



Procedure Number: 400.17
Subject: Guide to Shipping Biological Materials
Reference: DOT and IATA Regulations
Distribution: Personnel who prepares biological materials for shipment
Implementation Date: May 2009
Review Date: TBD

Purpose	The purpose of this biological materials management plan is to establish guidelines to be followed when shipping biological materials from East Tennessee State University in compliance with US Department of Transportation and the International Air Transporters Association.
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Overview

East Tennessee State University is involved in the shipment and receipt of hazardous materials on a regular basis. U.S. Department of Transportation (DOT) regulates shipping and receiving of biologics as Dangerous Goods. The International Air Transport Association (IATA) also regulates these shipments if they are transported by air. Anyone who prepares a hazardous material for shipment must be trained to know exactly how to classify, contain, pack, label, and manifest the material according to DOT/IATA requirements for safety. Compliance with these training and packing requirements will prevent accidental release of hazardous materials.

Scope

This Guideline applies to any employee who prepares biological materials for shipment or is responsible for receiving shipments of potentially bio-hazardous materials.

Definitions

Biologics – biologics include biological substances, infectious agents, patient specimens, genetically modified organisms and other biological materials.

Category A - An infectious substance which is transported 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. Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned UN 2814. Infectious substances which cause disease only in animals must be assigned UN 2900.

Category B - An infectious substance which does not meet the criteria for inclusion in Category A. Category B infectious substances are shipped with the proper shipping name “Biological Substance, Category B” and assigned to UN 3373.

Certification - Occupational Safety and Environmental Health Department (OSEH) is the authorized agency for hazmat shipping instruction and certification of training for hazmat employees on campus. OSEH provides this function, required of the Hazmat Employer. The necessary training can also be acquired through outside courses given by certified organizations.

Culture – are the result of a process by which pathogens are intentionally propagated. This definition **does not include human (i.e., throat swabs) intended for diagnostic purposes.**

Exposure - An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

Hazmats – short for “hazardous materials” as defined in the DOT regulations. These include infectious substances and biological substances. Hazardous chemicals or materials are not specifically covered in this guideline.

Hazmat Employee – an employee who transports a hazmat, prepares hazmat for shipment, or is responsible for receiving hazmat shipments. These employees have specific responsibilities for knowledge of the DOT regulations and performance of shipping systems for various hazmat materials.

Patient Samples - are human or animal materials, collected directly from humans or animals, including, but not limited to , excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Risk Group – means a ranking of a microorganism’s ability to cause injury through disease. A risk group is defined by criteria developed by the World Health Organization (WHO) that are based on the severity of the disease, the mode and ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of preventative agents and treatment. Risk groups may assist you in determining if a material you intend to ship contains a pathogen. Materials that contain pathogens must be shipped as infectious substances (Category A or B). Risk group 2 and 3 materials would qualify as infectious substances and are subject to these regulations.

Risk Group 2 – A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and , while capable of causing serious infection on exposure, for which there are effective treatments and preventative measures available and the risk of spread of infection is limited.

Risk Group 3 – A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.

Shipper's Declaration of Dangerous Goods – The shipper is responsible for the completion of a prescribed declaration form for each and every shipment containing dangerous goods. The form is a legal document. Only the shipper may complete and sign the Shipper's Declaration. The diagonal hatchings printed vertically in the margins must be printed in red. Non-infectious shipments or biological substances do not require a Shipper's Declaration. Category A infectious substances and Genetically Modified Organisms do require completion of a Dangerous Goods Declaration.

Training - Adequate training of a hazmat employee involves a systematic program of instruction, testing, and documentation that ensures they have knowledge of the hazardous materials for which they are responsible, and can perform their assigned shipping tasks in compliance with safety regulations.

Training Records - Written records of hazmat employee training must be prepared and retained by the employer. These records must include the employee's name, completion date, description of training materials, name of the trainer, and certification that the employee has been trained and performance tested for their specific functions.

Classification of Biological Materials

1. Infectious Substances
 - Category A Infectious Substances
 - Category B Infectious Substances
2. Diagnostic Specimens
3. Biological Products
4. Genetically Modified Organisms and Microorganisms
5. Unregulated Biological Materials

Infectious Substances

Infectious substances are known to be or reasonably expected to contain a pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion), or recombinant microorganism (hybrid or mutant), that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

Risk groups are no longer required in the DOT/IATA regulations; however, they may be used to assist you in determining if the material you intend to ship meets the definition of a pathogen. Risk groups classifications may be accessed at the American Biological Safety Association's website <http://www.absa.org/restriskgroup.html>

1. Category A Infectious Substances

An infectious substance which is transported 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. Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned UN 2814. Infectious substances which cause disease only in animals must be assigned UN 2900. Indicative examples of substances that meet these criteria are given in [Appendix A](#). Category A infectious substances will follow Packing Instruction 602 and continue to be packed in certified packaging systems.

***Note** - An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

Documentation

Shipping Papers - in order for a hazardous material to be shipped, it must be properly and accurately described on the shipping papers "Shipper's Declaration of Dangerous Goods." Anyone who handles or transports the hazardous material must be able to read and understand the information found on all forms of documentation.

The shipping papers must carry a full and accurate description of the hazardous material, from Shipping Name above. The trained shipper must certify by signature that all the information provided on the papers is accurate (See [Appendix B-Sample of Dangerous Goods Declaration](#).)

NOTE: Federal Express Shipping Papers must be typed.

NOTE: Shipper (laboratory) must record the date an item was accepted by the carrier and retain their copy of the paperwork for 2 years. It is recommended that a permanent file be established for this document retention (copy of the "customer copy" of the shipping papers). The Primary Investigator and Lab Manger must be aware of its location.

Dangerous Goods Declaration - Identification of Hazard Class, Shipping Name, and Packing Group for Category A Infectious Substances

Hazard Class - a category of hazard assigned to a hazardous material under criteria in 49 CFR 173 (DOT) and the provisions of the Hazmat Table.

Shipping Name - a specific uniform system for describing a hazardous material. This description must include a generic description from the Hazmat Table and technical name in brackets. In the case of a Category A Infectious Substance you would enter for example: **Infectious substances, affecting humans (Hepatitis B virus cultures)**.

Class or Division - The hazard class is **6.2** for infectious substances.

UN Number - The United Nations Specification ID number for the proper shipping name, preceded by the letters UN ex. "UN**2814** for Category A, Infectious Substances, affecting

humans. **UN2900** for Category A, Infectious Substances affecting animals. All this information must appear on the shipper's declaration of dangerous goods.

Packing Group - a grouping according to the degree of danger presented by a hazardous material. I - great danger, II - medium danger, III - minor danger. **This does not apply to infectious substances.** It would apply to dry ice, which has a packing group of III.

Quantity and type of packaging – The number of packages, type of material of the outer packaging, and the net quantity in each package must also be included on the shipper's declaration. For example: (1) 30 ml plate packed in one fiberboard box.

Packing Instruction – Minimum packaging requirements that may include receptacles and other components or materials necessary to perform its containment function. For example: Packing Instruction 602 must be followed for shipping Infectious Substances, Category A.

Additional Handling Information – This is the location where any required notices must be placed. For example:

- Emergency telephone number – The shipper's declaration requires that you give a 24-hour emergency phone number of a person knowledgeable of the hazardous material being shipped or has immediate access to a person who possesses such knowledge. There are very strict requirements for this phone number. Pager numbers are not acceptable. Cell phone numbers are acceptable but must remain on until the shipment is received. See [Appendix C for a Summary of Shipping Requirements for Biological Materials](#).

Packing and Marking

See [Appendix D](#) for Packing Instruction 602 and labeling requirements.

Proper Packing - Part 173.196 "Authorized packagings and components for Infectious Substances." This describes specifications for the primary receptacle, absorbent material, secondary packaging, and outer packaging. Packaging systems must meet UN specifications. Commercial products are available to meet these requirements. (See [Appendix E – Shipping System](#)). Such systems come with complete and accurate markings. They also come with instructions, including all labels and shipping papers necessary for safe and successful shipment.

Labeling

Hazard Label - Labels required for the outer package include address label, the shipper's address and information label, the hazard specific labeling. Also required are: labels for dry ice (if applicable), package orientation, and the appropriate permit label (if applicable). The Shipper's Declaration of Dangerous Goods must be fixed to the outside of the outer packaging.

NOTE: The size of the outer box must be able to accommodate the shipper's declaration without being folded.

2. Category B Infectious Substances

Category B Infectious Substance are materials that are infectious, however, they do not meet the criteria for inclusion in Category A. Category B infectious substances are shipped with the proper shipping name “Biological Substance, Category B” and assigned to UN 3373. Category B, Infectious Substances will follow Packing Instruction 650. See [Appendix F](#). A Dangerous Goods Declaration is not required for shipment of Category B, Infectious Substances.

Please refer to the [Appendix G](#) – Classification Guide for Infectious Substances and Biological Substances for further assistance in classifying your material.

Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are organisms and microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs or GMMOs that are not infectious but can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and assigned to UN 3245. A Dangerous Goods Declaration is required for shipment of GMOs or GMMOs * **Note** - GMOs and GMMOs that are infectious must be assigned to UN 2814, UN 2900 or UN 3373.

a. Packaging and Labeling

These materials are packed for shipment in the same way as Category A infectious substances, except there is no requirement for use of a certified packaging system. You may continue to use packages compliant with Packing Instruction 602. The outer container of a GMO or GMMO assigned to UN 3245 must display the following information:

- The sender and recipient’s name and address
- Class 9 label
- Genetically modified micro-organisms, UN 3245, and the net quantity

See [Appendix H – Packaging Instructions for GMO](#)

Receipt of Materials

Shipments of biologics must be received (generally) by those to whom it is addressed (see exceptions below). This is most easily accomplished via a certified carrier such as Federal Express.

Hazmat Employees should receive biologics in a designated and secure area of the laboratory. This person should have at-hand and utilize all appropriate personal protective equipment and containment devices (biological safety cabinet or chemical fume hood). Before accepting, the parcel should be carefully inspected for leakage indicated by broken or improperly sealed containers.

If the package is rejected (not accepted) due to leakage or other damage, the carrier will work with the shipper to resolve the problem. If the shipment is critical and must be

accepted, EH&S should be contacted at 9-6028, and further activities should be conducted with care in a containment device. All contaminated materials should be collected for proper disposal through consultation with EH&S.

Shipping with Dry Ice

The shipment of samples packed with dry ice is regulated by the US DOT and IATA when offered for shipment by air. Employees must review and sign the EH&S Guidance Document for Shipping Materials with Dry Ice. Signed sheets should be faxed back to EH&S office at 439-6030.

[Appendix I – OSEH Guidance Document for Shipping Materials with Dry Ice](#)

The following are not subject to IATA or DOT shipping regulations:

- **Materials that do not contain pathogens or only contains inactivated or neutralized pathogens**
- **Environmental samples that do not pose a significant threat of infection (i.e., food, water soil or dust samples)**
- **Dried blood spots, or fecal occult screening tests**
- **Blood or blood components collected for the purpose of transfusion**
- **Tissue or organs used for transplantation**
- **Patient Specimens**

ATTACHMENTS:

[Appendix A – Indicative Examples of Category A Infectious Substances](#)

[Appendix B – Sample of Dangerous Goods Declaration](#)

[Appendix C – Summary of Shipping Requirements for Biological Materials](#)

[Appendix D – Packaging Instructions 602](#)

[Appendix E – Shipping System](#)

[Appendix F– Packaging Instructions 650](#)

[Appendix G – Classification Guide for Infectious Substances and Biological Substances](#)

[Appendix H – Packaging Instructions for GMO](#)

[Appendix I – OSEH Guidance Document for Shipping Materials with Dry Ice](#)