

## Appendix 7

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# HIGH HAZARD MATERIAL MANAGEMENT (HHMM) POLICY

## High Hazard Material Management Policy

### 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 the Office of Environmental Health and Safety in accordance with Boston University Medical Center (BUMC) 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 BUMC facilities and those who are contracted services involved in the shipping, receiving, handling or other use of high hazard 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 high risk 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 high hazard materials transport.

### 2.0 Definitions

- 2.1 **“High Hazard Materials”** - are 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 BUMC OEHS 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 high hazard 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.

- 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 hazard material.
- 2.6 **“Shippers Declaration Form”**- the documentation that a high hazard 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.

### 3.0 Roles and Responsibilities

- 3.1 **The Office of Environmental Health and Safety (OEHS)** is responsible for the management and oversight of the High Hazard Materials Management program and for ensuring compliance with the procedures outlined within this policy by all employees and staff, visiting users of BUMC facilities and contracted services including associated transporters.
- 3.2 **The Office of General Services (OGS)**, through its Security Investigations Unit, will initiate, conduct and/or participate in audits and conduct investigations as necessary. OGS, 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.
- 3.3 **The Office of Mail Services** will provide support to OEHS and OGS with the screening/examination of delivered packages, with the staffing of designated locations, and with the management of contracted services.
- 3.4 **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 who are involved in the management and transport of materials determined to be high risk.
- 3.5 **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 BUMC policies including that addresses the type and frequency of training and necessity of additional training should laws, regulations or BUMC policies change at any time.

- 3.6 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 high hazard material transport.

#### 4.0 Procedures

- 4.1 OEHS and OGS** 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 OEHS 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. (see attached map).
- 4.2 OEHS** will train all users of the laws, regulations, polices and requirements involved in the shipping and receiving of materials determined to be high risk and will manage the tightly controlled, pre-approved, scheduling of shipment and delivery times. OEHS will train all 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 OEHS and OGS** will ensure that all 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 Packaging standards** will be determined by the appropriate regulatory authorities with all specified package integrity testing complete. These mandated packaging requirements will only be altered in the event that BUMC determines a need to exceed the standard and will only be altered with the approval of all relevant regulatory authorities.

- 4.5 Transport of Select Agents** will be done in accordance with all laws and regulations including the immediate notification of the U.S. Department of Health and Human Services, Center for Disease Control and Prevention, prior to being sent, and 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 OEHS, OGS and the Office of Purchasing** will select contractors for the transportation of high risk 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 single source provider for transport of all materials determined to be high risk.
  - 4.6.3** Ability to provide transport services in accordance with all regulatory standards.
  - 4.6.4** Ability to provide transport services in accordance with all BUMC standards.
  - 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 GPS tracking of packages or vehicles as determined appropriate.
  - 4.6.8** Ability to provide customized services that require adherence to BUMC determined routes of travel, audit procedures and strictly defined schedules for both pick-ups and deliveries.
  - 4.6.9** Ability to provide an all-inclusive chain of custody document upon delivery of each package.
  - 4.6.10** Ability to provide resources to participate in BUMC audits of services.
- 4.7 OEHS** 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.
- 4.8 Failure to receive** package within the specified time range of delivery will result in an immediate investigation involving the transport contractor, the shipper, BUMC and all applicable regulatory personnel.

- 4.9** Packages delivered to BUMC will be inspected, verified, documented and transported to the appropriate location within BUMC by OEHS.

**5.0 Key References and Resources**

U.S. Department of Transportation, 49 CFR Part 171 final rule, 09/14/02  
International Air Transport Authority 2004, 45<sup>th</sup> edition Dangerous Goods Regulations  
U.S. Public Health Service (HHS)/ CDC 42 CFR Part 73.0, "Possession, Use & Transfer of Select Agents and Toxins," 12/13/02  
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

**Websites**

BUMC, Office of Environmental Health and Safety (OEHS) [www.bumc.bu.edu/ehs](http://www.bumc.bu.edu/ehs)  
BUMC, Office of General Services [www.bumc.bu.edu/gs](http://www.bumc.bu.edu/gs)  
BUMC, Mail Services [www.bu.edu](http://www.bu.edu)  
BUMC, Purchasing [www.bumc.bu.edu](http://www.bumc.bu.edu)  
U.S. Department of Transportation [www.dot.gov](http://www.dot.gov)  
MA Department of Public Health-State Lab Institute [www.state.ma.us/dph/sli/htm](http://www.state.ma.us/dph/sli/htm)  
International Air Transport Authority [www.iata.org](http://www.iata.org)  
United Parcel Service, Hazardous Materials Support Center [www.ups.com](http://www.ups.com)  
The Centers for Disease Control and Prevention [www.cdc.gov](http://www.cdc.gov)  
CDC Select Agent Program, Laboratory Registration [www.cdc.gov/od/sap](http://www.cdc.gov/od/sap)  
United States Postal Service [www.usps.gov](http://www.usps.gov)  
Federal Express, Dangerous Goods Program [www.fedex.com](http://www.fedex.com)  
United States Public Health Service [www.usphs.gov](http://www.usphs.gov)  
USDA Select Agent Program <http://www.aphis.usda.gov/vs/ncie/bta.html>

