



**Environmental Health & Safety Policy Manual**

Date: 5/16/2011

Updated: 3/8/2021

Policy # EHS-300.05

**Shipping Biological Materials Policy**

**1.0 PURPOSE**

To ensure compliance with domestic and international transport regulations which govern the transport and shipment of biological materials. A list of transport regulations can be found in [Appendix A](#).

**2.0 SCOPE**

This policy applies to all LSUHSC personnel involved in the shipment, transport, and receipt of biological materials.

**3.0 RESPONSIBILITIES**

**3.1 Environmental Health & Safety Department (EH&S) shall:**

- Provide technical support to those who ship or receive biological materials.
- Provide training to personnel involved in the shipment of biological materials.
- Maintain training records.
- Conduct periodic audits to ensure compliance with this policy.

**3.2 Department Heads and Directors shall:**

- Ensure personnel involved in the shipment of biological materials comply with this policy.

**3.3 Personnel who ship Biological Materials shall:**

- Complete Shipping Biological Material Training every two years. See section 5.0 for directions training enrollment details.
- Maintain copy of shipping records for a period of two years after material is accepted by initial carrier [[49 CFR 172.201\(4\)\(e\)](#)].
- Ensure all hazardous materials are identified, classified, packaged, marked, labeled, documented, and shipped safely and in accordance with applicable shipping regulations.

**3.4 Personnel who Receive Biological Material Shipments shall:**

- Inspect package before opening for damage or leakage. Immediately report leakage or incident involving infectious substances to EH&S at 568-6585.



- Open infectious substances using appropriate containment practices, personal protective equipment, and adequate ventilation.
- Very itemized list of contents then notify shipper that materials arrived intact or if there were any discrepancies.

#### **4.0 SHIPMENT AND RECEIPT OF BIOLOGICAL MATERIALS**

##### **4.1 Shipment**

- Specific instruction on classifying, packaging, labeling, and documentation of biological materials is provided in the [Shipping Biological Materials Manual, Appendix B](#).
- Packages containing regulated biological materials shall not be left unattended (e.g., left outside the FEDEX drop-off box or on a loading dock). Packages [containing](#) regulated biological materials shall not be placed inside the FEDEX drop-off box. Note [non-infectious liquid clinical samples](#) should not be placed in a FEDEX drop-off box.
- Contact the carrier (e.g., FEDEX and UPS) to schedule a pickup directly from laboratory or clinic.
- FEDEX requires that a dangerous goods account be established prior to the shipment of dangerous goods. Proof of dangerous goods training is required to establish this dangerous goods account. LSUHSC “Shipping Biological Material” training satisfies their training requirement for shipping biological materials classified as dangerous goods. Contact FEDEX at 1-800-463-3339 to establish a dangerous goods account.

##### **4.2 Receiving**

- Packages are received by LSUHSC Receiving personnel and delivered to laboratories and clinics.
- For any packages containing biological materials delivered directly to laboratory or clinic, ensure compliance with responsibilities outlined in section 3.4 above.

##### **4.3 Import and Export Permits**

- Shipping and receiving biological materials may require the approval of federal agencies, both domestic and foreign. An [import](#) or [export](#) permit may be required when shipping biological materials internationally.
- All shipments entering the United States are processed by the U.S. Bureau of Customs and Border Protection. Import permits are required from the CDC and other regulators for importation of extremely infectious Select Agents, etiologic agents, toxins, hosts or vectors of human disease, international shipments and materials shipped by rail or vessel.
- Export control laws are federal regulations that control the conditions under which certain information, technologies, and commodities can be transmitted



overseas. The laws are implemented by the Department of Commerce through its Export Administration Regulations (EAR). The laws prohibit the unlicensed export of certain materials or information for reasons of national security or protection of trade. The Commerce Control List (CCL) is a list of items which includes commodities, software, and technology that are found in the EAR subject to the jurisdiction of the Department of Commerce. In order to comply with EAR, personnel must consult the [CCL](#) prior to shipping biological materials overseas. Coordinate with EH&S before shipping any biological materials on the CCL.

- For a summary of the transportation regulations that apply to Select Agents and the import or export of biological materials, consult [Appendix A](#).

## **5.0 TRAINING**

- Personnel who ship biological materials classified as dangerous goods must complete training which meets the requirements of the U. S. Department of Transportation (DOT), and if shipped by air, the requirements of the International Air Transport Association (IATA). Training must be designed to satisfy the General Awareness, Security Awareness, Function-Specific, and Safety requirements of [49 CFR 172.704](#).
- EH&S offers training that meets DOT and IATA requirements via the University's Knowledge Delivery System (KDS). Contact Genean Mathieu, Office of Compliance Programs, at [gmathi@lsuhsc.edu](mailto:gmathi@lsuhsc.edu) or 568-8652 to request enrollment into this training.

## **6.0 RECORDKEEPING**

- Personnel who ship biological materials will maintain a copy of shipping records for a period of two years after material is accepted by initial carrier.
- EH&S will maintain a copy of training records.

## **7.0 INSPECTIONS AND PROGRAM REVIEW**

Program effectiveness will be assessed annually by EH&S.

## **8.0 APPENDICES**

[Appendix A](#) – Transportation Regulations

[Appendix B](#) – Shipping Biological Materials Manual



## **TRANSPORTATION REGULATIONS**

There are several agencies which govern the shipment of biological materials. Most shipments at LSUHSC are shipped domestically by either ground or air and adhere to DOT and IATA regulations. Additional regulations apply to the shipment of extremely infectious Select Agents, international shipments, and materials shipped by rail or vessel. Below is a summary of the domestic and international agencies which regulate the shipment of biological materials:

- **U.S. Department of Transportation (DOT) 49 CFR 100-185**  
DOT is a U.S. federal agency which regulates the transport dangerous goods. These [regulations](#) apply to the shipment of infectious substances in commercial transportation within the United States. Violations of any hazardous materials regulations may be subject to a civil penalty of up to \$50,000 per violation, a criminal penalty up to \$500,000 in certain cases, and/or imprisonment for up to 5 years (49 CFR 107.329 and 107.333). Penalties double when the violation results in serious injury or death.
- **U.S. Postal Service (USPS) 39 CFR 20**  
Regulations on transporting infectious substances through the USPS are codified in Section 601.10.17 of the Domestic Mail Manual and Section 135 of the International Mail Manual. A copy of the Domestic and International Mail Manuals may be obtained from the U.S. Government Printing Office or at the USPS website: <http://bookstore.gpo.gov/>.
- **Occupational Health and Safety Administration (OSHA) 29 CFR 1910.1030**  
[Occupational Exposure to Bloodborne Pathogens](#) standard provides minimal packaging and labeling for blood and body fluids when transported within a laboratory or outside of it.
- **International Civil Aviation Organization (ICAO)**  
The *Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI)* applies to the shipment of infectious substances by air and is recognized in the United States and by most countries worldwide. A copy of these regulations may be obtained from the ICAO Document Sales Unit or from the ICAO Web site: <http://www.icao.int>.
- **International Air Transport Association (IATA)**  
IATA is an association of airlines, including American couriers such as Fed Ex and UPS, which work to increase efficiency and safety in air transport. Airlines that are members of IATA use the *Dangerous Goods Regulations (DGR)* which incorporates the ICAO TI but adds further restrictions. A copy of these regulations is available at:



<http://www.iata.org/index.htm> or <http://www.who.int/en> .

### **IMPORTATION OF ETIOLOGIC AGENTS**

- **Centers for Disease Control and Prevention (CDC) 42 CFR 71**  
This regulation requires an import permit from the CDC for importation of etiologic agents, hosts or vectors of human disease. The regulation, application form, and additional guidance is available at the CDC Web site: <http://www.cdc.gov/od/eaipp>.
- **U.S. Department of Agriculture (USDA) 9 CFR 122**  
The USDA, APHIS, Veterinary Services (VS) requires that a permit be issued prior to the importation or domestic transfer (interstate movement) of etiologic disease agents of livestock, poultry, other animals. Information may be obtained at (301) 734-5960, or from the USDA Web site: [http://www.aphis.usda.gov/animal\\_health](http://www.aphis.usda.gov/animal_health).
- **CDC Importation of Etiologic Agents of Human Disease 42 CFR 71**  
This regulation requires an import permit from the CDC for importation of etiologic agents, hosts or vectors of human disease. The regulation, application form, and additional guidance is available at the CDC Web site: <http://www.cdc.gov/od/eaipp>.
- **USDA Importation of Etiologic Agents and Other Materials of Livestock, Poultry 9 CFR 122**  
The USDA, APHIS, Veterinary Services (VS) requires that a permit be issued prior to the importation or domestic transfer (interstate movement) of etiologic disease agents of livestock, poultry, other animals. Information may be obtained from the USDA Web site: [http://www.aphis.usda.gov/animal\\_health](http://www.aphis.usda.gov/animal_health).
- **USDA Importation of Plant Pest 7 CFR 330**  
This regulation requires a permit for movement into or through the United States, or interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained at the USDA Web site: <http://www.aphis.usda.gov/permits>.

### **EXPORTATION OF ETIOLOGIC AGENTS**

- **Department of Commerce (DoC) 5 CFR 730-799**  
This regulation requires that exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents, will require an export license. Information may be obtained by calling the DoC Bureau of Export Administration at (202) 482-4811, or at the DoC Web site: <http://www.ntis.gov/products/export-regs.aspx>; or at <http://www.access.gpo.gov/bis/index.html>; and <http://www.bis.doc.gov>.



## **TRANSFERS**

- **Transfer of CDC Select Agents and Toxins 42 CFR Part 73**  
The CDC regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. The regulations, Select Agent Program forms, and additional guidance is available at the CDC Web site: [www.selectagents.gov](http://www.selectagents.gov).
- **Transfer of USDA Select Agents and Toxins 9 CFR 121**  
The USDA, APHIS, VS regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal health or animal products. The VS Select Agent Program oversees these activities and registers all laboratories and other entities in the U.S. that possess, use, or transfer a VS select agent or toxin. The regulations, Select Agent Program forms, and additional guidance is available at the APHIS Web site:  
[http://www.aphis.usda.gov/programs/ag\\_selectagent/index.shtml](http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml).
- **Transfer of USDA Plant Pests**  
The movement of Plant Pests is regulated under two distinct and separate regulations: (1) 7 CFR Part 331. Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; and (2) 7 CFR Part 330 Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. Information can be obtained at the USDA Web site:  
[http://www.aphis.usda.gov/programs/ag\\_selectagent/index.shtml](http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml).



# **SHIPPING BIOLOGICAL MATERIALS MANUAL**

**April 25, 2011**



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## **1.0 INTRODUCTION**

The LSUHSC-NO Shipping Biological Materials Manual is designed to aid personnel shipping biological materials domestically and internationally. Certain biological materials are regulated under the Department of Transportation (DOT) and the International Air Transit Authority (IATA) as dangerous goods and require specific packaging, labeling, and documentation. Prior to the shipment of biological materials, personnel must complete training which meets the requirements of DOT and IATA.

EH&S offers training which meets the DOT and IATA requirements via On Site, a web-based training software. To access the training, use your LSUHSC user name and password to login at <http://172.20.240.20:1568/>. Contact EH&S at [Safety@lsuhsc.edu](mailto:Safety@lsuhsc.edu) to establish an account or request assistance.

The purpose of shipping regulations, this manual, and training is to ensure packages arrive at their destination safely in good condition and to ensure compliance with domestic and international transport regulations which govern the transport and shipment of biological materials. For a list of federal and domestic regulations which regulate the shipment of biological materials both domestically and internally, including information on Select Agents and import or export permits, please see the [Shipping Biological Materials Policy, Appendix A](#).

The steps to properly ship biological materials are as follows:

- Classification
- Packaging
- Marking and Labeling
- Documentation

It is the shipper's responsibility for proper classification, identification, packaging, marking and labeling, and documentation of the material they wish to ship. It is the responsibility of the recipient to inspect the package before opening to detect damage or leaks. This manual provides instruction on how to perform each of these tasks. To begin, use the [classification flow chart](#) in section 2.0 to determine the shipment category. After you've identified the material, find the material's corresponding section for instruction on packaging, labeling, and documentation. Use [Appendix A](#), Shipping Checklist, as an additional guide.

Packages [containing](#) regulated biological materials shall not be left unattended (e.g., left outside the FEDEX drop-off box or on a loading dock) and shall not be placed inside the FEDEX drop-off box. Note [non-infectious liquid clinical samples](#) should not be placed in a FEDEX drop-off box. Contact the carrier to schedule a pickup directly from the laboratory or clinic. If you do not have a dangerous goods account with FEDEX, you will need to establish one by contacting them at 1-800-463-3339.



## **2.0 CLASSIFYING BIOLOGICAL MATERIALS FOR SHIPMENT**

There are nine classes of dangerous goods. Biological materials are found in hazard class 6, division 2, or "Division 6.2." Division 6.2 materials include material that is known or reasonably expected to contain a pathogen. Pathogens are microorganisms (e.g. bacteria, virus, parasites, rickettsiae, fungi), recombinant microorganisms, or other agents, such as prions, that can cause disease in humans or animals. Pathogens are not subject to shipping requirements if they are unlikely to cause human or animal disease. Infectious substances are subject to the regulations only if they are capable of spreading disease when exposure to them occurs. These materials are classified for transportation under the following categories:

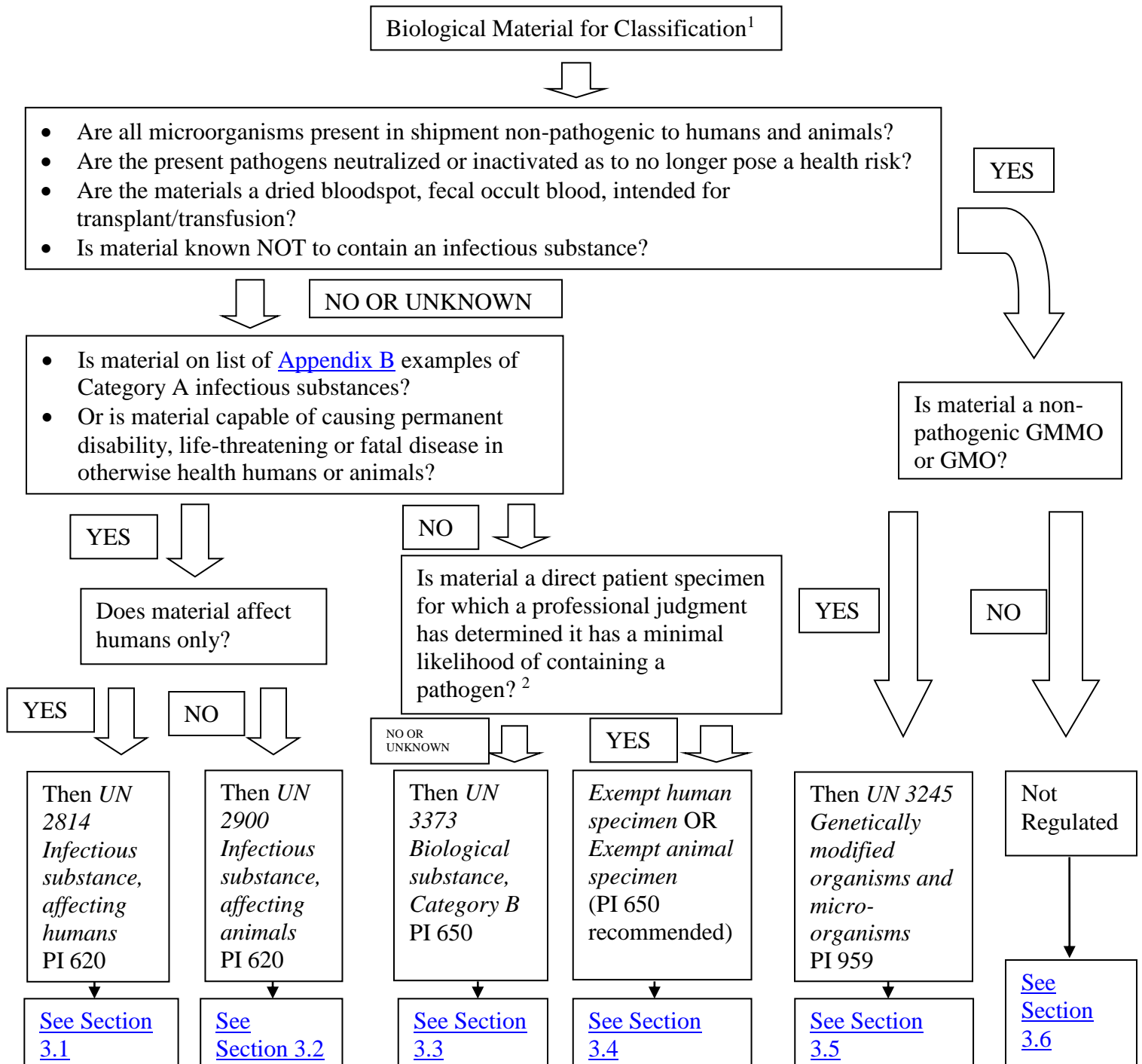
- Category A Infectious Substances
  - Infectious Substances Affecting Humans
  - Infectious Substances Affecting Animals
- Category B Biological Substances
- Exempt Human and Exempt Animal Specimens
- Genetically Modified Microorganisms (GMMOs) and Genetically Modified Organisms (GMOs)
- Non-Regulated Biological Materials

Use the classification flow chart on the next page to determine the category of the material for transport. Afterwards, use the corresponding section for instruction on packaging the material.



**CLASSIFICATION FLOW CHART**

*Note: Flowchart is to be used as a guide only and should not be construed as exact classification method.*



1. Anyone who attempts to classify an infectious substance must be trained and certified.  
2. Professional judgment shall be used and based on patient medical history, symptoms, and individual circumstances of the source, human or animal, and endemic local conditions.



### 3.0 PREPARING BIOLOGICAL SHIPMENTS

#### 3.1 CATEGORY A INFECTIOUS SUBSTANCES AFFECTING HUMANS SHIPPING INSTRUCTIONS

##### Category A Infectious Substances

- A Category A infectious substance is a substance which is transported in a form that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals if exposure occurs.
- Category A infectious substances are divided into two groups. This section describes *UN 2814 Infectious substances, affecting humans*. Substances that are infectious to both humans and animals must be classified as *UN 2814 Infectious substances, affecting humans*.
- [Appendix B](#) includes the types of substances that are considered Category A substances. This list is not exhaustive. Infectious substances, including new or emerging pathogens, which meet the criteria above, must be classified and shipped as Category A Infectious Substances. Your own judgment should be used based on your knowledge of the material you are shipping when deciding how to classify it. If there is any question regarding whether or not the substance warrants inclusion in Category A, then it must be shipped as Category A.

##### Category A IATA Table

- Below are the packing and labeling instructions from the IATA Dangerous Goods Regulations (DGR):

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN2814	<i>Infectious substance, affecting humans</i>	6.2	<i>Infectious subst.</i>	-	E0	620	50 mL or 50 g	4L or 4 kg

\* PG = Packing Group \*\*EQ = Excepted Quantities

##### Category A Packaging

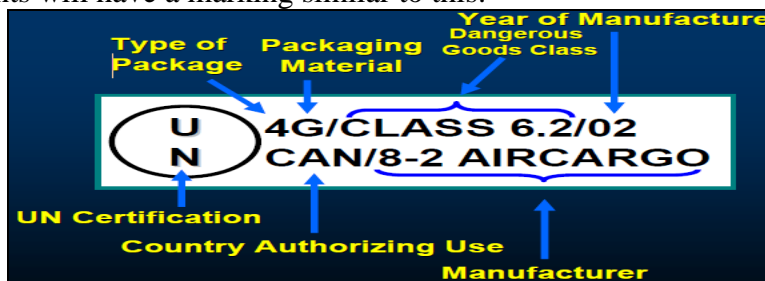
- Category A substances must be packed according packing instructions 620 of the IATA DGR (described below).
- The material must be placed inside a leak proof primary receptacle. This primary receptacle then must be placed in a leak proof secondary receptacle. Either the primary or secondary receptacle must be able to withstand 95 kPa of pressure and temperatures from – 40o C to 55o C. A Vacutainer<sup>tm</sup> fulfills this requirement as a primary container and some polyethylene bags fulfill the pressure and temperature requirements as a secondary container. Infectious shipper systems



require secondary and outer components meet these pressure and temperature requirements.



- The secondary receptacle is placed inside of an outer container. You must not consolidate inner packages containing infectious substances with inner packages containing unrelated materials. This poses a risk of cross contamination should the inner packages release the infectious substance. For example do not pack primary containers of healthy human blood with samples containing pathogens. The secondary container is placed inside of an outer container. The secondary container must be secured inside the outer container so it does not shift during transport. If you are using a refrigerant make sure the secondary container is braced by some means so that as the refrigerant dissipates or melts the secondary container remains braced.
- Place an itemized list of contents between the secondary and outer container. This can be attached to the outside of the secondary container.
- The outer container must meet specific quality tests and bear UN specific markings confirming it is constructed to meet these requirements. Boxes that meet these requirements will have a marking similar to this:



- This marking confirms that the package meets the UN certification requirements for class 6.2 infectious materials. The marking must show “CLASS 6.2” otherwise it was constructed for different specifications. Markings must be printed on the box not hand written. Make sure no labels are placed over this marking. These markings must be on the outer package of the triple package system. They are not necessary on the outside of an overpack if one is used.



- The maximum amount per outer package is 4 kg / 4 L. This does not apply to body parts or whole bodies.
- No other dangerous goods are allowed inside the outer package unless they are necessary for maintaining the viability of the material during shipment, for example a refrigerant (dry ice) or a preservative (formalin).

### **Category A Infectious Shipping Systems**

There are several commercially available Category A manufactured infectious shipping systems. These systems consist of secondary and outer packages that meet the above specifications and in most cases contain the appropriate hazard labels, absorbent material, and a mechanism to secure the secondary container within the outer package. A representative vendor list is available in [Appendix C](#).



### **Category A Labeling**

- Category A shipments must have a class 6 infectious substance label.
- If a package contains more than 50mL or 50g of a Category A infectious material then a “Cargo Aircraft Only” label is needed.

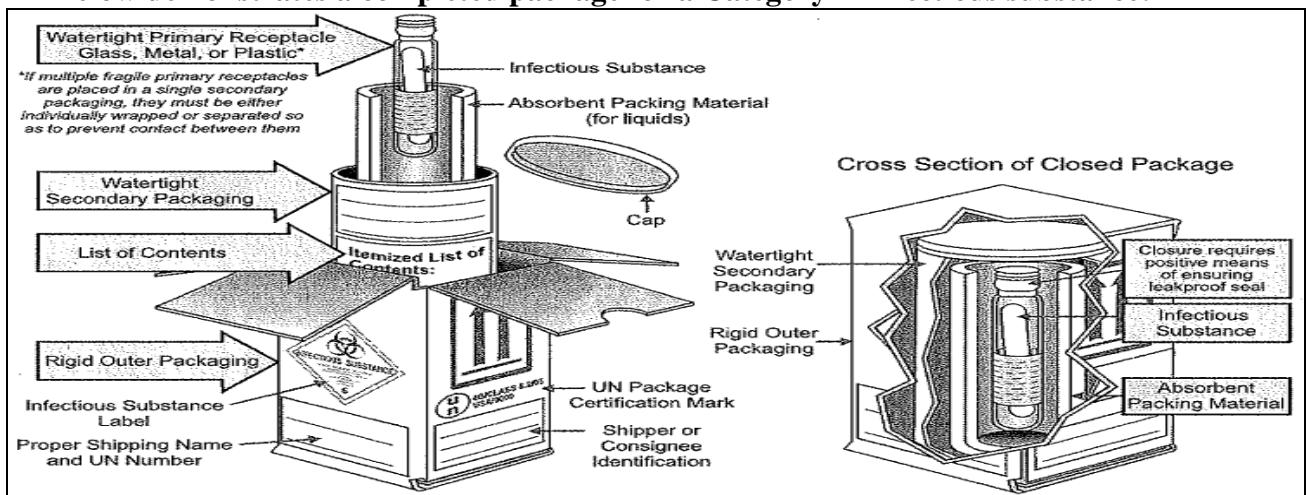


- All labels must be flat on one side of the package. Labels should not go around edges or cover up other relevant markings on the package. Be sure that no labels are covering up the UN marking on the box.





- Write or attach a label with the shipper’s name, address, and telephone number and the consignee’s name and address on the outside of the package.
- The outside of the box should be marked as follows:
  - **Infectious substance, affecting humans, UN2814, \_\_\_ mL/ kg** or
- If the substance is a liquid, use orientation arrows on the outside of the box or the word “THIS END UP” to specify the correct position in order to prevent leakage.
- Be sure to account for any other hazardous materials (ex. Dry ice) contained in the package with the proper labels and markings on the box.
- **Below demonstrates a completed package for a Category A infectious substance:**



**Category A Documentation**

- Category A infectious substances require a Declaration for Dangerous Goods for each shipment.
- Use the information from the IATA table to fill out the Nature and Quantity section of the Dangerous Goods Declaration.

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
UN2814	Infectious substance, affecting humans (Dengue virus cultures)	6.2		1 x fibreboard box x 15 ml	620	

- Note that the proper shipping name must be supplemented with the technical name in parentheses on the Declaration for Dangerous Goods. For example, a shipment of Dengue virus cultures you would type *Infectious substance, affecting humans (Dengue virus cultures)*.



- On the air waybill the **Handling Information** must read: *Dangerous Goods as per attached Shipper's Declaration*. For most carriers this is a box you would check on the side of the document.
- If applicable, the **Nature and Quantity** box on the air waybill should read: *Infectious substance affecting humans*.

#### **Preservatives**

- A quantity of 30 mL or less of dangerous goods from class 3 (Flammable liquids), 8 (Corrosives), or 9 (Miscellaneous Dangerous Goods) may be packed in each primary receptacle to maintain the viability, stability, or prevent degradation of the substances while in transit. Provided these materials are under 30 mL and packed for these purposes, no additional requirements need to be met regarding labeling or documenting these additional dangerous goods.
- Hazardous chemicals in larger amounts must be accounted for on the Dangerous Goods Declaration and with the proper labels on the outside of the package.

#### **Category A Carrier Information**

- Always confirm with the carrier before they pick up your shipment that they are able to transport a Category A infectious substance.
- FedEx and World Courier will transport Category A infectious substances. The US Postal Service and UPS may not.





### 3.2 CATEGORY A INFECTIOUS SUBSTANCES AFFECTING ANIMALS SHIPPING INSTRUCTIONS

#### Category A Infectious Substances

- Category A infectious substances affecting animals fall under *UN 2900 Infectious substances, affecting animals*. Substances that are infectious to both humans and animals must be classified as *UN 2814 Infectious substances, affecting humans*.
- [Appendix B](#) includes the types of substances that are considered Category A infectious substances affecting animals. This list is not exhaustive. If there is any question regarding whether or not the substance warrants inclusion in Category A, then it must be shipped as Category A.

#### Category A IATA Table

- Below are the packing and labeling instructions from the IATA DGR:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN2900	<i>Infectious substance, affecting animals</i>	6.2	<i>Infectious subst.</i>	-	E0	620	50 mL or 50 g	4L or 4 kg

\* PG = Packing Group \*\*EQ = Excepted Quantities

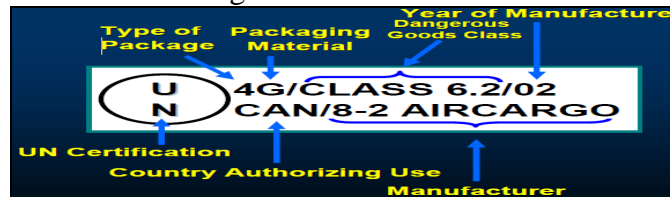
#### Category A Packaging

- Category A substances must be packed according packing instructions 620 of the IATA DGR (described below).
- The material must be placed inside a leak proof primary receptacle. This primary receptacle then must be placed in a leak proof secondary receptacle. Either the primary or secondary receptacle must be able to withstand 95 kPa of pressure and temperatures from – 40o C to 55o C. A Vacutainer™ fulfills this requirement as a primary container and some polyethylene bags fulfill the pressure and temperature requirements as a secondary container. Infectious shipper systems require secondary and outer components meet these pressure and temperature requirements.





- The secondary receptacle is placed inside of an outer container. You must not consolidate inner packages containing infectious substances with inner packages containing unrelated materials. This poses a risk of cross contamination should the inner packages release the infectious substance. For example do not pack primary containers of healthy human blood with samples containing pathogens. The secondary container is placed inside of an outer container. The secondary container must be secured inside the outer container so it does not shift during transport. If you are using a refrigerant make sure the secondary container is braced by some means so that as the refrigerant dissipates or melts the secondary container remains braced.
- Place an itemized list of contents between the secondary and outer container. This can be attached to the outside of the secondary container.
- The outer container must meet specific quality tests and bear UN specific markings confirming it is constructed to meet these requirements. Boxes that meet these requirements will have a marking similar to this:



- This marking confirms that the package meets the UN certification requirements for class 6.2 infectious materials. The marking must show “CLASS 6.2” otherwise it was constructed for different specifications. Markings must be printed on the box not hand written. Make sure no labels are placed over this marking. These markings must be on the outer package of the triple package system. They are not necessary on the outside of an overpack if one is used.
- The maximum amount per outer package is 4 kg / 4 L. This does not apply to body parts or whole bodies.
- No other dangerous goods are allowed inside the outer package unless they are necessary for maintaining the viability of the material during shipment, for example a refrigerant (dry ice) or a preservative (formalin).

### **Category A Infectious Shipping Systems**

There are several commercially available Category A manufactured infectious shipping systems. These systems consist of secondary and outer packages that meet the above specifications and in most cases contain the appropriate hazard labels, absorbent material, and a mechanism to secure the secondary container within the outer package. A representative vendor list is available in [Appendix C](#).



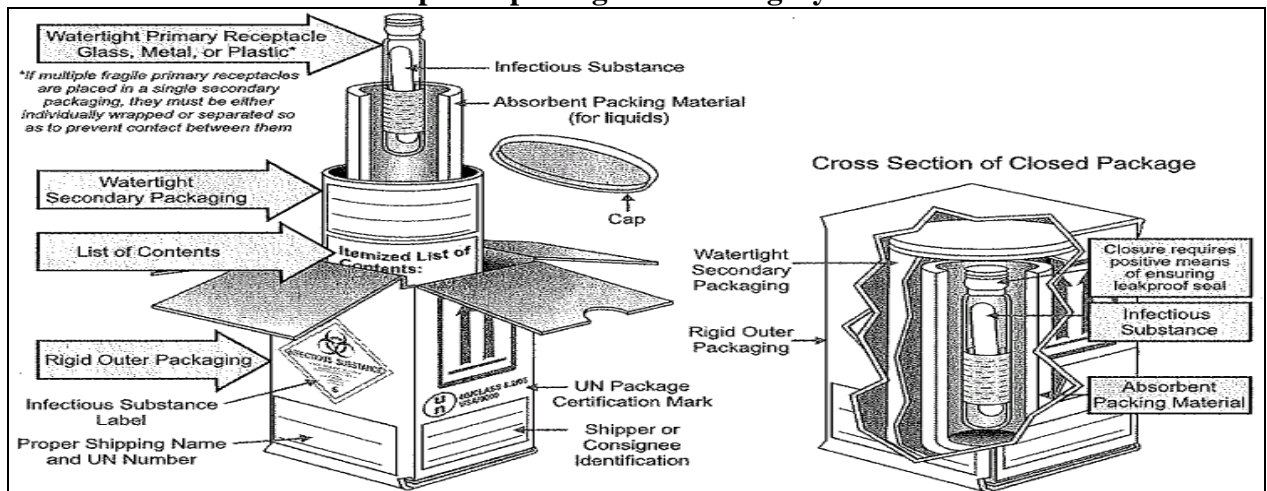


### Category A Labeling

- Category A shipments must have a class 6 infectious substance label.
- If a package contains more than 50mL or 50g of a Category A infectious material then a “Cargo Aircraft Only” label is needed.



- All labels must be flat on one side of the package. Labels should not go around edges or cover up other relevant markings on the package. Be sure that no labels are covering up the UN marking on the box.
- Write or attach a label with the shipper’s name, address, and telephone number and the consignee’s name and address on the outside of the package.
- The outside of the box should be marked as follows:
  - **Infectious substance, affecting animals, UN2900, \_\_\_ kg/ mL**
- If the substance is a liquid, use orientation arrows on the outside of the box or the word “THIS END UP” to specify the correct position in order to prevent leakage.
- Be sure to account for any other hazardous materials (ex. Dry ice) contained in the package with the proper labels and markings on the box.
- **Below demonstrates a completed package for a Category A infectious substance:**





**Category A Documentation**

- Category A infectious substances require a Declaration for each shipment.
- Use the information from the IATA table to fill out the Nature and Quantity section of the Dangerous Goods Declaration.

NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization	
UN2814	Infectious substance, affecting humans (Dengue virus cultures)	6.2		1 x fibreboard box x 15 ml	620		
UN2900	Infectious substance, affecting animals (Rinderpest virus cultures)	6.2		1 x fibreboard box x 15 ml	620		

- Note that the proper shipping name must be supplemented with the technical name in parentheses on the Declaration for Dangerous Goods. For example, a shipment of
- On the air waybill the **Handling Information** must read: *Dangerous Goods as per attached Shipper’s Declaration*. For most carriers this is a box you would check on the side of the document.
- If applicable, the **Nature and Quantity** box on the air waybill should read: *Infectious substance affecting animals*.

**Preservatives**

- A quantity of 30 mL or less of dangerous goods from class 3 (Flammable liquids), 8 (Corrosives), or 9 (Miscellaneous Dangerous Goods) may be packed in each primary receptacle to maintain the viability, stability, or prevent degradation of the substances while in transit. Provided these materials are under 30 mL and packed for these purposes, no additional requirements need to be met regarding labeling or documenting these additional dangerous goods.
- Hazardous chemicals in larger amounts must be accounted for on the Dangerous Goods Declaration and with the proper labels on the outside of the package.

**Category A Carrier Information**

- Always confirm with the carrier before they pick up your shipment that they are able to transport a Category A infectious substance.
- FedEx and World Courier will transport Category A infectious substances. The US Postal Service and UPS may not.



### 3.3 CATEGORY B BIOLOGICAL SUBSTANCE SHIPPING INSTRUCTIONS

#### Category B Biological Substance

- Category B biological substances are those that are not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. Examples include Hepatitis B infected blood, adenoviral vectors, or body fluids being shipped to diagnose an unknown (non-life threatening) illness. Regulated medical waste which does not contain Category A materials is also considered Category B. Category B infectious substance must be described as "Biological substance, category B" and assigned identification number UN3373.
- A Biological Substance, Category B contains pathogens but does not meet the criteria for inclusion in Category A. In other words, these are less severe infectious materials than Category A. Category B substances are assigned to UN 3373 *Biological substance, Category B*.

**NOTE:** Unknown samples of infectious substances shipped for analysis and diagnosis may be transported in accordance with requirements for Category B infectious substances. For situations where the identity of the agent or pathogen is not known, but sufficient information is available to strongly suspect a Category A infectious substance, the material should be shipped in accordance with all requirements for Category A infectious substances.

#### Category B IATA Table

- Below are the packing and labeling instructions from the IATA DGR:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN3373	<i>Biological substance, Category B</i>	6.2	<i>See below</i>	-	E0	650	<i>See packaging section</i>	<i>See packaging section</i>

\* PG = Packing Group \*\*EQ = Excepted Quantities

- No hazard label is listed on the IATA table. However, a package containing a Category B substance must have a diamond shaped label that reads “UN3373” (more details in labeling section).
- There is no limitation for passenger air carriage. Cargo aircraft only labels do not apply to Category B shipments.



### **Category B Packaging**

- Category B substances must be packed according packing instructions 650 of the IATA DGR (described below).
- The material must be placed inside a leak proof primary receptacle. This primary receptacle then must be placed in a leak proof secondary receptacle.
- Either the primary or secondary receptacle must be able to withstand 95 kPa of pressure and temperatures from  $-40^{\circ}\text{C}$  to  $55^{\circ}\text{C}$ . A Vacutainer<sup>™</sup> fulfills this requirement as a primary container and some polyethylene bags fulfill the pressure and temperature requirements as a secondary container.
- The secondary container is placed inside of an outer container. The secondary container must be secured inside the outer container so it does not shift during transport. If you are using a refrigerant make sure the secondary container is braced by some means so that as the refrigerant dissipates or melts the secondary container remains braced.
- Place an itemized list of contents between the secondary and outer container. This can be attached to the outside of the secondary container.
- The outer container does not need the specific UN markings like on a Category A box. The outer container must be of good quality and be able to withstand the shocks and pressures of transit.
- **For liquid substances:** primary receptacles cannot contain more than 1 L; outer packages cannot contain more than 4 L (excluding dry ice, wet ice, or liquid nitrogen).
- **For solid substances:** outer packages cannot contain more than 4 kg (excluding dry ice, wet ice, or liquid nitrogen). This does not apply when the package contains body parts, organs, or whole bodies. You must not pack other dangerous goods inside the outer package unless they are necessary for maintaining the viability of the material during shipment, for example a refrigerant (dry ice) or a preservative (formalin).

### **Category B Labeling**

- A Biological Substance, Category B shipment must have the below label on the outside of the outer package. The label must be of a contrasting color to the package, clearly visible and legible. The label must be at least 2 in x 2 in.

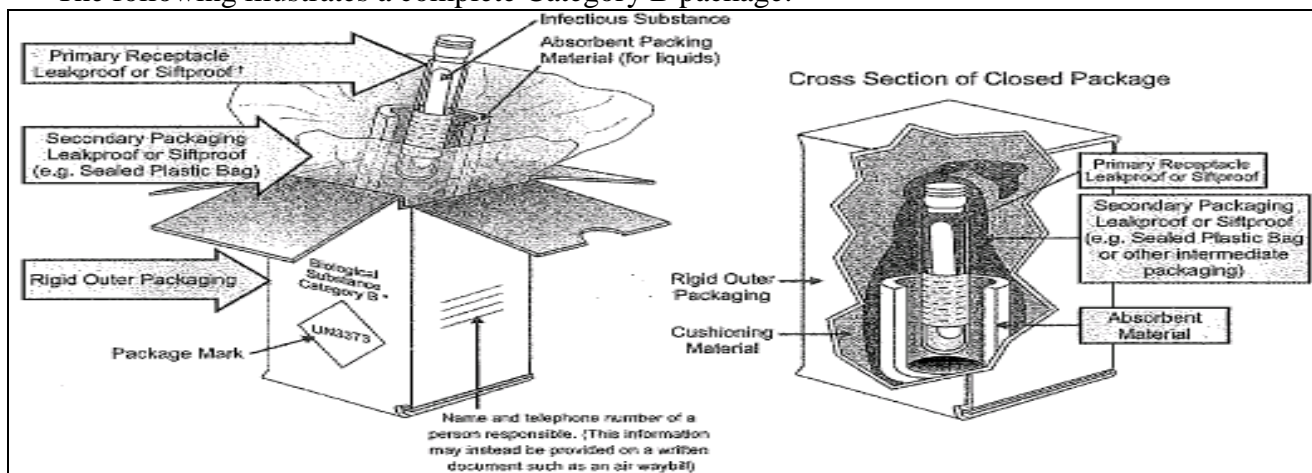


- All labels must be flat on one side of the package. Labels should not go around edges or cover up other relevant markings on the package.
- The proper shipping name: "**Biological Substance, Category B**" must be marked on the outer packaging adjacent to this label.
- Write or attach a label with the shipper's name, address, and telephone number and the consignee's name and address on the outside of the package.





- Be sure to account for any other hazardous materials (ex. dry ice) contained in the package with the proper labels and markings on the box.
- The following illustrates a complete Category B package:



### Category B Documentation

- A Declaration for Dangerous Goods is not required for Category B substances. You will need to specify when filling out the shipment information that this is a dangerous goods shipment but no shipper's declaration is required. Usually this is a box to check on your air waybill.
- If applicable, the "Nature and Quantity of Goods" section of the air waybill must be marked with "BIOLOGICAL SUBSTANCE, CATEGORY B" and "UN 3373".

### Preservatives

A quantity of 30 mL or less of dangerous goods from class 3 (Flammable Liquids), 8 (Corrosives), or 9 (Miscellaneous Dangerous Goods) may be packed in each primary receptacle to maintain the viability, stability, or prevent the degradation of the substances while in transit. Provided these materials are under 30 mL and packed for these purposes, no additional requirements need to be met regarding labeling or documenting these additional dangerous goods.



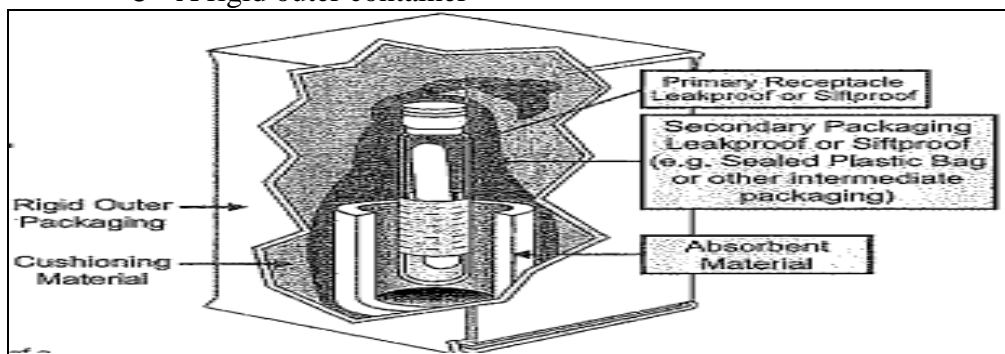
### 3.4 EXEMPT HUMAN AND EXEMPT ANIMAL SPECIMENS

#### Exempt Human or Exempt Animal Specimens

- Exempt Human or Animal specimens are specimens taken directly from a human or animal subject and transported for research, diagnosis, investigational activities, or disease treatment or prevention and have a minimal likelihood of containing pathogens. Patient specimens include excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media. Professional judgment is critical in determining the probability of pathogens being present in a specimen. The judgment should be based on the medical history of the source, symptoms and circumstances of the source, and endemic conditions of the local area.
- Examples of exempt specimens include blood or urine tests to monitor cholesterol, glucose, or hormone levels, or tests to monitor organ functions such as heart, liver, or kidney for humans or animals with non-infectious diseases. Also included in this provision are specimens for drug monitoring purposes, pregnancy tests, and biopsies for cancer detection or antibody detection.
- An example of a patient specimen not considered exempt: a patient in equatorial West Africa has become sick after being bitten by a wild rodent. You want to send a blood sample to a lab in the U.S. for diagnosis. You also know Monkeypox virus is endemic to the area. Since there is a good possibility this patient is infected with Monkeypox virus, you cannot ship a sample of his body fluid as an exempt human specimen, it must ship as a Category A substance.

#### Exempt Human and Animal Specimens Packaging

- Exempt human and animal specimens are packed according to the basic triple packing method:
  - A leak proof primary receptacle
  - A leak proof secondary receptacle
  - A rigid outer container



#### Exempt Human and Animal Specimens Packaging

The outer package must be marked with the words “EXEMPT HUMAN SPECIMEN” or “EXEMPT ANIMAL SPECIMEN”.





**Health Sciences Center  
New Orleans**

**Documenting Exempt Human and Animal Specimens:**

No Declaration for Dangerous Goods is needed as this classification is not considered a dangerous good. You will list the items on the air waybill by their technical name. For example: Human blood samples.



### 3.5 GENITICALLY MODIFIED MICROORGANISMS (GMMOs) AND GENETICALLY MODIFIED ORGANISMS (GMOs)

#### Genetically Modified Microorganisms (GMMOs) and Genetically Modified Organisms (GMOs)

Genetically Modified Micro-Organisms and Genetically Modified Organisms are organisms that do not meet the definition of infectious substances but are capable of altering animals, plants or microbiological substances in a way that is not normally the result of natural reproduction. GMMOs and GMOs that pose a risk of infection must be classified as Category A or Category B substances as appropriate. These materials must be assigned to UN 3245.

#### GMMOs and GMOs IATA Table

Below are the packing and labeling instructions from the IATA DGR:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN3245	Genetically modified organisms	9	Miscellaneous	-	E0	959	No limit	No limit
UN3245	Genetically modified micro-organisms	9	Miscellaneous	-	E0	959	No limit	No limit

\*PG = Packing Group    \*\*EQ = Excepted Quantities

#### GMMOs and GMOs Packaging

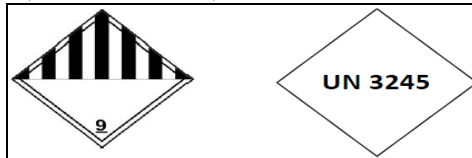
- GMMOs and GMOs follow packing instruction 959 of the IATA DGR (described below).
- The material must be placed inside a leak proof primary receptacle. This primary receptacle then must be placed in a leak proof secondary receptacle. The maximum amount per primary receptacle is 100 mL or 100 g.
- Either the primary or secondary receptacle must be able to withstand 95 kPa of pressure and temperatures from – 40° C to 55° C. A Vacutainer™ fulfills this requirement as a primary container and some polyethylene bags fulfill the pressure and temperature requirements as a secondary container.
- The secondary container is placed inside of an outer container. The secondary container must be secured inside the outer container so it does not shift during transport. If you are using a refrigerant make sure the secondary container is braced by some means so that as the refrigerant dissipates or melts the secondary container remains braced.
- Place an itemized list of contents between the secondary and outer container. This can be attached to the outside of the secondary container.



- No other dangerous goods are allowed inside the outer package unless they are necessary for maintaining the viability of the material during shipment, for example a refrigerant (dry ice) or a preservative (formalin).

**GMMOs and GMOs Labeling**

- You will need a class 9 (miscellaneous) label and a diamond shaped UN 3245 label:



- Write or attach a label with the shipper’s name, address, and telephone number and the consignee’s name and address on the outside of the package.
- The outside of the box should be marked with: **Genetically Modified Micro-Organisms, UN 3245, \_\_\_\_ml/g or Genetically Modified Organisms, UN 3245 \_\_\_\_ ml/g.**
- Be sure to account for any other hazardous materials (ex. dry ice) contained in the package with the proper labels and markings on the box.

**GMMOs and GMOs Documentation**

- GMMOs and GMOs require a Declaration for Dangerous Goods. Use the information from the IATA table to fill out the Declaration.

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
UN3245	Genetically modified micro organisms	9		1 x fibreboard box x 15 ml	959	

- On the Air Waybill, the **Handling Information** must read: Dangerous Goods as per attached Shipper’s Declaration. For most carriers this is a box you would check on the side of the document.

If applicable, the Nature and Quantity box should read: *Genetically Modified Organisms* or *Genetically Modified Microorganisms*.



### **3.6 NON-REGULATED BIOLOGICAL MATERIALS**

#### **Non-Regulated Biological Materials**

Not all biological materials are considered hazardous under IATA and DOT shipping regulations. Biological substances that do not contain pathogens or substances in which any present pathogens have been neutralized and do not meet the criteria of Exempt Human or Animal Specimens are not subject to IATA/DOT regulations unless they warrant inclusion in another class (i.e., GMMOs and GMOs). Examples of unregulated materials include:

- Substances containing microorganisms that are not pathogenic to humans or animals.
- Substances in a form that any present pathogens have been neutralized or inactivated so that they no longer pose a health risk.
- Environmental samples which are not considered to pose a significant risk of infection (e.g. food, water, or plant samples).
- Dried blood spots.
- Fecal occult blood screening tests.
- Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation. Note blood or blood products must be labeled with a Biohazard symbol on the primary and secondary containers. Do not place a biohazard symbol on the outside of the package.
- Tissues or organs intended for use in transplantation.

[Appendix D](#) contains the DOT/IATA exceptions list. Note IATA has slightly different exclusions from DOT.



## **4.0 OTHER REGULATED MATERIALS**

### **Other Regulated Materials**

- Dry ice is often packaged with infectious substances and diagnostic specimens. Dry ice falls into hazard class 9. Instructions for packaging dry ice can be found in [Section 4.1](#).
- Liquid nitrogen is classified as a non flammable gas and cryogenic liquid. Liquid nitrogen falls into hazard class 2.2. Instructions for packaging materials containing liquid nitrogen can be found in [Section 4.2](#).
- Formaldehyde solutions may fall into class 3, 8, or 9, depending on the concentration and other materials present. Specimens shipped in formalin solutions containing between 10-25% formaldehyde would be considered hazard class 9. Solutions containing less than 10% formaldehyde, and which contain no other hazardous material, are not regulated as a hazardous material.
- Wet ice and gel packs are other options for refrigerants. These two options are not subject to any dangerous goods regulations (unless other dangerous goods are in the package). Wet ice and gel packs keep items cold for shorter amounts of time and do not maintain as low of a temperature as dry ice or liquid nitrogen. When using wet ice be sure package is leak proof. Any type of leak, even if it is only water, will cause problems for your shipment.
- Preservatives used to ship biological materials to enhance product stability. For Category A infectious substances, Category B biological substances, and Genetically Modified Organisms and Microorganisms, a quantity of 30 mL or less of dangerous goods in Classes 3 (flammable liquids), 8 (corrosives), or 9 (miscellaneous) may be packed in each primary receptacle to maintain the substance's viability, stability, or to prevent its degradation. Provided the material is less than 30 mL, is from one of the specified classes, and used for these purposes no other requirements need to be met. If you are using a larger amount of preservative, you need to contact EHS for further training on how to pack, label and document that particular chemical.



#### 4.1 DRY ICE SHIPPING INSTRUCTIONS

##### Dry Ice

Dry Ice is considered a dangerous good under DOT and IATA regulations.

##### Dry Ice IATA Table

Below are the packing and labeling instructions from the IATA DGR:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN1845	Carbon dioxide, solid	9	Miscellaneous		E0	954	200 kg	200 kg

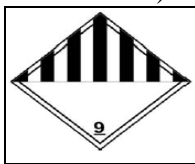
\*PG = Packing Group \*\*EQ = Excepted Quantities

##### Dry Ice Packaging

- Dry ice is packed according to packing instructions 954 in the IATA DGR (described below).
- Dry ice must be packaged in a container that will not be adversely affected by the low temperature. The package must not fail due to freezing.
- Do **NOT** completely seal packages containing dry ice. Packages must be vented or constructed to release CO<sub>2</sub> gas so as not to build up pressure and rupture.
- Any items being shipped on dry ice must be secured inside the package so they do not shift around after the dry ice dissipates. Inner packages should be braced by some means within the outer package.

##### Dry Ice Labeling

- Outer packages need a class 9 (miscellaneous) label



- Outer packages need to be marked with: **UN1845 Carbon dioxide, solid \_\_\_\_\_ kg** (*net weight of dry ice only*).
- Write or attach a label with the shipper's name, address, and telephone number and the consignee's name and address on the outside of the package.
- These outer markings are in addition to any other hazardous materials contained inside the package.



**Dry Ice Documentation**

- If dry ice is the only hazardous item in the package then a Declaration for Dangerous Goods is not required. If this is the case then you need to have the following in the Nature and Quantity of Goods section of the air waybill:

UN 1845  
Carbon dioxide, solid  
Class 9 1 x \_\_\_\_ kg

- If there are other dangerous goods in the package then you will fill out the Dangerous Goods Declaration as follows:

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
UN2814	Infectious substance, affecting humans (Monkeypox virus)	6.2		15 ml	620	
UN1845	Carbon dioxide, solid	9		10 kg	954	
				All packed in one fibreboard box		



## 4.2 LIQUID NITROGEN PACKAGING INSTRUCTIONS

### Liquid Nitrogen

Liquid nitrogen is classified as a non flammable gas and cryogenic liquid.

### Liquid Nitrogen IATA Table

- Below are the packing and labeling instructions from the IATA DGR:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG*	EQ**	Packing Inst	Max Qty. for passenger air carriage	Max Qty. for cargo only air carriage
UN1977	<i>Nitrogen, refrigerated liquid</i>	2.2	<i>Non-flamm. gas &amp; cryogenic liquid</i>		E1	202	50 kg	500 kg

\*PG = Packing Group      \*\*EQ = Excepted Quantities

- If the amount of liquid nitrogen you are shipping is 30 mL or less then you can ship under the excepted quantity rule. Packages must be adequately insulated and have venting mechanisms to prevent bursting.

### Liquid Nitrogen Packaging, Labeling, and Documentation

There are extensive regulations pertaining to shipping liquid nitrogen in open and closed cryogenic receptacles. If you wish to ship liquid nitrogen in an open or closed cryogenic receptacle, contact EH&S for details on packing, labeling, and documenting a liquid nitrogen shipment.

### Transporting Liquid Nitrogen in a Vapor Shipper

- You also have the option of using a Vapor Shipper to transport materials using liquid nitrogen as a refrigerant. Liquid nitrogen is not subject to these regulations if it is shipped in an approved Vapor Shipper. A Vapor Shipper is an insulated package containing liquid nitrogen fully absorbed in a porous material and is intended for transport at low temperatures of non- dangerous products. A Vapor Shipper must be constructed so it does not allow pressure to build up within the container and will not permit the release of liquid nitrogen regardless of how the package is oriented.
- A Vapor Shipper is specifically constructed for shipping materials. A small liquid nitrogen Dewar is not acceptable unless it is specified as a Vapor Shipper.
- If you are using a Vapor Shipper the words “Not Restricted” and special provision number A152 must be included in the description on the air waybill.
- Not all Vapor Shippers are constructed to transport infectious substances. If you are shipping an infectious or potentially infectious substance make sure the Vapor Shipper you have selected is properly constructed to contain infectious materials.





### 5.0 SHIPPER'S DECLARATION FOR DANGEROUS GOODS

- Packages may require a shipper to complete a legal document, or shipper's declaration, for shipments of dangerous goods (see section 5.1 for example form).
- Division 6.2 shipments containing UN 3373 Biological substances, Category B and Exempt Human/Animal Specimens do not require a shipper's declaration.
- For UN 1845 Dry Ice, a shipper's declaration is only required when it is used as a refrigerant for dangerous goods which require a shipper's declaration.
- If the shipment does not require a shipper's declaration, the information must be included on the waybill.
- The shipper must print the shipper's declaration form in color and sign it. Include two signed copies in the document pouch on the outside of your package. Keep one copy for your records.
- FEDEX will only accept dangerous goods declarations that were created using either their specific software or software from an approved vendor. This software can be obtained at <http://fedex.com/us/ship-manager/software/downloads.html>.

### 5.1 Example Shipper's Declaration For Dangerous Goods Form

Below is an example shipper's declaration form (see below form for descriptions):

SHIPPER'S DECLARATION FOR DANGEROUS GOODS						
Shipper LSU Health Sciences Center Jon Doe 123 Paved Avenue New Orleans, LA USA Tel: 5045681234				Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number (optional)		
Consignee Sam Doe 321 South Street Baton Rouge, LA Tel: 111-111-1111				Two completed and signed copies of this Declaration must be handed to the operator.		
<b>TRANSPORT DETAILS</b>				WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.		
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure		Airport of Destination		
<input type="checkbox"/> PASSENGERS AND CARGO - AIRCRAFT <input checked="" type="checkbox"/> CARGO - AIRCRAFT ONLY		<input type="checkbox"/> AIRCRAFT ONLY <input type="checkbox"/> AIRCRAFT ONLY		Shipment Type <i>(delete non-applicable)</i> NON-RADIOACTIV - <input checked="" type="checkbox"/>		
NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
UN2814	Infectious substance, affecting humans (Monkeypox virus)	6.2		15 ml	620	
UN 1845	Carbon dioxide, solid (Dry Ice)	9	III	0.5 kgts All packed in one fiberboard box	904	
Additional Handling Information						
Emergency Telephone Number 504-111-1111						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Jon Doe HAZMAT Manager Place and Date New Orleans, LA 1/14/2011 Signature		



**A. Shipper**

The name, address, and telephone number for the person sending this shipment. This telephone number is your office number, not a 24-hour emergency contact.

**B. Consignee**

The name and address of the person receiving this shipment.

**C. Passenger or Cargo Only Aircraft**

According to the information provided in the IATA table, specify if this shipment can be put on a passenger or cargo only aircraft

**D. Radioactive/Non-Radioactive**

Specify if this shipment is radioactive or not.

**E. Nature and Quantity of Dangerous Goods**

Using the information from the IATA table, fill in the required information for each dangerous good in this section.

**F. Emergency Response**

You must include a 24-hour emergency response contact on the dangerous goods declaration.

**G. Name, Title, Signature and Date**

- Type your name, title, place and date when you prepare this document. You may type all information but you must sign this form by hand, stamp, or facsimile. A typed signature is not allowed.
- When you have completed this form be sure to print 3 copies and sign them. Two copies must be in color (showing red hatchmarks on the sides) and the other is for your records. Place two copies in the clear document pouch on the outside of your package. Keep your copy for two years (domestic) or five years (international) from the date of the shipment.



## **6.0 PACKING TEST REQUIREMENTS FOR INFECTIOUS SUBSTANCES**

Packages designed for the shipment of Category A and Category B substances must be tested to ensure it can withstand a reasonable amount of damage without allowing the material to be exposed on the exterior of the outer package. Personnel must triple package the EQ shipment using a leak proof primary container, a leak proof secondary container (including absorbent materials if your material is a liquid), and a rigid outer container. Each completed EQ package must be able to pass the drop, load, and puncture tests described below and have documentation that a sample package has been tested. Personnel must test a complete package as prepared for transport (triple packaged) using a sample item of the same physical characteristics as the item you intend to ship. Tests may be performed on different but identical package components to the ones you will use to ship. Primary containers must be filled to at least 98% capacity with the sample item.

- **Drop Test:** Before the drop tests can be performed, the completed package must be pre conditioned. Preconditioning includes:
  - Water spray of 5 cm/hr for at least one hour.
  - Environment of -18C for a period of 24 hours. Drop test must be performed within 15 minutes after removal from environment.
  - If package allows for dry ice as refrigerant, the completed package must be filled with dry ice. When all dry ice has dissipated, the package is subjected to a drop test in the worst case orientation

Five identical packages must be used for the drop test and each one must be dropped in a different orientation after preconditioning:

- One drop flat on the bottom
- One drop flat on the top
- One drop flat on the long side
- One drop flat on the short side
- One drop on a corner

The complete package must be able to sustain the following drops from no less than 9 m (Category A) or 1.2 m (Category B) onto a rigid, non-resilient flat and horizontal surface without breaking or leaking of inner containers or substantial damage to the outer package.

- **Load Test:** Complete package must be able to sustain a load test consisting of a force equal to the mass of identical size and weight packages stacked to a height of 3 m (10 feet) applied to the top of the test package for 24 hours.
- **Puncture test:** Puncture tests are only required for Category A packages.
- **Criteria for passing:** No leakage or breakage of the inner containers and no significant reduction in effectiveness of any of the 3 layers of packaging. Personnel must complete these drop and load tests on each type of complete package used. You do not need test every package you send as long as you have documentation of testing the specific type of containers you are using.



**7.0 LIMITED AND EXCEPTED QUANTITIES**

**7.1 Limited Quantities**

Other dangerous goods (e.g., dry ice) shipped with infectious substances that exceed the 30 mL limit may be shipped as a “Limited Quantity”. The quantity of the material determines whether it can be shipped as a limited quantity. Contact EH&S for more information if dangerous goods in excess of 30 mL.

**7.2 Excepted Quantities**

- Small amounts of some dangerous goods can be shipped under the Excepted Quantity (EQ) rule. Hazardous biological materials do not have an Excepted Quantity exemption.
- The EQ column on the IATA dangerous goods table refers to excepted quantities allowed for each item. Some items, such as class 6.2 infectious materials, are not permitted to ship under the excepted quantity rules and have “E0” in this column.
- Other materials which are permitted under Excepted Quantities will have E1 through E5 in the EQ column of the IATA table. See below for EQ codes:

UN / ID no.	Proper shipping name	Class or Div. (Sub Risk)	Hazard Label(s)	PG	EQ	Packing Inst	Max Qty. for passenger air carriage
UN1264	Paraldehyde	3	Flamm. liquid	III	E1	355	60 L

EQ codes are explained in this table:

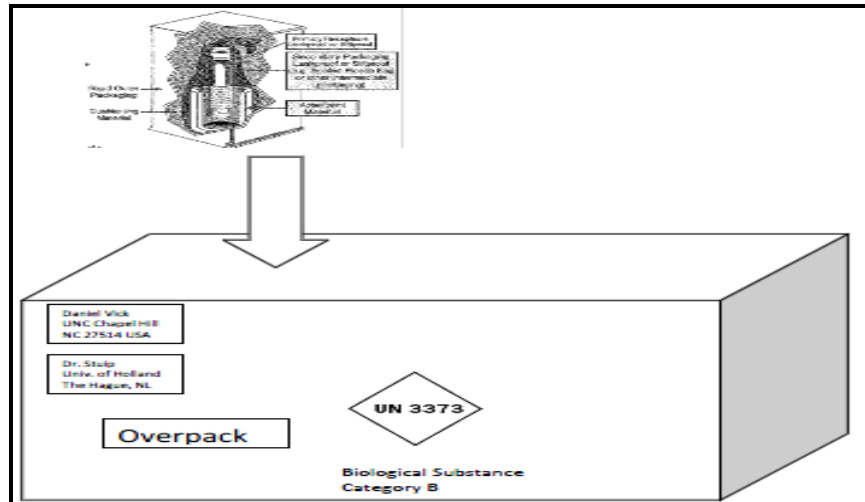
Code	Maximum Quantity per inner packaging	Maximum quantity per outer packaging
E0	Not permitted as Excepted Quantity	
E1	30g/30mL	1kg/1L
E2	30g/30mL	500 g/500mL
E3	30g/30mL	300g/300mL
E4	1g/1mL	500g/500mL
E5	1g/1mL	300g/300mL

- If your material fits within the limits of its EQ allotment then it can be shipped using an excepted quantities label instead of hazard labels and will not require a dangerous goods declaration for that material.
- The “Nature and Quantity of Goods” information on the air waybill should include the phrase “Dangerous Goods in Excepted Quantities.”



## 8.0 OVERPACKS

- Completed dangerous goods packages can be placed inside a larger package called an overpack. Overpacks are useful when there is not enough room for a refrigerant inside the outer package or if you want to ship multiple dangerous goods packages as one piece to save on cost.
- Every package contained in an overpack must be packed and labeled as if it were shipping by itself. The inner package markings must be reproduced on the outside of the overpack. The outer package must be clearly marked “OVERPACK”.
- The overpack must not contain packages of different substances that may react dangerously with each other or substances that must be segregated from other materials.





## **9.0 OTHER BIOLOGICAL MATERIAL DEFINITIONS**

- **Biological Product**

Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition in human beings or animals, unless otherwise excepted, a biological product known to reasonably expected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned the identification number UN2814 or UN2900.

- **Culture**

Culture means an infectious substance containing a pathogen that is intentionally propagated. This definition does not include a human or animal patient specimen.

- **Patient Specimen**

Patient specimen means human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secreta, blood and its components, tissue and tissue fluid swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles).



**SHIPPING CHECKLIST**

**I. Packaging:**

Use the following checklist to properly prepare package:

1. Follow manufacturer's instructions	<input type="checkbox"/>	8. Outer package displays UN specification mark (CATEGORY A ONLY)	<input type="checkbox"/>
2. Packaging materials in good condition	<input type="checkbox"/>	9. Rigid outer packaging (N/A to Exempt patient specimens)	<input type="checkbox"/>
3. Primary receptacles sealed and leakproof	<input type="checkbox"/>	10. Adequate minimum external area of outer package (all dimensions):	
4. Multiple primaries wrapped individually	<input type="checkbox"/>	• Category A – At least 100 mm	<input type="checkbox"/>
5. Adequate absorbent inside each secondary	<input type="checkbox"/>	• Category B – Two surfaces at least 100 mm x 100 mm	<input type="checkbox"/>
6. Primary or secondary receptacle 95 kPa compliant (N/A to Exempt patient specimens)	<input type="checkbox"/>	• GMOs – At least 100 mm	<input type="checkbox"/>
7. Itemized list of contents between secondary and outer packaging (N/A to Exempt patient specimens)	<input type="checkbox"/>	• Exempt patient samples – One surface at least 100 mm x 100 mm	<input type="checkbox"/>

**II. Marking and Labeling:**

Use to properly mark and label package (Note only marking on Exempt patient sample package is *Exempt human specimen* or *Exempt animal specimen*):

1. Shipper's address	<input type="checkbox"/>	5. Proper shipping name <sup>2</sup>	<input type="checkbox"/>
2. Recipient's address	<input type="checkbox"/>	6. Technical name (for CATEGORY A ONLY – optional on package)	<input type="checkbox"/>
3. Appropriate Hazard label/mark on package <sup>1</sup>	<input type="checkbox"/>	7. Quantity of dangerous goods (N/A for Category B)	<input type="checkbox"/>
4. UN number (Note: Category B already has UN # on label)	<input type="checkbox"/>	8. Responsible person name and telephone number (Note: Category B optional if on waybill; N/A for Dry ice)	<input type="checkbox"/>

 6	 UN3373	 9
<p>1. <b>Labels:</b> <b>Category A:</b> <b>Category B:</b> <b>GMOs/Dry Ice:</b></p> <p>2. <b>Technical Names:</b> <b>Category A</b> – <i>Infectious substance affecting humans OR Infectious substance affecting animals</i>; <b>Category B</b> – <i>Biological substance, Category B</i>; <b>GMOs</b> – <i>Genetically modified organism OR Genetically modified microorganism</i>; <b>Dry ice</b> – <i>Dry ice OR Carbon dioxide solid.</i></p>		



**III. Documentation:**

For Category A and GMO shipments, use the following checklist for completion of shipper's declaration form.

<b>Transport Information</b>	
1. Shipper's address (same as on package)	<input type="checkbox"/>
2. Recipient's address (same as on package)	<input type="checkbox"/>
3. Page 1 of 1 Pages	<input type="checkbox"/>
4. (Optional) Air waybill number (if known)	<input type="checkbox"/>
5. (Optional) Airport/city of departure (if known)	<input type="checkbox"/>
6. (Optional) Airport/city of destination (if known)	<input type="checkbox"/>
7. Strike-out non-applicable shipment type (Radioactive)	<input type="checkbox"/>
8. Strike-out non-applicable aircraft limitation box	<input type="checkbox"/>
<b>Nature and Quantity of Dangerous Goods</b>	
1. UN number (i.e., UN 2814, UN 2900, UN 1845, UN 3245)	<input type="checkbox"/>
2. Proper shipping name (e.g., <i>Biological substance, Category B</i> )	<input type="checkbox"/>
3. Technical name (CATEGORY A ONLY)	<input type="checkbox"/>
4. Class or Division (i.e., 6.2 and 9)	<input type="checkbox"/>
5. Type and number of package (e.g., 1 Fiberboard box)	<input type="checkbox"/>
6. Quantity (same as on package, volume or weight)	<input type="checkbox"/>
7. Packing instructions (i.e., 620, 954, 959)	<input type="checkbox"/>
8. Authorization (special provision A28)	<input type="checkbox"/>
<b>Additional Handling Information</b>	
1. Responsible person name and phone number	<input type="checkbox"/>
2. 24-hour emergency response telephone number (as required)	<input type="checkbox"/>
3. Name and title of personnel signing the declaration	<input type="checkbox"/>
4. Place and date of signature (printed or stamped only)	<input type="checkbox"/>
5. Certification statement	<input type="checkbox"/>
<b>Additional Considerations</b>	
1. Maintain three copies (one for shipper and two given to transporter)	<input type="checkbox"/>
2. Any changes: single line cross-out and certifier's full signature	<input type="checkbox"/>
3. IATA DGR compliant form (i.e., red hatchings, UN number in first column)	<input type="checkbox"/>





**EXAMPLES OF CATEGORY A INFECTIOUS SUBSTANCES**

**Category A Infectious Substances**

**UN 2814 Infectious Substances Affecting Humans**

<i>Bacillus anthracis</i> (cultures only)	Japanese Encephalitis virus (cultures only)
<i>Brucella abortus</i> (cultures only)	Junin virus
<i>Brucella melitensis</i> (cultures only)	Kyasanur Forest disease virus
<i>Brucella suis</i> (cultures only)	Lassa virus
<i>Burkholderia mallei</i> - <i>Pseudomonas mallei</i> - Glanders (cultures only)	Machupo virus
<i>Burkholderia pseudomallei</i> - <i>Pseudomonas pseudomallei</i> (cultures only)	Marburg virus
<i>Chlamydia psittaci</i> - avian strains (cultures only)	Monkeypox virus
<i>Clostridium botulinum</i> (cultures only)	<i>Mycobacterium tuberculosis</i> (cultures only)
<i>Coccidioides immitis</i> (cultures only)	Nipah virus
<i>Coxiella burnetii</i> (cultures only)	Omsk hemorrhagic fever virus
Crimean-Congo hemorrhagic fever virus	Poliovirus (cultures only)
Dengue virus (cultures only)	Rabies virus (cultures only)
Eastern equine encephalitis virus (cultures only)	<i>Rickettsia prowazekii</i> (cultures only)
<i>Escherichia coli</i> , verotoxigenic (cultures only)	<i>Rickettsia rickettsii</i> (cultures only)
Ebola virus	Rift Valley fever virus (cultures only)
Flexal virus	Russian spring-summer encephalitis virus (cultures only)
<i>Francisella tularensis</i> (cultures only)	Sabia virus
Guanarito virus	<i>Shigella dysenteriae</i> type 1 (cultures only)
Hantaan virus	Tick-borne encephalitis virus (cultures only)
Hantavirus causing hemorrhagic fever with renal syndrome	Variola virus
Hendra virus	Venezuelan equine encephalitis virus (cultures only)
Hepatitis B virus (cultures only)	West Nile virus (cultures only)
Herpes B virus (cultures only)	<i>Yersinia pestis</i> (cultures only)
Human immunodeficiency virus (cultures only)	Yellow fever virus (cultures only)
Highly pathogenic avian influenza virus (cultures only)	



**UN 2900 Infectious Substances Affecting Animals**

African swine fever virus (cultures only)  
Avian paramyxovirus Type 1 - Velogenic Newcastle disease virus (cultures only)  
Classical swine fever virus (cultures only)  
Foot and mouth disease virus (cultures only)  
Lumpy skin disease virus (cultures only)  
*Mycoplasma mycoides* - Contagious bovine pleuropneumonia (cultures only)  
Peste des petits ruminants virus (cultures only)  
Rinderpest virus (cultures only)  
Sheep-pox virus (cultures only)  
Goatpox virus (cultures only)  
Swine vesicular disease virus (cultures only)  
Vesicular stomatitis virus (cultures only)

Infectious substances meeting these criteria which cause disease in humans or both in humans and in animals must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900. Assignment to UN2814 or UN 2900 must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individuals circumstances of the source human or animal.

**NOTE:** The previous lists are not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the list but which meet the same criteria, must also be considered Category A. If there is doubt as to whether or not a substance meets the criteria it should be included in Category A.



**LIST OF MANUFACTURERS OF SHIPPING CONTAINERS FOR INFECTIOUS  
SUBSTANCES AND DRY ICE**

<p>Air Sea Atlanta 1234 Logan Circle Atlanta GA 30318 Phone: 404-351-8600 <a href="http://www.airseatlanta.com">http://www.airseatlanta.com</a></p>	<p>All-Pak, Inc. Corporate One West 1195 Washington Pike Bridgeville, PA 15017 Phone: 800-245-2283 <a href="http://www.all-pak.com">http://www.all-pak.com</a></p>	<p>CARGOPak Corporation 3215-A Wellington Court Raleigh, NC 27615 Phone: 800-266-0652 <a href="http://www.cargopak.com">http://www.cargopak.com</a></p>
<p>DG Supplies, Inc. 5 Boxal Drive Cranbury, NJ 08512 Phone: 800-347-7879 <a href="http://www.dgsupplies.com">http://www.dgsupplies.com</a></p>	<p>EXAKT Technologies, Inc. 7416 N Broadway Ext., Suite E Oklahoma City, OK 73116 Phone: 800-923-9123 <a href="http://www.exaktpak.com">http://www.exaktpak.com</a></p>	<p>HAZMATPAC, Inc 5301 Polk St., Bldg 18 Houston, TX 77023 Phone: 800-347-7879 <a href="http://www.hazmatpac.com">http://www.hazmatpac.com</a></p>
<p>Inmark, Inc. 220 Fisk Drive S.W. Atlanta, GA 30336-0309 Phone: 800-646-6275 <a href="http://www.inmarkinc.com">http://www.inmarkinc.com</a></p>	<p>JIT Certified, Inc. 1740 Fenpark Drive Fenton, MO 63026 Phone: 800-962-8636 <a href="http://www.jitcertifed.com">http://www.jitcertifed.com</a></p>	<p>Polyfoam Packers Corporation 2320 S. Foster Avenue Wheeling, IL 60090 Phone: 888-765-9362 <a href="http://www.polyfoam.com">http://www.polyfoam.com</a></p>
<p>SAF-T-PAK, Inc. 10807 - 182 Street Edmonton, Alberta, Canada, T5S 1J5 Phone: 800-814-7484 <a href="http://www.saftpak.com">http://www.saftpak.com</a></p>	<p>Source Packaging of New England, Inc. 405 Kilvert St. Warwick, RI 02886 Phone: 800-200-0366 <a href="http://www.sourcepak.com">http://www.sourcepak.com</a></p>	<p>Therapak Corporation 1440 Arrow Highway, Unit A Irwindale, California 91706 Phone: 888-505-7377 <a href="http://www.therapak.com">http://www.therapak.com</a></p>



## **ITEMS EXEMPT FROM INFECTIOUS SUBSTANCE SHIPPING REGULATIONS**

The following are not subject to the DOT requirements as Division 6.2 materials:

- A material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.
- Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic material.
- A material containing microorganisms that are non-pathogenic to humans or animals.
- A material containing pathogens that have been neutralized or inactivated such that they no longer pose a health risk.
- A material with a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include: Foodstuffs; environmental samples, such as water or a sample of dust or mold; and substances that have been treated so that the pathogens have been neutralized or deactivated, such as a material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.
- A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture.
- Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act (42 U.S.C. 264–272) and/or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).
- Blood, blood plasma, and blood components collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped as a Category A or Category B infectious substance, as appropriate.
- Dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material.
- A Division 6.2 material, other than a Category A infectious substance, contained in a



patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

- A human or animal sample (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

Note that live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the DOT Associate Administrator for Hazardous Materials Safety.

The shipping names "Diagnostic specimens" and "Clinical specimens" will no longer be permitted. Keep in mind that routine shipment of human or animal blood or tissue samples which are not known or suspected of containing a pathogen, and which are not being sent for pathogen testing, **are not considered infectious substances for shipping purposes and are therefore not regulated by DOT**. It is best to call these sorts of materials "patient specimens".

### **IATA Exceptions for Division 6.2 – IATA DGR 3.6.2.2.3**

The following substances are exempt from Division 6.2 materials as per the IATA Dangerous Goods Regulations:

- Substances that are not likely to cause disease in humans or animals.
- Substances containing micro-organisms which are not pathogenic to humans or animals.
- Substances in a form that any present pathogens have been neutralized or inactivated to the extent they no longer pose a health risk.
- Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection.

Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests, and blood or blood components collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for transplantation.



- There is also an exception for patient specimens for which there is minimal likelihood that pathogens are present. This exception does require special packaging and package marking.