manages, and controls all of the critical building systems.

6.0 OPERATIONAL PROCEDURES

In addition to the engineering features of the building, the operations of the facility itself are based on the safety requirements and best management practices.

The overall management strategy for the NEIDL is an integrated Health and Safety Management System where all processes and practices are coordinated and developed to minimize any potential health and safety hazard to employees or to the environment. This management system approach brings together employees from all segments of the NEIDL's operations such as the research labs, facilities management, health and safety, public safety, and occupational health to collaborate and develop comprehensive operational plans that promote and facilitate the safe conduct of science. Appropriate health, safety and environmental plans and implementation procedures are established in writing and are communicated to all employees. Furthermore, all employees are expected to know their roles and responsibilities, and to understand that they are accountable for their performance.

The fundamental premise of the management system is based on the concept of plan-do-check-act:



The Plan Phase is the identification of the health, safety and environmental aspects of the proposed research activity and its objectives, and validation that the research protocol is consistent with established policies and procedures. At the NEIDL, the team approach in developing operational procedures ensures that all safety plans are incorporated into the operational procedures. In addition, review by oversight Committees helps to ensure that all plans are consistent with established policies and criteria.

The Do Phase is the implementation of procedures and the operation of the facility (i.e., conduct of research). This includes the documentation and communication of roles and responsibilities, provision of appropriate training, assurance of adequate internal and external communication, written management system documentation as well as appropriate document control procedures, documented procedures for operational controls, and documented and communicated emergency response procedures.

The Check Phase is the periodic inspection and audits conducted by various oversight and operational entities to verify that the policies, procedures, and implementation approaches are working as established and planned. The results of these reviews are evaluated, any variances are identified, and corrective action plans are developed and implemented.

The final stage of the process is the Act Phase during which actions are taken for any necessary improvements. In some instances, for example, if a problem appears to be systemic, an overall review of all aspects of the management system (Plan, Do, Check, Act) for the particular research activity is conducted and the processes are modified as necessary to achieve improvement. All operational procedures at the NEIDL are reviewed whenever new protocols or new equipment or materials are introduced that might impact the health and

safety of those conducting the procedures. Further, all procedures are subject to a routine annual review to ensure they are in accord with the actual processes.

7.0 TRAINING

Boston University has long recognized the significance and value of relevant training - it is the most important factor in ensuring worker safety and environmental protection. The BU leadership team embraced this concept as a strategic focus for the NEIDL and established an Environmental Health and Safety Core charged with creating and carrying out a stellar training program.

All researchers working in the NEIDL must undergo training relevant to their activities. In addition, all individuals working in high containment areas at the NEIDL are required to demonstrate competency in working in a high containment environment. To meet this requirement, all training at the NEIDL is customized to the particular group receiving the training to include a full simulation of the use of the equipment and the procedures that they will perform inside the facility. The current training given by Environmental Health and Safety served as a model for the NEIDL's general laboratory safety training components.

Training topics include laboratory safety, chemical and biological safety, fire and emergency response training, blood borne pathogen training, select agent program training, and animal research, along with Public Safety training for all personnel working at the facility. Principal investigators and their staff working in BSL-4 areas receive additional laboratory-specific safety training. The maximum containment (BSL-4) training encompasses multiple sessions in a simulator, before moving into a mentored training environment in the BSL-4 suites.

The Training Simulator at the NEIDL supports the NEIDL's core mission of performing cutting-edge basic and clinical research on emerging infectious diseases, while providing quality training at a facility built and operated with the highest attention to community and laboratory safety. The Training Simulator is a specially designed "simulation laboratory" that fully duplicates a BSL-4 laboratory environment, including the personal protection equipment, entry and exist process, and the equipment used in the BSL-4 laboratory. The Training Simulator provides the opportunity for hands-on training for all NEIDL research staff and faculty as well as support personnel, including public safety, facilities management, maintenance personnel, contractors, and emergency responders. This Training Simulator is a national resource to train individuals on how to work in and around maximum containment research facilities.