Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 16: BSL-3 / BSL-4 TRANSPORTATION PLAN

Boston University

National Emerging Infectious Diseases Laboratories

May 2013

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1.0 INTRODUCTION

The National Emerging Infectious Diseases Laboratories (NEIDL) is a high and maximum containment biosafety research facility that will perform research on a variety of emerging and re-emerging infectious diseases. The facility houses general research laboratories at Biosafety Levels (BSL) 1, 2, 3 and 4. The research will include the use of biological materials at all biosafety levels.

This document, in its entirety, describes the NEIDL-specific processes that will be followed for shipments of Select Agents (BSL-3 or BSL-4).

All other shipments will be completed in accordance with applicable regulations as described specifically in section 2.0 below.

This document will be reviewed and updated to address changing operational and regulatory requirements and will undergo review by applicable regulatory agencies when updated.

2.0 REGULATORY FRAMEWORK

The transportation of hazardous materials, which includes biological agents and toxins, is governed by a number of regulations and requirements. These requirements must be followed during all shipping and transportation of biological materials. Any violations are subject to legal actions that include fines and potential jail sentences. The following is a brief summary of the major requirements.

2.1 Department of Transportation

The general requirements for transportation of hazardous materials (including biological agents) are governed by the US Department of Transportation (DOT) Hazardous Materials Regulations (49 CFR Parts 171-et. seq.) and all shipments must comply with the provisions of the DOT regulations. DOT regulations establish strict requirements for packaging, labeling and documentation of the

materials as well as training of the transporters. The regulations have specific requirements for the transporters that must be met prior to being approved by the DOT as carriers of hazardous materials. These include DOT-mandated training for their employees, proper equipment, and comprehensive emergency response and contingency plans.

2.2 Centers for Disease Control and Prevention

In addition to the DOT requirements, a subset of biological agents and toxins are also classified as "select agents" and further regulated by the requirements of the Centers for Disease Control and Prevention (CDC), 42 CFR Part 73 and US Department of Agriculture (USDA), 7 CFR Part 331, 9 CFR Part 121 Select Agent Rules.

2.3 International Air Transportation Authority

The International Air Transportation Authority (IATA) establishes specific regulations for all air-cargo including hazardous materials. The International Air Transport Association's (IATA) Dangerous Goods Regulations (DGR), latest edition, is the worldwide gold standard for shipping. The IATA regulations apply to all air transport, both domestic and international flights. Following IATA's DGR ensures that a package will also meet US DOT requirements for ground transport.

2.4 World Health Organization

IATA requirements follow the United Nations, World Health Organization, *Guidance on Regulations for the Transport of Infectious Substances 2013–2014.* This guideline provides information for the appropriate classification, packaging and compliance with applicable international regulations for the shipment and transport of infectious substances.

2.5 Biosafety in Microbiological and Biomedical Laboratories

The CDC / NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, 2009, contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is generally considered the standard for biosafety and is the basis for the overall Biosafety Program at BU. Adherence to the BMBL is a requirement under the Boston Public Health Commission (BPHC) Laboratory Regulations.

2.6 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Research involving recombinant deoxyribonucleic acid (DNA) shall comply with the National Institute of Health's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.* These Guidelines apply to all recombinant DNA research and provides specific practices, procedures and facilities when constructing, handling and working with recombinant

nucleic acid molecules, as well as synthetic nucleic acid molecules. The guidelines also include those molecules that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and cells, organisms, and viruses containing such molecules.

3.0 ACRONYMS / DEFINITIONS

BFD: Boston Fire Department

BPD: Boston Police Department

BPHC: Boston Public Health Commission

BSO: Biosafety Officer

RO: The Responsible Official as defined in the Select Agent Rule (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121)

ARO: Alternate Responsible Official as defined in the Select Agent Rule (42 CFR Part 737 CFR Part 331, 9 CFR Part 121)

Select Agents: Select Agents are biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety. These agents are listed in the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) in the Federal Register on October 05, 2012. Certain select agents and toxins are classified as Tier 1 and are subject to additional requirements.

Shippers Declaration Form: The documentation required when a high-risk material will be shipped. These documents will be maintained in accordance with all laws, regulations and BU policies including standards for the maintenance of original forms to be maintained by the shipper, the transporter and the receiver.

Subject Materials: A substance or material in a quantity and form that may pose a high level of risk to health, safety or property when received, transported and/or stored. These materials include, but are not limited to, toxic/infectious substances (including select agents), radioactive materials, chemicals and any other materials that the BU Environmental Health and Safety (EHS) deems a material that should be managed throughout its transport plan.

4.0 ROLES AND RESPONSIBILITIES

4.1 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.

4.1.1 Environmental Health and Safety (EHS) 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

4.2 The Executive Director of Public Safety and Chief of Police is responsible for all 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 the Public Safety Officers 24 hours a day, seven days a week. They are responsible for initiating notification procedures involving all emergency responses and all phases of disasters occurring in and around the NEIDL. They are also responsible for notifying BU public relations of any security incidents that may require a public safety advisory. In addition, they are responsible to coordinate with other public safety organizations.

4.2.1 The Public Safety Officers assigned to the NEIDL are the individuals with responsibility to control access to the NEIDL in accordance with established protocols and to respond to all select agent emergencies and incidents 24 hours a day, seven days a week. Emergencies and incidents include: 1) loss, theft, release of select agents or toxins; 2) unauthorized personnel entry; and, 3) all security system alarms and video breaches on the grounds and at the pedestrian and vehicle entry points. The 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 all security-related equipment is functioning at all times; and, 4) reporting malfunctions immediately to the Command and Control Center for response and repair

4.2.2 The Boston University Police Department 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. The Department will participate in all contingency disaster phase planning prior to and following a security incident involving the NEIDL

4.3 The Principal Investigator (PI) is an authorized individual approved by the Responsible Official (RO) who 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; 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.

4.4 The Associate Vice President Research Compliance (AVPRC) has responsibility for the Animal Services Center (ASC), Environmental Health & Safety (EHS), the Research Occupational Health Program, the Institutional Biosafety Committee (IBC), The Laboratory Safety Committee, the Institutional Animal Care and Use Committee (IACUC) and other research-related oversight committees.

The AVPRC serves as an Associate Director for the NEIDL and has responsibility for services listed above as well as the Emergency Response Planning, Facilities and Public Safety Cores

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

4.5 Sender

The sender of a biological material plays an important role in the process. This includes: ensuring that the biological materials sent are those requested and supplying documentation for such; proper packaging of the materials to ensure that the package complies with all regulatory requirements; and, ensuring that all proper documentation and manifests are completed and submitted to the carrier.

4.6 Carrier

The carrier, or the transporter, is the critical component of the transportation process and its primary responsibility is to ensure that shipment is safely delivered to the receiving institution. The carrier must ensure that it has the appropriately issued permits, trained staff, equipment, security plan to include background checks for drivers and emergency response procedures in place for transporting the shipment.

4.7 Receiver

The receiver of the shipment is the final component of the transportation process and is responsible for ensuring that the delivered package is the correct shipment by checking to ensure that the packaging material remained intact, verifying and ensuring that each individual agent requested and contained in the package matches exactly with the APHIS/CDC Form 2 declaration including the name of select agent and/or toxin, characterization of the agent, number of items, form, and total amount. Once the shipment has been successfully verified, the RO/ARO completes and signs section 3 of the APHIS/CDC Form 2 declaration and send a copy to the sender and APHIS/CDC within 2 business days of receipt. The receiver is also responsible for notifying APHIS/CDC and other appropriate authorities in the event that the anticipated shipment is not received within 48 hours of the expected delivery, if the package has been damaged to the extent that the agent is released or discrepancies in the shipment received.

5.0 THE PROCUREMENT PROCESS

The actual shipment of any BSL- 3 or BSL-4 Select Agent biological material and/or toxin is a component of a more comprehensive procurement process that includes four distinct phases. The four phases combined are developed to meet the requirements of the possession, use and transfer of select agents and toxins (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which is commonly referred to as the "Select Agent Rule". The following provides a general description of the four phases.

5.1 Authorization to Possess

In order to initially procure the select agent, the Principal Investigator (PI) must submit a research protocol to the Institutional Biosafety Committee (IBC) for approval. The IBC reviews the protocol and ensures that the PI has identified the hazards and risks associated with the agent and type of research work and all appropriate mitigation measures (e.g., training, facilities, safety equipment [biosafety cabinets, safety needles]), and personal protective equipment to protect employees and the environment.

Upon approval of the IBC, the research protocol is submitted to the BPHC for review and approval as required in the BPHC Laboratory Regulation.

The Responsible Official submits the necessary documentation mandated by 42 CFR Parts 72 and 73 (e.g., personnel involved for a Department of Justice Background check, list of select agents, security and risk assessment plans, emergency response plans) to the CDC for obtaining the permit to possess, use and store the select agent.

The successful completion of these approvals, registrations and permits provides the NEIDL with the authorization to possess and use the materials.

5.2 Authorization to Obtain and Transfer Select Agent

Once the authorization to possess the select agent is granted, BU will obtain the necessary transfer permit from CDC to obtain and possess the agent. This process is summarized in the "*APHIS/CDC Select Agent Transfer Procedures"*. A copy of the procedure is included at the end of this document. This procedure is also available at:

http://www.selectagents.gov/resources/Form%202%20Recipient-Sender%20Procedure%20(FINAL).pdf. (attached)

5.3 Shipping/Transportation

After all appropriate permits have been obtained, BU will request that the shipper (i.e., the sending institution) package the materials in accordance with the regulatory requirements and ship them to the NEIDL. The shipper is required to follow transportation regulations and requirements (federal and international) and any additional requirements imposed by BU. The following describes the critical requirements:

5.3.1 Packaging Requirements

The packaging requirements for shipment of biological materials are specified in DOT regulations, WHO Guidelines and the BMBL. Detailed requirements for packaging are described in the BU's BPHC Biological Laboratory Safety Permit Application, Section 2, BSL-4 Biosafety Manual, Chapter 11 (January 31, 2009). The requirements are consistent with the three documents referenced above.

The packaging must follow the "triple packaging" (See Appendix 1 for a diagram of the packaging system), which requires the following:

- The innermost primary receptacle(s) is leak-proof.

- A leak-proof secondary receptacle with absorbent material is placed between the primary and secondary receptacles to prevent the release of liquid during transport and to shield multiple primary receptacles from coming in contact with one another.
- Rigid, tertiary outer packaging that is at least 100 mm (4 in) in its smallest external dimension.

In additional, shipments of Category A and Category B materials must be packaged according to IATA Packing Instructions 602 and 650, respectively. These guidelines require the following:

- Shipments must be prepared in such a way that they arrive at their destination in good condition and present no hazard to persons or animals during shipment.
- Outer packaging must meet structural strength requirements and carry defined specification markings.
- Packages must be at least 100 mm (4 in) in their smallest external dimension.
- An itemized list of contents must be enclosed between the secondary container(s) and the outer packaging.
- All packages containing infectious substances must be marked durably and legibly on the outside of the package with the name and telephone number of a person responsible for the shipment.
- The shipper must make advance arrangements with the recipient and the operator to ensure the shipment can be transported and delivered without unnecessary delay.
- Substances shipped must be in primary receptacles made from plastic or metal, with a positive means of ensuring a leak-proof seal. Glass shall be avoided (unless necessary). Screw caps and seals shall be reinforced.
- Substances shipped refrigerated or frozen must carry the refrigerant outside the secondary container. If wet ice is used, the packaging must be leak-proof. If dry ice is used, the packaging must permit the release of carbon dioxide gas.
- Primary and secondary containers must retain their integrity across the full range of pressures and temperatures experienced under normal and loss-of-refrigerant conditions.

- Package labeling is in the form of standardized pictures that must be affixed to the outside. The color and design of each label is prescribed in the IATA regulations. All labels must be at least 2 inches on the smallest side.
- All regulatory mandated documentation and shipping manifests must be completed and accompany the packages.

Once a biological material has been packaged in accordance with these requirements, it may be handed to a carrier that has been pre-approved by BU (see Section 6 below) for transport and delivery to the NEIDL.

The carrier, or transporter, must comply with the provisions of 49 CFR, Part 171, which imposes specific requirements including staff training, vehicle inspections, security plans, labeling of the vehicle, security plans and emergency response plans. Additionally 49 CFR Part 107 requires that "persons who transport or offer for transportation certain hazardous materials are required to annually file a registration statement" which establishes the transporter registration program.

5.4 Receipt and Usage

Once the package is scheduled for delivery to the NEIDL, the RO or ARO will proceed with the following steps.

5.4.1 Steps Prior to Arrival

- Responsible Official (RO), or the ARO, Biosafety Officer (BSO), and Principal Investigator (PI) verify that laboratory and/or storage facilities are available and ready to receive the agents.
- RO or ARO and Executive Director of Public Safety, or designee, review security procedures for receipt and transfer prior to the day of scheduled arrival. This includes the time and exact location of the delivery, process for vehicle entry into the facility, route of transport from the delivery site to the laboratory, etc.
- The Executive Director of Public Safety, or designee, will ensure that a BU public safety officer is available to provide escort for the RO or ARO and subject materials package during the acceptance of the package and delivery to the final laboratory room/suite for which the shipment is destined.
- Appropriate federal, state and local agency notifications will be made (see Appendix 3).

5.4.2 Arrival and Receipt

Upon arrival of the carrier at the designated delivery site, the RO or ARO and Executive Director of Public Safety or their designee(s) shall:

- Ensure that the vehicle is within a secured location where it can remain until the entire receipt process is completed.
- Check the carriers' driver's licenses and verify that their identities match the photographs and names provided by their company to Boston University the day before the shipment of the materials.
- Instruct the carriers to stand by and not depart until the package has been opened in the lab and all shipment has been accounted for.
- Perform a visual inspection of the package and verify to make sure that it does not show any visible sign of tampering or damage.
- Transport the package to the select agent laboratory with escort from Public Safety officer.

5.4.3 Verification of Shipment

- After donning the appropriate personal protective equipment (PPE) and following established laboratory procedures, the PI and RO or ARO or their designee(s) take the unopened package to a previously designated biological cabinet in the laboratory.
- The PI and RO or RO or their designee(s) further examines the exterior of the package for any signs of tampering, damage, or leaks. The package is opened and the interior packaging is carefully inspected for damages and leaks. The contents of the package is individually removed and each labeled container is carefully inspected and verified to match exactly with the APHIS/CDC Form 2 declaration including the name of select agent and/or toxin, characterization of the agent, number of items, form, and total amount.
- The public safety officer will wait outside the laboratory while verification of the shipment occurs.
- If all is in order (no non-conformities) and the contents are verified, the RO or ARO or designee finalizes the transporter's shipping papers.
- The driver is allowed to leave the premises.

5.4.4 Notification and Documentation

Routine

- The RO or ARO completes blocks 41 and 42 of Form 2, faxes, and mails the form within 24 hours of receipt to the shipper's RO and APHIS/CDC.
- The PI enters the select agent into inventory per established procedure.

Discrepancies

In the event of non-conformity with the shipment, the RO or ARO will immediately notify:

- Public Safety to hold the transporter
- The Emergency Response Planning Division to activate emergency notifications and plans
- The CDC, local law enforcement, Department of Justice, and the Boston Public Health Commission
- Complete and transmit APHIS/CDC Form 3 and send to the CDC

Damaged Packages

As stated in Section 4.7.2 above, all packages arriving at NEIDL will be inspected for signs of external damage (e.g., crushed box, torn outer container) or visible signs of leakage (e.g., wet spots or water damage marks). If any such indicators are noticed, the BU Emergency Response Team (ERT) will be activated to evaluate the situation and take the appropriate action. The actions taken will be dependent upon a number of factors including, but not limited to, the type and nature of the damage observed; the possibility that a leakage has occurred; advisability of moving the package from the cargo area to prevent further spread of contamination; potential contamination of personnel during removal, etc.

The RO or ARO, BSO and the Public Safety will:

- Inform the driver that the vehicle must not be moved.
- Notify federal (CDC) and local (BPHC, BFD, EMS and BPD) of the event.
- Evaluate the nature of the damage and determine the best course of action based on their professional knowledge and training. These actions could include:

- The over-packing of the package and removing it to a laboratory for safe handling and further inspections
- Neutralization of the cargo area by use of an agent-appropriate disinfectant
- Placement of the package in a container filled with agent-appropriate disinfectant prior to removal
- Isolation of the vehicle, and the sealing of the cargo area, until local or federal agencies arrive for consultation on further action necessary
- Contacting the carrier's emergency response contractor for assistance

Notes:

- All BU-ERT members have a full HAZWOPER 40-hour initial training and annual refresher training, as well as the select agent specific training.
- The actual content of the shipments are in plastic vials that typically contain low (less than 10) milliliter quantities. With the packaging requirements that include two inner containers that are leak-proof, and the absorbent materials that can absorb multiples of the volumes of the contents of the vial, the likelihood of actual damage during the transportation that could result in a leakage are extremely low.

5.5 Usage

Once the package has met the acceptance criteria, it is delivered to the designated laboratory and released for use under the conditions specified by the IBC and the BPHC.

6.0 NEIDL TRANSPORTATION MITIGATION POLICY

The regulatory requirements described above establish defined roles and responsibilities for the three principal participants of the shipping and transportation process. In accordance with the recommendations of the WHO Guidelines described in Section 1.1.3, BU has taken an active role in the shipper-carrier-receiver collaboration and has established specific criteria for actively seeking pre-qualified carriers that will meet these requirements prior to the selection of a final carrier or carriers.

The pre-qualification criteria have been developed to ensure that the shipments destined for the NEIDL are transported by carriers who exceed regulatory requirements. The BU Materials Transportation Management Policy is attached as Appendix 1. The policy provides details on the specific roles and responsibilities of various offices as well as definition of terms. Any carrier used to transport shipment of BSL-3 or BSL-4 select agents to the NEIDL must fully comply with all of

the provisions of the federal and international regulations and requirements for transportation of hazardous materials.

Additionally, BU has committed in the Comprehensive Emergency Management Plan (CEMP) to ongoing communication, training and exercises with external responders in collaboration with the Boston Public Health Commission. These commitments include the involvement of City of Boston responders in transportation GPS tracking and notifications of deviations from all transportation plans.BU will monitor transportation at all times by activating the incident command system and will have BU personnel with expertise in the material being shipped available to provide direction if an incident occurs.

The information below provides specific additional requirements of the BU policy that exceeds the regulatory requirements.

- The carrier's Commitment to provide services as a qualified provider for the transport of all subject materials.
- Commitment to provide transport services in accordance with all BU standards including the use of a dedicated vehicle with two qualified drivers assigned to the service
- Commitment to provide staffing that has undergone, and continues to undergo on an annual basis, appropriate background checks, including but not limited to criminal background checks, driving record and other checks designated by BU.
- Commitment to provide carrier services that may require that the transportation be initiated and completed by a single set of individuals.
- Commitment to provide advanced information on the identity of the drivers.
- Commitment to provide GPS tracking of packages or vehicles.
- Commitment to provide customized services that require adherence to BU determined routes of travel, audit procedures and strictly defined schedules for both pick-ups and deliveries.
- Commitment to provide an all-inclusive chain of custody document upon delivery of each package.
- Commitment to provide resources to participate in BU audits of services.

- The carrier must pre-designate an emergency response company for notification in the event of an incident. BU reserves the right to require different or additional emergency response capabilities.
- Notification of BU of any accidents during transportation.

7.0 SHIPMENTS FROM NEIDL

If there is a need to ship packages containing BSL-3 or BSL-4 select agents from the NEIDL to another entity, the requirements will be the same as those described above; however, the roles would change in that in those instances the NEIDL will be the "shipper" and the other entity will be the "receiver".

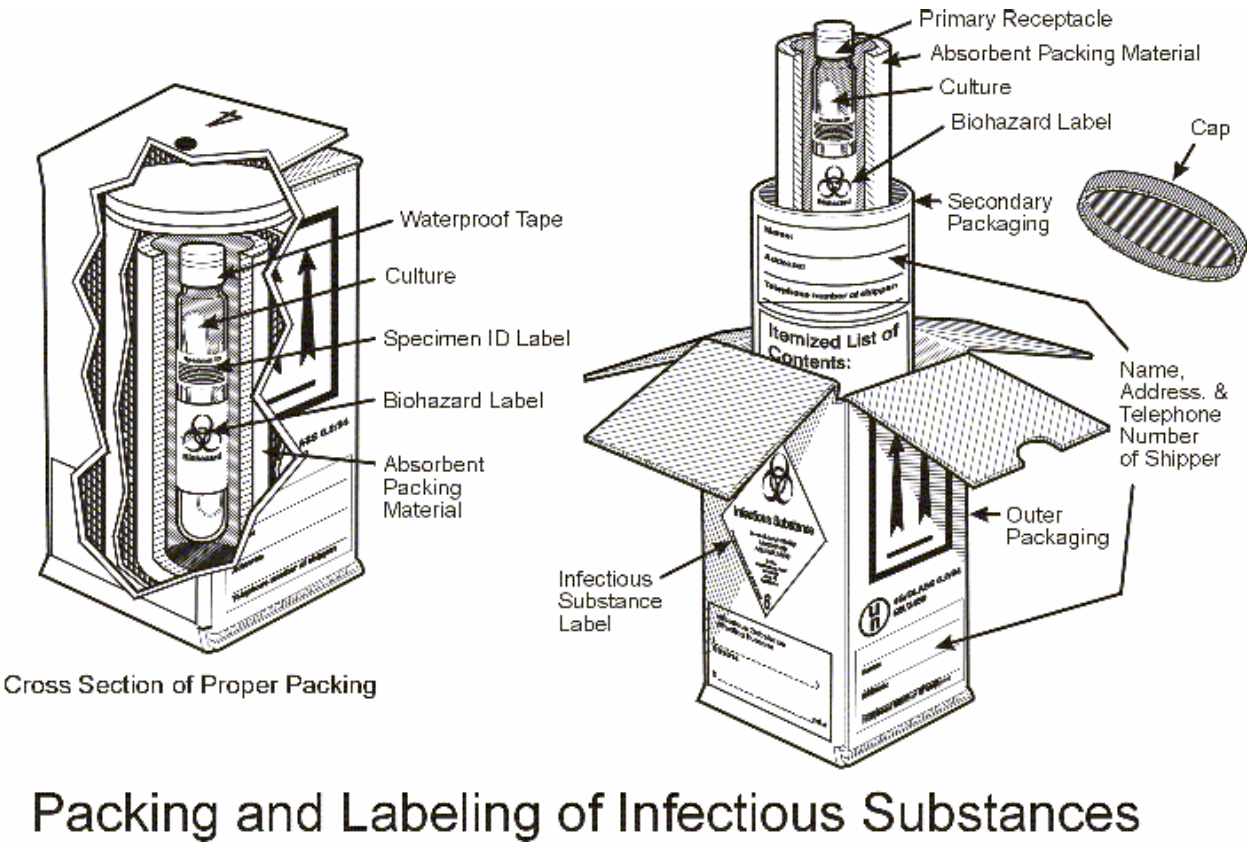
Notes:

1. With the selection of pre-qualified carrier or carriers who are able to meet these requirements, BU will request that the shipper only use the approved carrier identified by BU for a given shipment.
2. BU is committed to using ground transportation for shipment from within the United States or Canada.
3. Shipment originating from locations where ground transportation is not an option will follow the IATA regulations for transportation of dangerous goods during the air transportation, and DOT during the ground transportation
4. All prohibitions and restrictions related to transportation of hazardous materials through public streets will be followed. Examples of these include prohibition on transport of hazardous materials through public tunnels, bridges or ports of a city.

APPENDIX 1: PACKAGING REQUIREMENTS FOR SHIPMENT OF BIOLOGICAL AGENTS

As described in Section 5.3 above, regulations establish specific criteria for packaging of biological materials. The following description is excerpted from BMBL Appendix C, 5th Edition, and provides a complete overview of packaging system.

> "Figure 1 shows an example of the UN standard triple packaging system for materials known, or suspected of, being a Category A infectious substance. The package consists of a watertight primary receptacle or receptacles; a watertight secondary packaging; for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles; and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. Each surface of the external dimension of the packaging must be 100 mm (3.9 inches) or more. The completed package must pass specific performance tests, including a drop test and a water-spray test, and must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The completed package must also be capable of withstanding, without leakage, temperatures in the range of -40 ºC to +55 ºC (-40 ºF to 131 ºF). The completed package must be marked "Infectious substances, affecting humans, UN 2814" or "Infectious substances, affecting animals, UN 2900" and labeled with a Division 6.2 (infectious substance) label. In addition, the package must be accompanied by appropriate shipping documentation, including a shipping paper and emergency response information."


Waterproof Tape
Culture
Specimen ID Label
Biohazard Label
Absorbent Packing Material
Cross Section of Proper Packing
Primary Receptacle
Absorbent Packing Material
Culture
Biohazard Label
Cap
Secondary Packaging
Itemized List of Contents:
Name, Address. & Telephone Number of Shipper
Outer Packaging
Infectious Substance Label
Packing and Labeling of Infectious Substances

APPENDIX 2: BUMC MATERIALS TRANSPORTATION MANAGEMENT POLICY

1. Purpose and Applicability

The purpose of this policy is to define the procedures used to manage the shipping, receiving, and transportation of items determined to be high-risk by the Environmental Health and Safety Department in accordance with Boston University and Boston Medical Center (BU/BMC) policies and procedures and all applicable laws and regulations.

This policy applies to all items determined to be high-risk and to all employees and staff, including those who are visiting users of BU/BMC facilities and those who are contracted services involved in the shipping, receiving, handling or other use of subject materials as described below.

This policy defines the protocols for the selection of contracted services to be used in the shipping, receiving and transport of subject materials. It also includes standards for packaging, transporting, delivery routes and the quality controls to be utilized to ensure that all those involved in the management of subject materials transport adhere to these standards.

2. Definitions

Subject Materials: A substance or material in a quantity and form that may pose a high level of risk to health, safety or property when received, transported and/or stored. These materials include, but are not limited to, toxic/infectious substances (including select agents), radioactive materials, chemicals, compressed gases, and any other materials that BU/BMC Environmental Health and Safety (EHS) deems a material that should be managed throughout its transport.

Select Agents: Biological agents and toxins that have the potential to pose a threat to public health and safety if used for bioterrorism purposes. The list includes over 80 bacteria, viruses, toxins, rickettsia, and fungi. The program is regulated by the Department of Health and Human Services (DHHS) and Department of Agriculture (USDA) under the Federal Regulation for Select Agents [42 CFR 73.0; 7 CFR 331; 9 CFR 121].

Shipper: The shipper is the person who packages the subject material and signs the shipper's declaration form. This person is responsible for the material to be classified, identified, packaged, marked and labeled, with all appropriate documentation included with the package. This individual is required to have shipping training, and notify the receiver regarding the planned shipment of high-risk material.

Transporter: The transporter is the individual, operator or contracted service that obtains the package from the shipper, verifies it has been packaged correctly, and carries the package to the receiver.

Receiver: The receiver, for the purposes of this policy, is the individual who receives the package. This individual is required to have shipping training. The receiver notifies the shipper upon receipt of the planned delivery of high-risk material.

Shippers Declaration Form: The documentation that a high-risk material will be shipped. These documents will be maintained in accordance with all laws, regulations and BU/BMCMC policies including standards for the maintenance of original forms to be maintained by the shipper, the transporter and the receiver.

Qualified Vendor: A vendor who meets or exceeds the criteria in Section 6.

3. Roles and Responsibilities

3.1 Environmental Health and Safety

The Environmental Health and Safety Department (EHS) is responsible for the management and oversight of the Materials Transportation Management Policy and for ensuring compliance with the procedures outlined within this policy by all employees and staff, visiting users of BU/BMC facilities and contracted services including associated transporters.

3.2 Office of Mail Services

The Office of Mail Services will provide support to EHS and Public Safety with the screening/examination of delivered packages, with the staffing of designated locations, and with the management of contracted services.

3.3 Office of Purchasing Services

The Office of Purchasing Services will be responsible for facilitating the selection of contracted service providers who are capable of providing services in accordance with this policy and in compliance with all applicable laws and regulations. The Office of Purchasing Services will select, monitor, manage and discharge all contracted services that are involved in the management and transport of subject materials.

3.4 Department of Public Safety

The Department of Public Safety (DPS) will, through its Investigations Unit, initiate, conduct and/or participate in audits and conduct investigations as necessary. DPS, through its Systems and

Operations Units, will be responsible for maintaining the security of locations determined to be appropriate for the receiving, shipping and storage of designated materials as well as the screening and examination of vehicles, packages and personnel. DPS will provide security at the point of receipt of the high hazard material and escort the package from the point of entry to the final destination in the BU. Transport of select agents from one location to another outside of a contained area may require security escort to verify that the transporter is BU/BMCMC select agent authorized.

3.5 Emergency Response Planning

The Emergency Response Planning Division of EHS (ERP) will provide recommendations to the EHS, Facilities Management and Planning, DPS and the Emergency Response Team related to emergency management planning, training and response coordination. In addition, the ERP will participate in the development and implementation of emergency response plans, exercises, risk reduction initiatives and risk prevention measures; and serve as the liaison to the Boston Mayor's Office of Emergency Preparedness, the Massachusetts and Federal Emergency Management Agencies.

3.6 The Shipper

The Shipper will be responsible for ensuring that the material being shipped is appropriately packaged including classifying, identifying, marking, labeling and providing appropriate documentation with the package. The shipper must be trained in accordance with all applicable laws, regulations and BU/BMC policies including those that address the type and frequency of training and necessity of additional training should laws, regulations or BU/BMC policies change at any time.

3.7 The Transporter

The Transporter will be required to do the following: accept, store, load, inspect and deliver packages to an approved location using approved access routes; report any and all violations of law, regulation or policy; retain all records; and have proper shipping training. The inspection of packages includes requirements involving damage to packages, reporting guidelines and immediate communication to the shipper and receiver, public health and regulatory authorities. In addition to these requirements, transport companies may have their own specific safety requirements for subject material transport.

4. Procedures

EHS and DPS will determine the best location for the receipt, control, audit, transport, and shipping of all items under this policy. Such location(s) will be operated or provided with oversight by representatives of EHS and other related user departments. These areas will be routinely audited. Transport to and from this location will be by major routes of travel that immediately border BU/BMC and are limited to Albany Street, Massachusetts Avenue and the highway/connector system in the rear of BioSquare.

EHS will train all users of the laws, regulations, polices and requirements involved in the shipping and receiving of subject materials and will manage the tightly controlled, pre-approved, scheduling of shipment and delivery times. EHS will train all BU/BMC users in the approved procedures for the packaging of materials, the approved contracted services to be used in the transport of such materials and the penalties of failing to follow all aspects of this policy.

EHS and DPS will ensure that BU/BMC staff involved in the high-risk materials shipping / receiving areas undergo a background clearance check, as appropriate, consistent with the select agent regulatory requirements prior to being approved to work in these locations.

EHS and DPS will determine the packaging requirements to be used in the shipping and receiving of subject materials. These requirements will comply with all applicable regulatory standards. These mandated packaging requirements would only be altered after obtaining any required approval from all relevant regulatory authorities.

Transport of select agents will be done in accordance with all laws and regulations including the approval from the U.S. Department of Health and Human Services, Center for Disease Control and Prevention, prior to shipment, and notification within 24 hours of receipt. The transport will also include the utilization of appropriate forms and the reporting of registration numbers of all parties involved in shipping, transporting and receiving packages.

EHS, DPS and the Office of Purchasing will select contractors for the transportation of subject materials based on criteria including, but not limited to, the following:

- Past performance on similar contracts.
- Ability to provide services as a qualified vendor for transport of all subject materials.
- Ability to provide transport services in accordance with all applicable regulatory standards.
- Ability to provide transport services in accordance with all applicable BU/BMC standards including the use of a dedicated vehicle.

- BU/BMC requires that the DOT-compliant triple packaging be placed in a non-crushable liquid tight solid container for an added layer of safety.
- BU/BMC requires that packages be secured in the vehicle away from potential impact on outer walls.
- Ability to provide staffing that has undergone, and continues to undergo on an annual basis, appropriate background checks.
- Ability to provide courier services that may require that a single individual pick up and deliver packages.
- Ability to provide GPS tracking of packages or vehicles.
- Ability to provide vehicles that are inspected in accordance with all applicable inspection standards at least every six months.
- Ability to provide customized services that require adherence to BU/BMC determined routes of travel, audit procedures and strictly defined schedules for both pick-ups and deliveries.
- Ability to maintain and to provide an all-inclusive chain of custody document upon delivery of each package.
- Ability to provide resources to participate in BU/BMC audits of services.
- Any transportation vendor personnel having relative proximity to the package must report all occurrences of illness to the Boston Public Health Commission for a period of three weeks from the delivery departure date.

Tracking Shipments: EHS will schedule all deliveries and will track the delivery with the contracted service performing the transportation by means of contractor-provided tracking methods. BUMC will initiate its own tracking methods at its discretion and will determine the type of packaging that the shipper, receiver and transportation company uses, and that it is in compliance with all laws and regulations.

Prior to the transport of a shipment to the NEIDL of a select agent, the ERP will ensure that the appropriate Commonwealth and Boston emergency response departments having jurisdiction are notified.

Off Peak Delivery: EHS will schedule all deliveries to arrive at off peak traffic hours through the city of Boston to ensure transport and reduce the possibility of accident or delay due to traffic congestion.

Clear Loading Dock: DPS will ensure that the loading dock or other facility where the transporter is delivering the high hazard material is free and clear of all parked vehicles to enable safe, secure transfer and receipt. Areas used for deliveries will include secure loading or vehicle inspection areas in which the delivery vehicle can be isolated from movement.

Delayed Receipt: Failure to receive package within the specified time range of delivery will result in an immediate investigation involving the transport contractor, the shipper, BU/BMC and all applicable regulatory personnel.

Receipt of Packages: Packages delivered to BU/BMC will be inspected, verified, documented and transported to the appropriate location within BU/BMC by EHS.

Prior to receipt of the package, the Responsible Official will verify with the driver that the package's integrity is intact. In the event that the package's integrity is compromised, the transport compartment will be sealed and the transporter's emergency protocols will be followed. ERP will notify all appropriate local response agencies and initiate the BU/BMC Emergency Response Plan, the BU/BMC Select Agent Incident Response Plan, and Incident Command System.

Problems or Incidents on Route: The transporter will contact the relevant law enforcement agency having jurisdiction for any problem or incident that may occur during transit or transport of the subject material. The transporter will also notify BU/BMC immediately of any such event.

The transporter will ask that the public safety agency having jurisdiction notify the local emergency responders having jurisdiction where any incident occurs.

Upon notification of an incident enroute to BU/BMC, ERP will ensure that the local emergency response departments having jurisdiction are notified.

The transporter will have a reputable hazardous materials cleanup contractor available on a 24-hour by seven days a week basis for response for a biological incident mitigation. The contractor will coordinate those mitigation efforts with the local emergency responder incident commander.

Notice of Successful Transport: Upon the successful receipt of a shipment under this policy, ERP will notify all the appropriate public safety agencies of the conclusion of the transport.

5. Key References and Resources

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, February 2007
- U.S. Department of Transportation, 49 CFR Part 171 Final Rule, 03/18/05
- International Air Transport Authority 2006, 46th Edition Dangerous Goods Regulations
- U.S. Public Health Service (HHS)/ CDC 42 CFR Part 73.0, "Possession, Use & Transfer of Select Agents and Toxins," 03/18/05
- Morbidity and Mortality Weekly Report Vol. 1 No. RR-19, "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents" 12/06/02
- National Institutes of Health *Guidelines for Research Involving Recombinant DNA Molecules*

6. Web Sites

BU, Environmental Health and Safety (OEHS): www.bumc.bu.edu/ehs

BUMC, Public Safety Department: www.bumc.bu.edu/publicsafety

BUMC, Purchasing: www.bu.edu/purchasing

Centers for Disease Control and Prevention: www.cdc.gov

CDC Select Agent Program, Laboratory Registration: www.cdc.gov/od/sap

Federal Express, Dangerous Goods Program: www.fedex.com

International Air Transport Authority: www.iata.org

MA Department of Public Health-State Lab Institute: www.state.ma.us/dph/sli/htm

United Parcel Service, Hazardous Materials Support Center: www.ups.com

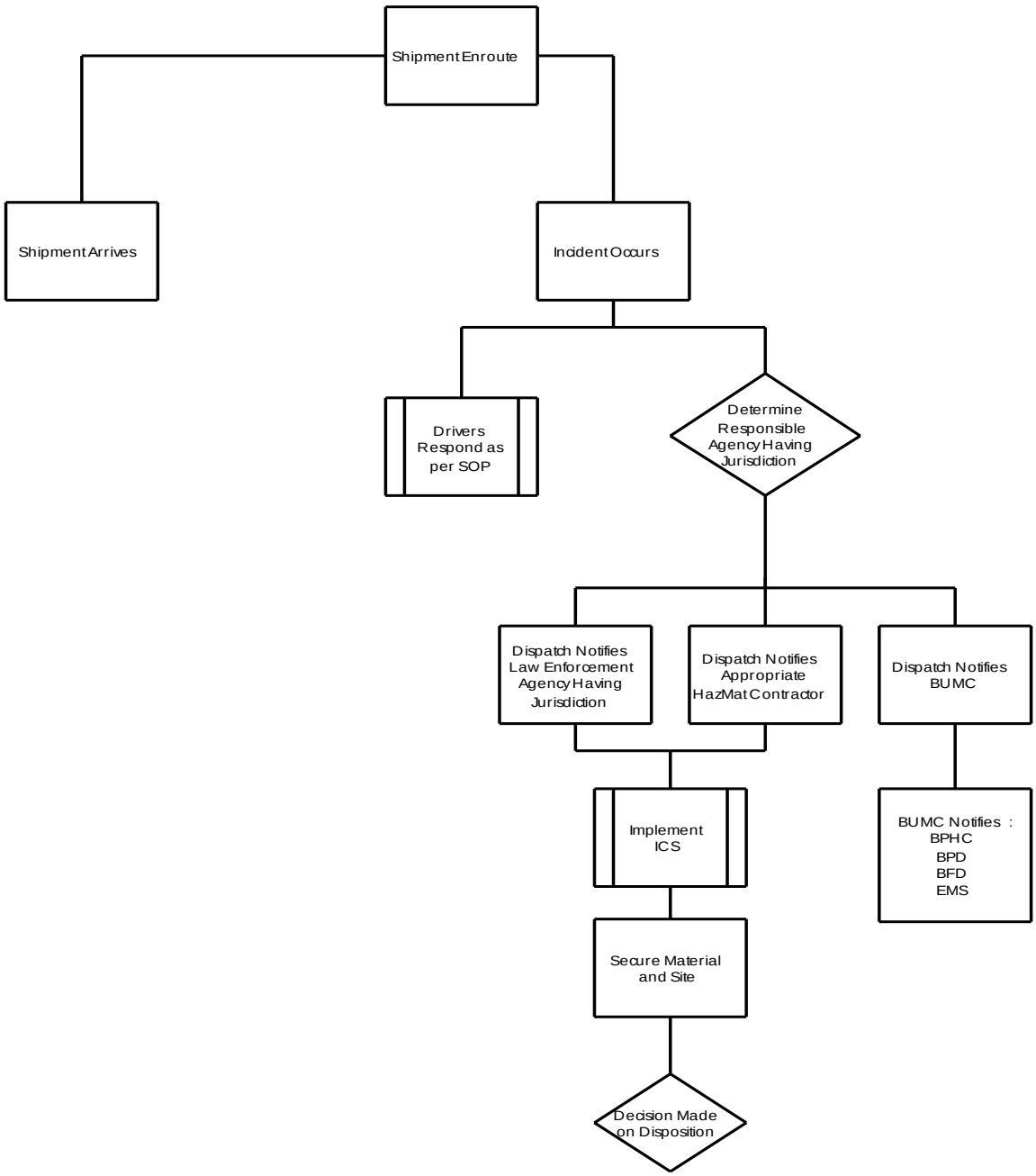
USDA Select Agent Program: http://www.aphis.usda.gov/vs/ncie/bta.html

United States Postal Service: www.usps.gov

United States Public Health Service: www.usphs.gov

U.S. Department of Transportation: www.dot.gov

APPENDIX 3: SELECT AGENT TRANSPORTATION FLOW CHART



APPENDIX 4: NOTIFICATION MATRIX FOR SELECT AGENT SHIPMENTS

The following chart depicts the events and agencies that will be notified during the transportation process. This chart covers the period from when a package is ordered to the final time of its arrival, whether being sent or received by BU/BMC.

Activity	Agency						
	CDC	FBI	BPHC	Boston Emergency Operations (911)			
				BPD	BFD	EMS	EOPS
Routine shipping information*			X	X	X	X	X
Changes in shipping information			X	X	X	X	X
Arrival - No discrepancy / damage	X		X	X	X	X	X
Arrival - Lost or stolen	X		X	X	X	X	
Arrival - Paperwork discrepancy	X	X	X	X	X	X	
Arrival - Damaged package with no leakage			X	X	X	X	
Arrival - Damaged package with suspected leakage	X		X	X	X**		

* The information will include shipment date, carrier, arrival date, routes and biological agents.

** EMS will be notified if there is evidence of personnel contamination (e.g., driver).

APPENDIX 5: RESPONSIBLE OFFICIAL CONTACT INFORMATION

Responsible Official – Boston Public Health Commission

Kathryn Mellouk

Associate Vice President, Research Compliance

Charles River Campus Address:

One Silber Way, 8th Floor

Boston, MA 02115

Phone: 1.617.353.2230

Medical Campus Address:

85 E. Newton Street, M-810H

Boston, MA 02118

Phone: 1.617.638.7660

Responsible Official – CDC/USDA Select Agent

Ron Morales

Director of Research Safety

85 E. Newton Street, M-439

Boston, MA 02118

Phone: 1.617.638.8838

24-hour Contact:

BUMC Control Center

1-.617-.638-.4144