



Packaging and Shipping Exempt Human Specimens for Research

Institutional Policy

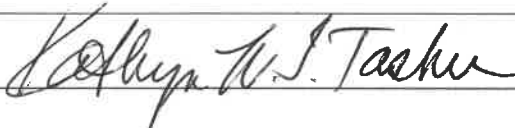
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1 Purpose

The packing and shipping of biological specimens are subject to state, federal and international regulations. The intent of this policy is to identify the requirements of the HSL workforce for the shipment of Exempt Human Specimens for research, currently the only type of research specimens allowed for shipment to external (non-HSL) laboratories. There are numerous regulations that cover material that is transported through the “public domain” which includes roadways, airways, and sea lanes accessible to the public. The purpose of the regulations, and this policy, is to prevent accidental exposure to personnel who may handle the material during its shipment.

2 Scope

The policy applies to HSL workforce members who package, label, ship, prepare shipping documents, or offer packages of Exempt Human Specimens for research to carriers for shipment to external laboratories. At this time, only specific laboratory personnel at the Roslindale Campus are trained, and permitted, to package, label, ship, and prepare shipping documents, transport, or



offer packages of Exempt Human Specimens for research to carriers described in this policy document.

3 Definitions

Term: Biological Substance, Category A

An infectious substance which in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. The proper shipping names for these substances are: UN2814 (infectious substances, affecting humans) and UN2900 (infectious substances, affecting animals).

Term: Biological Substance, Category B

An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in category B must be assigned to UN 3373. DOT Hazardous Materials Division 6.2 materials can include:

- Biological products
- Cultures and stocks
- Diagnostic specimens
- Material of trade
- Regulated medical waste
- Sharps
- Toxin
- Used health care product

Term: Exempt Human or Animal Specimens

A human or animal sample (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) transported for routine testing not related to the diagnosis of an infectious disease. Typically, exempt human specimens are specimens for which there is a low probability that the sample is infectious, such as specimens for drug or alcohol testing; cholesterol testing; blood glucose level testing; prostate-specific antigens (PSA) testing; testing to monitor heart, kidney, or liver function; pregnancy testing; and testing for diagnosis of noninfectious diseases such as cancer biopsies. Exempt human or animal specimens are not subject to regulation as hazardous materials but must be packaged according to US Department of Transportation (DOT) and the International Air Transport Association (IATA) regulations.

Term: Hazardous Material



A hazardous material is defined as any substance or material could adversely affect the safety of the public, handlers or carriers during transportation. All DOT hazardous materials are listed in the [DOT's Hazardous Materials Table](#).

4 Policy Statement

All shipments of biological specimens, including Exempt Human Specimens, hazardous materials or dangerous goods are regulated by the U. S. Department of Transportation (DOT) and the International Air Transport Association (IATA). HSL workforce members who package, label, ship, prepare shipping documents, or offer packages of Exempt Human Specimens to carriers for shipment are required to complete appropriate training and comply with all federal, international and local regulations and HSL policies. At this time, HSL will ship only Exempt Human Specimens for research and will not receive any specimens (exempt or non-exempt) from external laboratories.

5 Procedures

The following procedures should be followed when HSL workforce members are responsible for packaging, labeling and shipping Exempt Human Specimens for research to an external laboratory for analysis:

Packaging

All biological samples must be packed according to DOT and IATA regulations; this includes triple-packaging all samples, even if Exempt materials:

Primary Receptacle

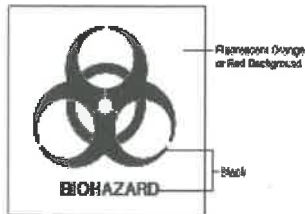
- Material must be triple-packaged in leak-proof (for liquids) or sift proof (for solids) primary receptacles.
- A single primary receptacle must not contain more than 500 ml of a liquid specimen or 500 grams of a solid specimen.
- Two or more primary receptacles whose combined volume does not exceed 500 ml (for liquids) or 500 grams (for solids) may be enclosed in a single secondary container.
- Sufficient cushioning and absorbent materials must surround each primary receptacle containing liquid.

Secondary Container

- The secondary container cannot serve as the outer shipping container.
- The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. The outer shipping container must be rigid.



- The secondary container must be marked with the international biohazard symbol shown below.



Outer Shipping Container

- The outer shipping container must be marked on the address side with the words “Exempt Human Specimen”. In addition, at least one surface of the outer packaging must have a minimum dimension of 3.9 inches by 3.9 inches (100 mm by 100 mm).

Pre-Transportation Labeling and Cooling

- Label information must include the category of the biological material or agent, (i.e. Exempt Human Specimen), and the sending and receiving laboratory identification.
- Each individual container must have enough label information to identify its contents. In addition, a sheet containing a description of contents should be placed inside the container between the outer and secondary packaging.
- Any dry ice or other coolant can now be added between the secondary and outer packaging layers. This coolant material should be placed in a shipping box that contains a Styrofoam liner or other appropriate material to ensure that the outer box is not damaged by moisture from cold packs or other coolants.
- All required DOT/IATA labeling and marking information should be on the outside of the package.

Transportation

- The HSL shuttle system, MBTA, taxi cabs/Ubbers, ZipCars, or other payment for transport methods must not be used for transportation of infectious agents or other biohazardous materials.
- If the package contains Exempt Human Specimens, or materials that fall under the “Category B Infectious Substances” category, the package may be moved over U.S. roadways by a member of the laboratory.
 - This exclusion, called “Materials of Trade (MOT)” by the DOT allows some materials that are Exempt or Category B Infectious materials to be transported by a research or clinical laboratory personnel.
 - Courier services fall under the “Exclusive Use” Exemption under DOT.



- This exclusion does not apply to Category A infectious substances or other categories of Dangerous Goods.
- This individual must have undergone shipping training in the last two years.
- This package must follow all requirements as described above.
- Contact the [Manager of HSL Laboratory Services](#), for further information and questions about these DOT exemptions.
- The container should be shipped directly to the intended laboratory and not taken to offices, cafeterias, or other public or inappropriate locations.
- Upon delivery, the receiving laboratory personnel should be informed and the material properly stored. The package should be carefully inspected for signs of leakage or other contamination and, if necessary, decontaminated before opening.

Classification and Identification

If shipping an exempt patient specimen, the only marking required is:

- Exempt Human Specimen

Training Requirements

HSL workforce members involved in the packaging and shipping of biological specimens must undergo training every two years or when regulations change. DOT and IATA regulations require that any person involved in the shipment of dangerous goods receive periodic and function-specific training. HSL uses the Collaborative Institutional Training Initiative (CITI) program for its training certifications to meet DOT and IATA requirements.

Additional Considerations

- **Informed Consent:** Prior to any agreement to ship biological specimens to external laboratories, HSL workforce members should confirm with the HSL Investigator that informed consent has been obtained (or a waiver of informed consent, or element of consent) from the persons who provided the specimens. In general, when specimens are obtained for research purposes, whether or not the specimen will be shipped for analysis at an external laboratory, informed consent would have been obtained prior to the initiation of any research procedures.
- **Material Transfer Agreement:** Ordinarily, biological specimens that have been obtained as part of a research project do not require Material Transfer Agreements (MTAs) when those specimens are being shipped to an external laboratory for analysis as described in the research protocol. MTAs may be required, however, when research specimens and their associated data may be obtained and used by others for secondary research (i.e. not the research for which the specimens were originally collected). Informed Consent (or a waiver of informed consent or elements of consent) ordinarily would have been obtained from the persons who provided the specimens for initial and any secondary research uses. MTAs are legal contracts that set terms

and uses for materials and associated data to be used by other institutions. These agreements are intended to protect the proprietary interest of the HSL Investigator and the institution, as well as to share research materials and data with the broader research community. All MTAs are negotiated by the HSL Legal and Compliance Office.

6 Reference Materials

- US DOT Hazardous Materials Regulations [Title 49 Subtitle B Chapter I Subchapter C Part 171](#)
- IATA Dangerous Good Regulations 3.6.2, [Division 6.2 Infectious Substances](#), [Packing Instruction 650](#),
- [Regulations for UN3733](#), UN3733 Packaging Requirements for Biological and Infectious Substances – [General Guide](#) , [Flowchart for the classification of infectious substances and patient specimens](#), [Packaging UN3733](#)
- [USPS Packaging Instruction 6H](#)
- Boston University, [Chapter 11: Transportation of Biological Materials](#)
- Harvard University, EHS, [Shipping and Transporting Research Materials](#)

7 Document Properties

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