1.0 Purpose and Applicability

1.1 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 Environmental Health and Safety in accordance with Boston University (BU) policies and procedures and all applicable laws and regulations.

1.2 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 facilities and those who are contracted services involved in the shipping, receiving, handling or other use of subject materials as described below.

1.3 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 these standards are adhered to by all those involved in the management of subject materials transport.

2.0 Definitions

2.1 “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 the BU Environmental Health and Safety (EHS) deems a material that should be managed throughout its transport.

2.2 “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 70 bacteria, viruses, toxins, rickettsia, and fungi and 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].

2.3 “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.
2.4 "Transporter" – The transporter is the individual, operator or contracted service who obtains the package from the shipper, verifies it has been packaged correctly, and carries the package to the receiver.

2.5 "Receiver" – The receiver, for the purposes of this policy, is the individual who receives the package. This individual is required to have shipping training, and notify the shipper upon receipt of the planned delivery of high risk material.

2.6 "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 BUMC policies including standards for the maintenance of original forms to be maintained by the shipper, the transporter and the receiver.

2.7 "Qualified Vendor" – A vendor who meets or exceeds the criteria in section 4.6.

3.0 Roles and Responsibilities

3.1 Environmental Health and Safety (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 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 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 The Department of Public Safety will, through its Investigations Unit, initiate, conduct and/or participate in audits and conduct investigations as necessary. 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 the transporter is BUMselect agent authorized.
3.5 The Emergency Management Division (EMD) will provide to Environmental Health and Safety, Facilities Management and Planning, the Department of Public Safety and members of the Emergency Response Team recommendations related to emergency management planning, training and response coordination. In addition, the EMD 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 Management, the Massachusetts and Federal Emergency Management Agencies.

3.6 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 policies including those that address the type and frequency of training and necessity of additional training should laws, regulations or BU policies change at any time.

3.7 The Transporter will be required to do the following: to accept, store, load, inspect and deliver packages to an approved location using approved access routes; to report any and all violations of law, regulation or policy; to retain all records; and to 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.

4.0 Procedures

4.1 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 BUMC and are limited to Albany Street, Massachusetts Avenue and the highway/connector system in the rear of BioSquare.

4.2 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 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.
4.3 **EHS and DPS** will ensure that BU staff involved in the high risk materials shipping/receiving areas will undergo a background clearance check, as appropriate, consistent with the Select Agent law requirements prior to being approved to work in these locations.

4.4 **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 will only be altered after obtaining any required approval from all relevant regulatory authorities.

4.5 **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.

4.6 **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:

4.6.1 Past performance on similar contracts.
4.6.2 Ability to provide services as a qualified vendor for transport of all subject materials.
4.6.3 Ability to provide transport services in accordance with all applicable regulatory standards.
4.6.4 Ability to provide transport services in accordance with all applicable BU standards.
4.6.4.1 BU requires that the DOT compliant triple packaging be placed in a non-crushable liquid tight solid container for an added layer of safety.
4.6.4.2 BU requires that packages be secured in the vehicle away from potential impact of outer walls.
4.6.5 Ability to provide staffing that has undergone, and continues to undergo on an annual basis, appropriate background checks.
4.6.6 Ability to provide courier services that may require that a single individual pick up and deliver packages.
4.6.7 Ability to provide real time, GPS tracking of packages or vehicles as determined appropriate and approved by BU.
4.6.8 Ability to provide transport service vehicles that are inspected in accordance with all applicable inspection standards and at least every six months.
4.6.9 Ability 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.

4.6.10 Ability to maintain and to provide an all-inclusive chain of custody document upon delivery of each package.

4.6.11 Ability to provide resources to participate in BU audits of services.

4.6.12 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.

4.7 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. BU 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.

4.7.1 Prior to the transport of a shipment to the NEIDL of a Select Agent, the Emergency Management Division will ensure that the appropriate Commonwealth having jurisdiction and the Boston Public Health Commission are notified.

4.7.1.1 It is the responsibility of the Boston Public Health Commission to notify the appropriate city of Boston departments.

4.8 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.

4.9 Clear Loading Dock: Department of Public Safety 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 availability for 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.

4.10 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 and all applicable regulatory personnel.

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

4.11.1 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. The Director of Emergency Management will notify the all appropriate local response agencies and initiate the BU Emergency Response Plans, the BU Select Agent Incident Response Plan and Incident Command System.

4.11.1 If the incident occurs within the city of Boston, the notification will be made through the 9-1-1 Dispatch Operations Center.

4.11.2 If the incident occurs outside the city of Boston, the notification will be made to the Boston Public Health Commission, who will be responsible for the notifications to all the appropriate city of Boston departments.

4.12 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 immediately of any such event.

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

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

4.12.1.2 If the incident occurs within the city of Boston, the notification will be made through the 9-1-1 Dispatch Operations Center.

4.12.2 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.

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

5.0 Key References and Resources

- U.S. Department of Transportation, 49 CFR Part 171, 10/1/11
- International Air Transport Authority 2006, 55th edition Dangerous Goods Regulations
U.S. Public Health Service (HHS)/ CDC 42 CFR Part 73.0, “Possession, Use & Transfer of Select Agents and Toxins,” 04/03/13
National Institutes of Health Guidelines for Research Involving recombinant DNA Molecules

Websites

BU, Environmental Health and Safety (OEHS)  www.bu.edu/ehs
BUMC Public Safety Department  www.bumc.bu.edu/publicsafety
BUMC, Purchasing  www.bu.edu/purchasing
U.S. Department of Transportation  www.dot.gov
MA Department of Public Health-State Lab Institute  www.state.ma.us/dph/sli/htm
International Air Transport Authority  www.iata.org
The Centers for Disease Control and Prevention  www.cdc.gov
CDC Select Agent Program, Laboratory Registration  www.cdc.gov/od/sap
United States Postal Service  www.usps.gov
Federal Express, Dangerous Goods Program  www.fedex.com
United States Public Health Service  www.usphs.gov
USDA Select Agent Program  http://www.aphis.usda.gov/vs/ncie/bta.html
6.0 Appendices

6.1 Select Agent Transportation Flow Chart

- Shipment Enroute
- Shipment Arrives
- Incident Occurs
- Drivers Respond as per SOP
- Determine Responsible Agency Having Jurisdiction
- Dispatch Notifies Law Enforcement Agency Having Jurisdiction
- Dispatch Notifies Appropriate HazMat Contractor
- Dispatch Notifies BUMC
- BUMC notifies Boston Police and Public Health Commission
- Implement ICS
- Secure Material and Site
- Decision Made on Disposition