Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 12: BSL-3 / BSL-4 SECURITY PLAN

Boston University

National Emerging Infectious Diseases Laboratories

October, 2014

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1.0 PURPOSE AND APPLICABILITY

The purpose of the BSL-3 / BSL-4 Security Plan for the National Emerging Infectious Diseases Laboratories (NEIDL) located at the Boston University Medical Campus (BUMC) is to establish policies and procedures that ensure the physical security of the NEIDL and the control of Select Agents and Toxins against unauthorized access, theft, loss, and release. This Plan establishes security standards in accordance with U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA) Rules and Regulations on the possession, use, and transfer of Select Agents and Toxins (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) and the Boston Public Health Commission's Biological Laboratory Regulation.

The development of the Security Plan started during the design phase of the NEIDL, in that planned protective measures were incorporated into the development of building systems and infrastructure, and the building's construction. Those early decisions led to operational planning during design so that the eventual protection of the NEIDL included a thoughtfully designed mix of a safe and securely built environment, the installation of technologies that allow for different levels of physical security, and an operations and staffing plan that utilizes the technology and manages the environment.

The development of the Security Plan continued in concert with other plans addressing

comprehensive emergency management, transportation of hazardous materials, and other areas related to biosecurity.

The Security Plan, as implemented through the design, construction, commissioning, and operations of the NEIDL has included a deliberate and thorough use of protective layers, beginning with the NEIDL site perimeter fencing system. As those with authorization pass through these layers, they progress through a variety of security checks, including those done by armed NEIDL Public Safety officers, those enforced by card or biometric access systems, those monitored and recorded by closed circuit television, and those requiring additional staff—as outlined in the two-person guideline of the Personal Suitability and Reliability Policy (attached). These and other security technologies are safeguards that are in place at the NEIDL to prevent unauthorized access, theft, loss, or release of moderate-to-high-risk Select Agents and Toxins that require containment in BSL-3 and BSL-4 laboratories and suites.

Select Agents and Toxins are subject to distinct levels of protection. The NEIDL meets or exceeds the federal, state, and local requirements for each of these levels. The determination of compliance with required protection, including Tier 1 agents, is the responsibility of the Responsible Official and the Executive Director of Public Safety.

2.0 ROLES AND RESPONSIBILITIES

2.1 Public Safety Personnel

The Executive Director of Public Safety is responsible for all Boston University Police and Public Safety functions at both the Charles River and the Medical Campuses, including the NEIDL. The Public Safety Supervisors and Managers assigned to the NEIDL are responsible for providing supervision of Public Safety Officers 24 hours a day, 7 days a week, and for initiating notification procedures involving responses for all phases of an emergency occurring in and around the NEIDL. They are also responsible for notifying the BU Public Relations department of any security incidents that may require a public safety advisory. In addition, they are responsible for coordinating with other public safety organizations.

2.1.1 NEIDL Public Safety Officers

The Public Safety Officers assigned to the NEIDL are responsible, 24 hours a day, 7 days a week, to control access to the NEIDL in accordance with established protocols and to respond to all emergencies and incidents. Emergencies and incidents include: 1) loss, theft,or release of Select Agents or Toxins; 2)

unauthorized personnel entry; and 3) any security system alarms and video breaches on the grounds and at pedestrian and vehicle entry points. The Public Safety Officers are also responsible for: 1) complying with the protocols and procedures in the Public Safety Policy and Procedure Manual; 2) attending all training programs and drills appropriate to their responsibilities; 3) ensuring that all security-related equipment is functioning at all times; and 4) reporting malfunctions immediately to the Boston University Control Center for response and repair.

2.1.2 Boston University Police Department

The Boston University Police Department (BUPD) is the primary law enforcement entity for Boston University. The Department is responsible for responding, consistent with the requirements of the notification system, to any security incident or police matter that necessitates additional resources up to and beyond what is currently available at the NEIDL. Boston University Police Department participate in all contingency emergency-phase planning prior to and following a security incident involving the NEIDL.

2.1.3 Public Safety Audit / Access Coordinator

The Public Safety Audit / Access Coordinator is responsible for: 1) accepting all requests for access to the NEIDL; 2) ensuring confirmation of all necessary background requirements, credentials, and approvals; 3) issuing, control and return of NEIDL identification badges; and 4) monitoring entry locations for each badge entering the NEIDL.

2.1.4 Public Safety Systems Integration Coordinator

The Public Safety Systems Integration Coordinator is responsible for managing records and ensuring the operational integrity of the building and security information systems, including but not limited to access control, closed-circuit television, and record retention and storage.

2.2 Director of Information Technology and Telecommunications

The NEIDL Core Director of Information Technology and Telecommunications, with oversight by Boston University Information Services & Technology (IS&T), is responsible for developing,

implementing, and ensuring the operational integrity of the secure NEIDL laboratory data and information systems.

2.3 Principal Investigator

The Principal Investigator (PI) is an authorized individual approved by the Responsible Official (RO). The PI is responsible for the scientific and technical direction of a Select Agent or Toxin project or program. Security responsibilities of the PI include: 1) ensuring that all authorized individuals under his or her direction comply with and maintain all BU security provisions, such as implementing proper Select Agent or Toxin registration; receipt and handling procedures; successful completion of security training and drill exercises; adhering to all appropriate Standard Operating Procedures (SOPs) in performing their work; and correct use of Select Agent or Toxin access and inventory procedures; and 2) reporting all incidents, accidents, and exposures related to Select Agent or Toxin materials to the Responsible Official and the Research Occupational Health Program. .

2.4 Responsible Official

The Responsible Official (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with the DHHS and USDA Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins. BU/BMC designated the Director of Research Safety to serve as the Responsible Official. The Director of Research Safety is a voting member of the Institutional Biosafety Committee.

2.4.1 Environmental Health & Safety

The Boston University Environmental Health & Safety (EHS) department is responsible for the management of the NEIDL's Select Agent Program as well as all site-specific EHS functions and, within the NEIDL, reports to the Director of Research Safety. This responsibility includes providing safety and security training for: 1) all individuals approved by the Responsible Official to possess, use, and transfer Select Agents and Toxins; 2) BU staff who support the operations and maintenance of the NEIDL; 3) individuals who respond to incidents at the NEIDL; and 4) individuals who protect the perimeter security of the NEIDL.

2.5 Associate Vice President for Research Compliance

The Associate Vice President for Research Compliance (AVP-RC) has responsibility for the

Animal Services Center (ASC), Environmental Health & Safety (EHS), the Research Occupational Health Program (ROHP), the Institutional Biosafety Committee (IBC), the Laboratory Safety Committee (LSC), the Institutional Animal Care and Use Committee (IACUC), and other research-related oversight committees.

The AVP-RC, or his or her designee, serves as an Associate Director of the NEIDL and has responsibility for services listed above as well as the Emergency Response Planning, Facilities, and Public Safety Cores.

The AVP-RC serves as the Responsible Official (RO) for the City of Boston's Public Health Commission Biological Laboratory Regulation and has appointed the Director of Research Safety as the Responsible Official for DHHS and USDA Rules and Regulations, as reflected in section 2.1 above. The AVP-RC develops and ensures communication between the IBC, IRB, and IACUC-sponsored research offices, and regulatory agencies (e.g., City of Boston, CDC).

3.0 SECURITY PROCEDURES

3.1 Nature of Potential Threat

Examples of potential threats include: 1) theft of a Select Agent, Toxin, or sensitive information; 2) unintentional loss or release of a Select Agent or Toxin; and 3) nefarious misuse of a Select Agent or Toxin.

Note: Any loss or theft of a Select Agent or Toxin must be reported to the RO immediately. The RO (as defined by CDC) will notify the BPHC immediately and the CDC within 24 hours using the appropriate APHIS/CDC Form 3.

3.2 Sources of Potential Threat

Examples of sources of potential threats include: 1) intrusion by an unauthorized individual not affiliated with the NEIDL; 2) intrusion by an unauthorized individual affiliated with the NEIDL; 3) access to a Select Agent or Toxin by an unauthorized individual; and 4) access to a Select Agent or Toxin by an authorized individual for the purpose of illegal activity.

3.3 Controlling Threat, Vulnerability, and Risk

Security procedures that prevent unauthorized access to Select Agents and Toxins can reduce threat, vulnerability, and risk. Security assessments for controlling access to the NEIDL grounds, to the NEIDL facility, to BSL-3 laboratories and BSL-4 laboratories and suites within the NEIDL facility, and to Select Agent storage, information, and research data led to the development of security methods for Inventory Control, Area Access Control, and Container Access Control. The following sections address these security methods for controlling access to Select Agents and Toxins.

3.3.1 Inventory Control System

An electronic inventory control system tracks detailed information on every transaction that involves accessing Select Agents and Toxins from a secure container used for storing Select Agents or Toxins (i.e., lockbox, refrigerator, or freezer). The detailed information includes the identity and strains of Select Agents and Toxins; the quantities received, removed, and destroyed; the identity of the authorized individual making each transaction; and the date, time, and duration of each transaction. Authorized individuals enter the details of their transactions at secure workstations requiring the use of confidential IDs and passwords. The secure workstations have dedicated connections to secure servers within the NEIDL data center. These servers have no access to the public internet or the internal firewalled BU network. Use of the laboratory data and information systems and access to the data and information are restricted to authorized individuals. Access to the NEIDL data center limited to authorized Information Technology, Public Safety and Facilities personnel.

3.3.2 Area Access Control for Protecting Select Agents and Toxins

NEIDL employees must display their IDs when entering the NEIDL grounds and at all times when on NEIDL property. Sharing of IDs with anyone is prohibited.

Access control to the NEIDL facility, BSL-3 laboratories, ABSL-3 facilities, and BSL-4 suit rooms consists of proximity card readers at the entrance to the NEIDL facility and the entry doors to the BSL-3 laboratories, ABSL-3 facilities, and BSL-4 suit rooms. A biometric iris scanner controls access from the suit rooms to the entry door to the BSL-4 laboratories where Select Agents and Toxins are used and stored. Access to the BSL-4 suit rooms and laboratory spaces are limited to authorized individuals who have the appropriate training and security clearances.

- **Access to Laboratories** is controlled and limited to individuals approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General and authorized by the RO.
- **Access to ABSL Suite** is controlled.
- **Animal Procedure and Animal Holding Rooms are** controlled and all access from this point is limited to individuals approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General and authorized by the RO.
- **Access to Select Agent Storage Room** is controlled and all access from this point is limited to individuals approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General and authorized by the RO.
- **Access to Storage Container** is controlled on storage device/freezer and Pass through Boxes.

The listed security barriers and devices are intended to deter, detect and delay an intruder from accessing a select agent or toxin while allowing sufficient time for responders to arrive. All entry doors controlled electronically and equipped with Intrusion Detection with two types of alarm. All alarms are monitored 24/7 at the NEIDL Security Command and Control Center. Response protocol includes visually inspecting CCTV of the area in alarm for suspicious activity and dispatching to investigate the alarm. The RO and EHS would be notified of any laboratory related issues and/or criminal activity.

Animals that are intentionally or accidentally exposed to a select agent will be properly safeguarded from unauthorized access, theft, loss or release through the limited access measures described above. These infected animals and infected animal carcasses inside containment are secured, monitored and tracked according to Animal Science Core SOP on Daily Animal Tracking. In the event of a discovery of any problem with an animal or animals accidentally exposed or infected, Public Safety will be notified and the area containing the animal or animals will be immediately restricted until notification to the RO and appropriate measures are in place to investigate the matter.

If in an emergency an authorized individual is not available and the incident is time-sensitive, the NEIDL Public Safety Supervisor will authorize access to the NEIDL facility

via the computerized access control system. This procedure will result in a NEIDL Public Safety Incident Report to document the authorization, the purpose of the entry, and the reason for the time-sensitive necessity. The Responsible Official, the NEIDL Director and other key personnel will be notified of such events immediately.

3.3.3 Container Access Control

Container access control consists of a mechanical locking device designed to prevent access to a storage container for Select Agents and Toxins, such as a lockbox, refrigerator, or freezer. Locking devices are reviewed prior to selection and installation by representatives of Environmental Health & Safety and Public Safety. Access via mechanical locking device into the lockbox, refrigerator, or freezer is restricted to authorized individuals. When accessing a storage container, the authorized individuals must follow the two-person guideline as outlined in the Personal Suitability and Reliability Policy (attached). Access to inventory storage requires two authorized personnel.

Video cameras are positioned throughout the laboratories to monitor the storage containers and are displayed on monitors and can either be reviewed live time or, afterwards given digital recording.

The Principal Investigator of a BSL-3 laboratory or BSL-4 suite is required to immediately notify the Responsible Official and NEIDL Public Safety at extension 4-4444 upon the termination of employment or access privileges for any authorized individual. The purpose of this notification is to remove the individual's access to all registered spaces and assess the need to change locking devices, combinations and PIN codes. In the event a combination or PIN is compromised, Public Safety will work with the PI and RO to immediately replace and/or change combination locks on pass through boxes and storage containers..

3.3.4 Suitability and Reliability

Personnel suitability and reliability processes include both initial clearances and ongoing monitoring in accordance with federal regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121). These regulations describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 Select Agent or Toxin and have been addressed at BU in the Personal Suitability and Reliability Policy attached as Appendix A.

The following programs are implemented and reviewed accordingly:

(1) Environmental Health & Safety coordinates efforts with Public Safety management to ensure security of Tier 1 Select Agents and Toxins and to share, as appropriate, relevant information.

(2) EHS also monitors procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 Select Agent or Toxin. The procedures include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with Select Agents and Toxins, or to safeguard Select Agents and Toxins from theft, loss, or release;

(ii) Training of NEIDL employees with access to Tier 1 Select Agents and Toxins on NEIDL policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and

(iii) Implementation of ongoing suitability monitoring of individuals with access to Tier 1 Select Agents and Toxins.

3.3.5 Notification Procedures

The Public Safety Operations Supervisor or his designee will be responsible for notifying external law enforcement agencies, including Federal, State and local authorities when necessary, of any suspicious activity or behavior that are criminal in nature, is detected in or around select agent locations.

The Responsible Official will be notified by the Public Safety Operations Supervisor or his designee of all instances of suspicious activity or behavior, that are criminal in nature, occurring in or around select agent location or involving personnel engaged in activity related to the Boston University Select Agent Program.

3.3.6 Normal SA Laboratory Operating Hours

Select Agent Laboratory Normal Operating Hours are from 0630hrs – 2000hrs. The laboratory is accessible to employee authorized under 42 CFR 73.10 as long as they have received prior approval from the RO. This approval may be requested on an as needed basis for studies requiring after-hours access or in cases where frequent access may be necessary such as animal care technicians. The Public Safety Department will

provide the RO or his designee a card access report every thirty days identifying all access into the SA space twenty four hours a day for that time period. This report will be used to ensure compliance with laboratory operating hours.

3.3.7 Visitors

Visitors to the NEIDL will undergo a background screening using public access databases through a third party vendor. Visitors will not have access to any SA spaces and will be required to be escorted at all times. All visitors will undergo x-ray screening of their packages upon entry to the NEIDL. A list of prohibited items is posted at the NEIDL entry (see attached). Property lockers are located in the Pedestrian Gate House for the secure storage of visitor property. The Public Safety Operations Supervisor will approve or deny any requests for exceptions to this rule. Visitors are not permitted to bring personal vehicles onto the NEIDL site.

4.0 AREA CLEANING, MAINTENANCE, AND REPAIR PERSONNEL

Routine cleaning, maintenance, and repairs are restricted to areas of the NEIDL that are outside of the BSL-4 and BSL-3 laboratories. The NEIDL facilities and custodial personnel assigned to work in these restricted areas go through institutionally mandated clearances and biosafety and security training before receiving approval from BU Public Safety and the Responsible Official to begin their assignments. The facilities and custodial personnel will not receive authorization to enter an operational ("hot") BSL-4 or BSL-3 suite. Access authorization to perform cleaning, maintenance, and repair functions in a BSL-4 or BSL-3 suite is permissible only after decommissioning and decontamination of the BSL-4 or BSL-3 suite. Routine cleaning and maintenance within restricted areas is done by the research staff in those areas in accordance with the Personal Suitability and Reliability Policy (attached).

Maintenance within the BSL-4 suite is performed by those with clearance to enter the space or requires that a person with clearance escort the person performing the maintenance at all times. Such clearances are in accordance with 42 CFR 73.10

5.0 INFORMATION SYSTEMS, RECORD MANAGEMENT AND CONTROL

5.1 Information Systems

The NEIDL acquires its network and Internet access via redundant high-speed fiber-optic connections to the Boston University (BU) trunk systems. BU Information Services & Technology (IS&T) staff include an Incident Response Team (IRT) that identifies and responds to security

issues that are actively identified on campus, notifies administrators of security breaches, and provides the University with forensic and auditing capabilities. The team actively coordinates with IS&T management to effect policy changes and enforcement, and works with the director of the NEIDL Information Technology and Telecommunications Core to mitigate risks and respond to emerging security issues. The team also develops tools and hones techniques for incident handling, develops strategies to increase the University's detection and response capabilities, and maintains contacts with other universities and law enforcement.

Within the NEIDL, the computer systems are separated into four distinct networks with increasing levels of security. One level is the desktop computer, which is commonly a wired connection and allows for unrestricted Internet access. Another level is for wireless devices (laptops, tablets, communication badges, smartphones, etc.); and this network uses the Institute of Electrical and Electronics Engineers (IEEE) 802.1x and WPA2 security protocols, which encrypt transmission of data packets. The NEIDL server network is "behind" the BU hardware firewall and access is restricted to specific authenticated users for scientific and administrative uses only. These servers do not have the ability to access the public internet. The final level is for building systems such as the building automation system (BAS), which is on its own internal network and has no connections to the Internet, the NEIDL server network, or desktop/laptop computing. These controls will prevent malicious code from compromising systems which manage access to registered spaces or select agent and toxin records.

Access to Select Agent data and related information is acquired on an as-needed basis set forth by the BU Responsible Official (RO) and associated senior science staff of the NEIDL. Computer access to the Select Agent data is allowed only from specific non-networked computer terminals. These terminals are in full view of a recording camera and have "key logging" software installed to monitor use. Each user is also required to provide an additional tier of authentication, iris recognition, or ID card reader, to enter the computer terminal room. As the roles of the user are changed, the access to specific information on Select Agent storage and use will be adjusted to the new roles. Specific examples of this would be limitation of viewing Select Agent inventory for their work only, not accessing information systems of master stock or working stock quantity or storage locations.

5.2 NEIDL Record Management and Control

Record management comprises the planning, controlling, directing, organizing, training, promoting, and other managerial activities related to the lifecycle of records, which are conducted to achieve

adequate and proper documentation of NEIDL policies and transactions.

A “record” is an information resource, in any format, that is:

- created in the course of research,
- received for action, or
- needed to document NEIDL activities.

Records are relevant books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by the NEIDL in connection with the transaction of research.

The NEIDL record’s lifecycle is the life span of a record from its creation or receipt to its final disposition, during which the following events occur:

Records are to be managed and used throughout two lifecycle phases:

- **Active records** are used to conduct current NEIDL research and are maintained in office space and equipment.
- **Inactive records** are not needed for current research and are maintained in less critical off-site storage or deleted.

Maintenance and control of the NEIDL records are under the direction of the Responsible Official. The Responsible Official ensures that all paper records pertaining to Select Agents and Toxins, including logbooks, are kept in locked files or containers and under the control of an authorized individual. The Public Safety Systems Integration Coordinator maintains and controls all building and security information records. The NEIDL Core Director of Information Technology and Telecommunications establishes and maintains protocols, in collaboration with the Public Safety Systems Integration Coordinator, to protect and store electronic information. These protocols

include backup security measures, and regular patching and updates to operating systems and individual applications used within the NEIDL. The information is backed up on a regular basis.

6.0 RECEIPT AND HANDLING PROCEDURES

An authorized individual who receives a BSL-3 or BSL-4 Select Agent or Toxin will verify receipt of the shipment and enter the identity and strain of the Select Agent or Toxin, the quantity received, and the date of receipt into the BSL-3 laboratory's inventory control system or the BSL-4 suite's inventory control system. After verification of its identity, the Select Agent or Toxin is placed and kept in secured storage except when in use and under the direct control of an authorized individual approved by the Responsible Official to possess, use, and transfer Select Agents and Toxins. The authorized individual can transfer a Select Agent or Toxin to another facility in accordance with 42 CFR Part 73.16, Transfers, or destroy the Select Agent or Toxin on-site by autoclaving, incineration, or other recognized sterilization or neutralization process. The Principal Investigator must notify the Responsible Official of the decision to transfer or destroy a Select Agent or Toxin and the Responsible Official or his or her designee must witness the transfer or destruction. Records of all such actions are maintained in accordance with 42 CFR Part 72.15, Records.

In the event an unexpected package or shipment of select agent materials arrives at the laboratory, Public Safety will be notified at X4-4444. Public Safety will secure the immediate area and isolate the package. The RO will be notified and attempts to ascertain information from the sender and/or recipient will be made. If the package appears suspicious in nature or displays any suspicious indicators external law enforcement will be notified to investigate. If no threat is detected Public Safety will work in collaboration with the RO and Environmental Health and Safety to safely and appropriately determine an action plan.

7.0 INTERNAL TRANSPORT

Authorized individuals approved by the Responsible Official can transport a Select Agent or Toxin from one BSL-3 laboratory to another BSL-3 laboratory and from one BSL-4 suite to another BSL-4 suite if the recipient authorized individual has met all requirements for obtaining and handling that Select Agent or Toxin. The authorized individual and recipient authorized individual must record the transfer in their respective BSL-4 suite electronic inventory control systems to document the chain of custody. Packaging of a Select Agent or Toxin for internal transport requires tertiary containment as specified in Section 16: Transportation Plan of BU's Biological Laboratory Safety Permit Application.

8.0 POWER DISRUPTION

The NEIDL is equipped with redundant forms of back-up power sources should there be a disruption in normal power. All of the security and access control devices, including card readers, Biometric IRIS readers, electronic handsets and closed circuit television (CCTV) cameras are supplied. All CCTV and intrusion detection is monitored 24x7 by NEIDL Public Safety Officers . In addition we have locations for systems monitoring. In the event of normal power interruptions all Select Agent area remain secure. The RO will be contacted in the event of power interruptions. A Public Safety Officer will be assigned to restrict and/or control access to any select agent location in the event of system failure or system damage.

9.0 SECURITY TRAINING FOR AUTHORIZED INDIVIDUALS AND OTHER PERSONS ASSIGNED TO THE NEIDL

All authorized individuals will receive security training before the Responsible Official approves their assignment to work in the NEIDL BSL-3 laboratories or BSL-4 suites, and before the Department of Public Safety will issue ID badges and proximity cards that allow entry into the NEIDL and the assigned BSL-4 suites. All operations, maintenance, and support personnel and Public Safety Officers whose general work assignments are restricted to non-containment areas of the NEIDL will receive security training before the Department of Public Safety will issue ID cards that allow entry into the NEIDL. The Department of Public Safety also requires that operations, maintenance, and support personnel and Public Safety Officers pass a Criminal Offender Record Background Information Check before receiving the security training and their assignment to work in the NEIDL.

9.1 Security Training for Authorized Individuals

The security training content for authorized individuals addresses: 1) identification of safety and security emergencies and security breaches, and methods for reporting them; 2) mandatory reporting requirements and those responsible for the reporting; 3) security procedures for entering the NEIDL; 4) security procedures for controlling access to Select Agents and Toxins; 5) security responsibilities for escorting unauthorized individuals while they are in the NEIDL; 6) inspection of packages that escorted individuals may carry when they leave the NEIDL; 7) safeguards that secure electronic Select Agents and Toxins inventory records and protect the confidentiality of sensitive information; and 8) security measures that are implemented when a release of a Select Agent or Toxin occurs.

The security training program emphasizes that authorized individuals are required to

immediately report to the Responsible Official and the Executive Director of Public Safety any incident that involves: 1) the sharing, compromise, or loss of keys, badges, or passwords; 2) the loss of documentation, whether electronic or paper, which would provide specific information as to quantity, location, or access to Select Agents and Toxins; 3) any suspicious persons, packages, or activities that are observed at the NEIDL or at personal residences; 4) the loss or theft of a Select Agent or Toxin; 5) the release of a Select Agent or Toxin; and 6) any sign of an alteration or compromise of a Select Agent or Toxin inventory or use records.

Individuals whose IDs are lost or left elsewhere do not get access until they have recovered or replaced ID credentials. Public Safety can replace an ID or facilitate the approval (with RO) of an authorized escort immediately.

The training program provides specific instructions on how the authorized individual should report incidents and the nature of the incident response. For example, an incident report to the Responsible Official or the Executive Director of Public Safety involving the theft of a Select Agent will result in an immediate alert to the Boston University Police Department Detectives. The area will be secured and controlled by the on-scene NEIDL Public Safety Officer for evidence collection, if necessary. Public Safety may also notify the Boston University Police and other local, state, and federal agencies for assistance, as necessary. The Responsible Official will immediately notify the Boston Public Health Commission, Centers for Disease Control and Prevention, USDA, and others, as necessary, and will ensure availability of all BU records and personnel during ongoing investigations involving such agencies.

On the report of a suspicious person or package, Public Safety Officers will immediately respond to the incident. Suspected alteration of inventory records will initiate a review by Public Safety of all relevant records. Public Safety will make the determination regarding whether or not there was an alteration of the records.

Environmental Health & Safety provides training for the secure control of Select Agents and Toxins that are stored in lockboxes, refrigerators, and freezers within the BSL-3 laboratories and BSL-4 suites. EHS also reinforces biosafety training by addressing response procedures for an incident involving the release of a Select Agent or Toxin within a BSL-3 laboratory or BSL-4 suite.

9.2 Security Training for Public Safety Officers

Security training for Public Safety Officers includes an orientation course on the principles of biosafety and security. This course introduces basic concepts of biological safety, containment, and security, and addresses the particular needs of the individual, the work he or she will do, and the

risks posed by the Select Agents and Toxins. The course also emphasizes the security measures that control access to Select Agents and Toxins, and review safeguards that protect the public health from accidental and intentional release of a Select Agent or Toxin. Other relevant security training content addresses: 1) standard response protocols for encountering a suspicious person or package, including the use of the standard Field Investigation Observation interview procedures and arrest policies; 2) standard response protocols to isolate and secure an incident area, such as an area for medical emergency assistance involving BSL-3 laboratory personnel or BSL-4 suite personnel, and authorize escorted access to external first responders; and 3) standard protocols and procedures for controlling security incidents, such as workplace violence, protests and civil disturbances, bomb threats, hostage situations, and incidents that may involve authorized individuals at other campus locations.

Training also includes drills to maintain high standards of excellence in emergency response team procedures to assist in securing a biocontainment exterior perimeter. Refresher training and drills occur annually.

9.3 Security Training for Operations, Maintenance, and Support Personnel

Security training for operations, maintenance, and support personnel includes the orientation course on the principles of biosafety and security described in Section 8.2 of this Plan. They receive additional instruction on: 1) security procedures for entering the NEIDL, including procedures for obtaining a NEIDL ID badge, and proximity card, if necessary; 2) response protocols for encountering a suspicious person or package; 3) identification of emergencies; and 4) response protocols for emergency incidents.

9.4 Security Training for Escorted Persons

A person authorized to enter NEIDL under escort must first take the basic orientation course on the principles of biosafety and security before Public Safety will provide a temporary ID badge and grant approval for entering the NEIDL. The NEIDL employee providing the escort will be mindful of the need to ensure that the escorted person adheres to all safety and security requirements that apply. The escorted person will relinquish the temporary ID badge upon exiting the NEIDL. No escorted person can enter a NEIDL BSL-3 laboratory or BSL-4 suite without: 1) the approval of the Responsible Official; 2) experience working in a BSL-3 laboratory or BSL-4 suite; and 3) being an authorized individual at another BSL-3 laboratory or BSL-4 facility.

10.0 ANNUAL REVIEW, DRILLS, AND EXERCISES

The Public Safety department reviews and revises, as necessary, the NEIDL written Security Plan at least annually. Public Safety participates in drills and exercises each year in accordance with the NEIDL Comprehensive Emergency Management Plan to test and evaluate the effectiveness of the Plan, and revises the Plan as needed.

11.0 DEFINITIONS

Access: "Access" means having possession of a Select Agent or Toxin, or the ability to gain possession of a Select Agent or Toxin.

Authorized Individual: "Authorized Individual" means a person whom the DHHS Secretary or USDA Animal and Plant Health Inspection Service (APHIS) Administrator, and the Responsible Official have approved to have access for the possession and use of Select Agents at the NEIDL..

Command Center: "Command Center" means the designated location for coordinating all communications during an emergency.

Container: "Container" means a lockbox, refrigerator, or freezer for storing Select Agents and Toxins.

EHS: "EHS" stands for Environmental Health & Safety, the Boston University department responsible for managing the Select Agent Program at the NEIDL.

Principal Investigator: "Principal Investigator" means an authorized individual approved by the Responsible Official (RO) to direct a Select Agent or Toxin project or program and who is responsible for the scientific and technical direction of that project or program.

Risk Assessment: "Risk Assessment" means a process using qualitative and quantitative techniques to assess: 1) the potential for loss, theft, or release of a Select Agent or Toxin from a containment laboratory; and 2) the risk to the public health from such loss, theft, or release. The risk assessment provides the basis for selecting security control measures to safeguard the public health.

Responsible Official: The "Responsible Official" (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with the DHHS and USDA Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins.

Security: "Security" means both the biosecurity and physical security measures that protect Select Agents and Toxins, and critical relevant information, against loss, theft, and release.

Select Agent: "Select Agent" means a biological agent or toxin that has the potential to pose a severe threat to public health and safety. The DHHS Secretary and the USDA Animal and Plant Health Inspection (APHIS) Service Administrator have responsibility for determining Select Agents. Select agents are listed in §73.3 of 42 CFR Part 73 and in §121.3 of 9 CFR Part 121.

Vulnerability: "Vulnerability" means a deficiency, exploitable capability, or weakness in the physical security system of a laboratory facility or in the implementation of security operational standards that could compromise the security of Select Agents and Toxins.

12.0 KEY REFERENCES AND RESOURCES

- DHHS 42 CFR Part 73, Select Agents and Toxins
- USDA 7 CFR Part 331, Possession, Use and Transfer of Select Agents and Toxins
- USDA 9 CFR Part 121, Possession, Use and Transfer of Select Agents and Toxins
- BUMC Department of Public Safety Policy and Procedure Manual
- BU Personnel Suitability and Reliability Policy
- NEIDL Comprehensive Emergency Management Plan
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), U.S. Department of Health and Human Services. Centers for Disease Control and Prevention and National Institutes of Health. 5th Edition. 2009. Washington: U.S. Government Printing Office.