UNIVERSITY OF TOLEDO

SUBJECT: SHIPPING, PACKAGING AND RECEIPT OF HAZARDOUS MATERIALS

Procedure No: HM-08-031

PROCEDURE

Employees of the University of Toledo transporting hazardous materials, commercially or non-commercially, on or off the grounds of the institution, shall conform to the following guidelines.

PURPOSE OF PROCEDURE

To provide general guidelines for transportation of hazardous materials and dangerous goods on or off the grounds of the University of Toledo by employees in accordance with all applicable local, state and federal regulations.

PROCEDURE

A. DEFINITION OF HAZARDOUS MATERIAL

Hazardous material is generally defined as any substance that could adversely affect the safety of the public, and handlers or carriers during transport. There are nine classes of hazardous materials. Hazardous material, as defined by the Department of Transportation (DOT), is any substance that meets the definition of any of the nine hazard classes listed below.

- 1. Explosives
- 2. Gases
- 3. Flammable liquids
- 4. Flammable solids
- 5. Oxidizing substances and organic peroxides
- 6. Toxic and infectious substances
- 7. Radioactive material
- 8. Corrosives
- 9. Miscellaneous dangerous goods

Hazardous material regulations may apply to commercial products, chemical mixtures, and newly synthesized compounds. Various types of batteries, fuel containers and cleaning products are examples of materials that are regulated for shipment.

B. SCOPE OF REGULATIONS

Shipments of hazardous materials must comply with regulations any time they are transported by ground, air, or water. Shipments by ground are regulated when they are considered to be "in commerce". Material carried by any commercial transport company such as FedEx or by U.S. Mail is considered to be "in commerce". However, hazardous material transported in a *university vehicle* for use in a *university project* is not considered to be "in commerce". However, hazardous material is required to meet DOT packaging requirements. Environmental Health and Radiation Safety (EHRS) will provide guidance on how to package hazardous material transported by university vehicles. Contact EHRS whenever you wish to transport hazardous material.

If you are shipping a hazardous material that is a commercially available product, it is more cost-effective in many cases to purchase the material at the location to which you wish to ship it. For example, if you are planning field work which requires the use of hazardous chemicals, you may find it easiest to have a vendor ship the chemicals directly to (or near) the location where you will be working.

Certain hazardous materials are exempt from shipping regulations when shipped in small quantities. These exempted quantity limits vary by material. EHRS will determine the regulatory status of the material, including any possible exceptions, based on information submitted in the Intent form.

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Due to the complicated nature of hazardous material shipments, you must contact EHRS with your intentions to ship information at least two weeks prior to your expected shipping date. EHRS will determine what regulations, if any, apply to your shipment and notify you of what shipping materials you will need to ship your material. Your department will be responsible for providing all packaging materials required for your shipment.

D. TRANSPORT OF HAZARDOUS CHEMICALS

- 1. A bill of lading with a complete inventory of hazardous chemicals being transported must be attached to the shipping container.
- 2. Items should be shipped in original container or other leak-proof container.
- 3. Liquids should be packaged in a suitable absorbent capable of handling the entire volume of liquid being shipped.
- 4. The items should be separated as to hazard class (i.e., flammables separate from corrosives, etc.).
- 5. These separate groups should then be labeled with an appropriate Department of Transportation (DOT) label (i.e., Flammable or Corrosive diamond shaped label).
- 6. The Environmental Health and Radiation Safety offices of both sending and receiving institutions must be contacted prior to shipment.
- 7. It is highly recommended that both a spill kit and fire extinguisher be accessible to trained individuals involved in the transport.
- 8. If a researcher or University staffer is transporting hazardous chemicals in their private vehicle they need to consult with EHRS to ensure safe and legal transport of hazardous chemicals by such means.

E. TRANSPORT OF RADIOACTIVE MATERIALS

- 1. DOT regulations for the transportation of Radioactive Materials must be followed at all times.
- 2. All radioactive materials must meet Ohio Department of Health license requirements prior to arriving on campus.
- 3. The Radiation Safety Offices of both sending and receiving institutions must be contacted prior to shipment.

F. TRANSPORT OF BIOLOGICAL AND INFECTIOUS SUBSTANCES

There are very specific regulations that apply to the transport of infectious substances and related biological materials. This section is intended to meet the requirements for shipping of biologicals to ensure the protection of the public, wildlife, and environment through the proper packaging of these materials; and to comply with regulations from the Department of Transportation (DOT), the International Air Transport Association (IATA), the Federal Aviation Administration (FAA) and others.

Unlike some of the general laboratory safety guidelines, very rigid laws govern the transport of infectious substances and related materials. Those found in violation of these legal requirements may face criminal and civil liability which may include fines and imprisonment. The bulk of the shipping responsibility rests with the shipper. The shipper is responsible for classifying the material that will be shipped and identifying which regulations apply. The shipper must also ensure that the proper permits have been obtained, and the shipment is packaged, labeled, and shipped in compliance with all applicable regulations. Those transporting and receiving infectious substances should also be familiar with the shipping responsibilities so they can verify compliance with the process. The shipper ultimately has to sign the shipping documents and thus becomes legally responsible for the contents during the transfer of the material. The employer bears the responsibility to ensure employees comply with the applicable regulations. A separate training is available for shippers of infectious or biological substances within UT's Online Training.

If you have any questions regarding the shipping regulations or need assistance in a matter pertaining to the shipment of infectious substances and other potentially hazardous biological materials, please contact EHRS for assistance at 419-530-3600.

G. REGULATIONS FOR THE TRANSPORT OF SELECT AGENTS AND TOXINS

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Existing transport regulations from the CDC, USDA, APHIS, DOT, FAA and IATA govern the shipment and transfer of substances or goods which represent a threat to humans, animals, plants, or the environment. They also regulate the transport of these materials on public roadways and by air carriage. Similar regulations apply to transport by rail or sea.

Regarding the shipment and receipt of Select Agents and Toxins as defined by the CDC and USDA please refer to EHRS Procedure HM-08-030. Shipments of this nature can only be initiated by the Environmental Health and Radiation Safety (EHRS)Department and the Responsible Official and not covered specifically by this policy.

Key features of these regulations include:

1. Classification

Category "A" Substances are infectious substances which are transported in a form that, when exposure to them occurs, are capable of causing permanent disability, life-threatening or fatal disease to humans or animals. These substances are specifically designated pathogens which can be dangerous to individual's health and the public's health.

Category "B" Substances are infectious substances which do not meet the criteria for inclusion in Category A. Category "B" includes those that are regarded as diagnostic or clinical specimens that are shipped/transported for diagnostic or other patient care purposes, and microorganisms NOT on the Category "A" list.

Note that some organisms are listed in both categories, depending on the form in which they are shipped, i.e., in patient specimens (clinical materials) or cultures – where the number of organisms present may be considerably greater than in clinical material. Plant pathogens are also a concern and will be dealt with on a case-by-case basis. (Contact Environmental Health and Radiation Safety (EHRS), 419-530-3600 MC)

The OSHA term "potentially infectious" does not apply to shipping regulations. A substance is either an infectious substance, a clinical or diagnostic specimen, or a biological product. United Nations (UN) approved packaging and the infectious substance label must be used for all shipments of infectious substances or select agents.

Diagnostic specimens, clinical samples, and biologic products don't require the performance tested packaging, but must be shipped in a leak proof manner. The biohazard symbol must accompany any shipments of human blood, body fluids, tissues or cell lines inside of package.

PLEASE NOTE: Diagnostic specimens and infectious substances cannot be consolidated into one shipping package. They must be shipped separately.

2. Packaging and Labeling (UN certified shipping containers)

Packing requirements for DOT, CDC, FAA and IATA are very specific and are described in detail in the online formal shipping class. A brief handout that combines the requirements of these 3 regulations is available from EHRS. Also, please realize that all of the labeling requirements for infectious substances also must include other dangerous goods (such as dry ice and nitrogen) if utilized in the packaging of biologicals.

3. Permit or Authorization

Shipment or transport of infectious agents may require a permit from the U.S. Public Health Service, Department of Commerce, the United State Department of Agriculture, or the U.S. Animal Plant Health Inspection Service. The shipper is responsible for obtaining authorization, the required permits, and for ensuring that the material is packaged in compliance with applicable regulations. Copies of permit applications for the CDC and the USDA are available online. Please contact EHRS at 419-530-3600 if you have any questions regarding the permit process. All final copies of these permits must be retained by EHRS.

To obtain a permit for the transport of human pathogens, contact the Centers for Disease Control

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Phone: (404) 498-2243, FAX: (404) 498-2275. Please contact EHRS and the Office of Research and Sponsored Programs as necessary to obtain material transfer agreements and IBC Committee approval for certain agents.

USDA PERMITS

Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animalsource materials. Materials which require a permit include animal tissues, blood, cells, cell lines, RNA/DNA extracts, hormones, enzymes, monoclonal and polyclonal antibodies, antisera, immunoassay components/kits, transgenic mice, and microorganisms including bacteria, viruses, protozoa and fungi.

Exceptions to this requirement are human and non-human primate tissues, serum, and blood. However, if the human or non-human primate materials are cell culture derived or that have been exposed to animal serum, a USDA permit is required.

Import permit applications and other import information can be obtained through the <u>Animal and Plant</u> <u>Health Inspection Service</u> web page

4. Transport

Transport and shipping via Public Roadways or Air Transport of potentially hazardous biological material on public roadways is regulated by the U.S. Department of Transportation and the U.S. Public Health Service. The International Air Transport Association (IATA) regulates the transport of these agents by air. Agents infectious to humans or animals may not be hand-carried by a passenger or transported within the passenger section of the aircraft. Appropriately packaged shipments must be declared with the airline upon checking in and accompanied by the applicable permits and shipping declaration forms. Please register any new infectious agents received by your laboratory for compliance with specific EHRS Procedures and the Institutional Biosafety Committee (IBC).

On Campus Transport (between labs or buildings) must have two leak proof containers.

- Sealed primary container
- Sealed secondary container
- Absorbent (paper towels) between the primary and secondary containers suitable for volume transported
- Biohazard sticker with agent name, lab address and phone number
- Utilize plastic containers whenever feasible.
- Sealed plastic (not glass) primary vials can be transported within sealed labeled plastic bags.
- Place glass primary containers within a sealed rigid plastic container with absorbent and padding to cushion the vial during transport.
- Transport of biological agents and infectious substances must be done in a vehicle designated for this purpose. This is considered a "dedicated" vehicle.
- 5. Receipt and Storage
 - a. The researcher (PI) will be notified in advance of shipments. A request will be made to the sender to provide prior notice of shipment date and expected receipt.
 - b. Senders will be directed to ship directly to researcher (PI) in their laboratory.
 - c. Upon arrival of a shipment, the researcher (PI) will inspect all packages and sign for the shipment from the carrier. A copy of the shipment receipt will be maintained by the researcher (PI).
 - d. The researcher (PI) will remove the outer shipping container (cardboard box) in the open area of their lab. The inner shipping container will be taken into a biological safety cabinet.
 - e. The researcher (PI) will open the inner container for inspection. The researcher (PI) will confirm by inspection that the shipped materials are received in good condition with no breakage or spills.
 - f. All biologic materials including attenuated strains, genetic materials, plasmids and other materials sent or received from other institutions must meet the following criteria:
 - The sending institution must provide written assurances to the receiving institution that the material being sent is indeed that material and is not contaminated with any other biological or hazard that may present a risk to the receiving institution. These assurances may be made through documented

culturing activities and identification techniques that can provide proof of the exact content of the materials being transferred (i.e., PCR, etc.).

- Likewise the receiving facility is required to perform similar testing to provide confirmation that the materials received from the sender are as described on shipping documents.
- These procedures will prevent the inadvertent sending and receipt of potentially contaminated materials or the movement of materials that are not labeled properly as to their content.
- g. Materials in good condition, and the contents assured as described above, will be forwarded to the designated storage area (freezer, refrigerator). Storage areas should be labeled appropriately, warning employees of the risk group and possible hazard.
- h. In the event there was breakage/spillage of any containers in shipment the researcher (PI) will close the container and seal it. The departmental procedures for a biohazardous spill will be implemented. The sender will be consulted about the breakage and best way to manage the residual materials. The Environmental Health and Radiation Safety (EHRS)Department will be notified at 419-530-3600.
- i. All contaminated materials used in clean-up will be placed in biohazard bags for disposal.

H. TRANSFER AND RECEIPT OF SELECT AGENTS AND TOXINS

Extramural transfers of Select Agents and Toxins may not occur without prior authorization of the Responsible Official (RO) at the facilities of the transferor and recipient. This is accomplished by contacting EHRS and requesting that the RO complete Form 2 as required by the CDC. The University RO will request that the PI provide contact information regarding the individual/site requesting a Select Agent or Toxin, transfer or receipt in order to expedite the process.

Intramural transfer of the Select Agents or Toxins must be approved by the RO before the transfer occurs.

The process for Extramural receipt of a Select Agent or Toxin from an outside entity will adhere to the following steps:

- 1. The RO and the laboratory director/manager will have received prior notification of a pending shipment of a Select Agent or Toxin as the RO will have received a specialized form from the registered shipping facility.
- 2. The RO will contact the laboratory director/manager and confirm the date of shipment and arrival with the registered shipping facility.
- 3. The RO will contact the Shipping and Receiving Department on the day of the shipment and again the next day to notify the Receiving Department that a dangerous goods shipment of a biologic agent will be arriving via a carrier service on a predetermined date.
- 4. The RO will request that they, or another designated approved individual, be stationed at the receiving dock, or be notified immediately when the carrier service arrives, and sign for the shipment.
- 5. The RO or designee will proceed to the dock immediately to receive the Select Agent or Toxin from the carrier service driver and take it from there directly to the BSL3 facility where it will be secured.
- 6. All paperwork associated with the shipment will be collected and maintained by the RO.
- I. TRAINING

Individuals must be certified and trained on packaging and shipping regulations for the IATA, FAA and DOT. Training is required prior to shipping infectious substances and every 2 years thereafter. Both general awareness and performance specific training must be provided. Those involved in the shipping process must receive training in their specific application (classification, packaging, labeling, documentation, transport, handling, or receipt). Contact EHRS 419-530-3600 for information on taking the shipping class.

J. ADDITIONAL INFORMATION

Contact Environmental Health and Radiation Safety (EHRS) Department at 419-530-3600 for questions relating to chemical and biological agents or 419-383-4301 for questions relating to radioactive materials.

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