

Louisiana State University Health Sciences Center New Orleans



Shipping Biological Materials Training

May 20, 2011

Training Overview

- Personnel who ship or prepare material classified as dangerous goods must complete training which meets the requirements of the U.S. Department of Transportation (DOT) and International Air Transport Association (IATA).
- This training satisfies the General Awareness, Security Awareness, & Function-Specific requirements of **49 CFR 172.704** and IATA Dangerous Goods Regulation (DGR) 1.5.
- See the **Shipping Biological Materials Policy & Manual** for more information.
- Note throughout the presentation **hyperlinks** are available to provide additional information.



Training Outline



PART I

- Training Overview
- Transportation Regulations
- Roles & Responsibilities
- Classifying Biological Materials for Shipment
- Packaging & Labeling Instructions
- Documentation – Shipper’s Declaration
- Packing Test Requirements
- Limited & Excepted Quantities
- Overpacks
- Other Definitions

PART II

- Security Awareness Video
- Shipping Biological Materials Quiz

Transportation Regulations



- **Several agencies** govern biological material shipments. Most shipments at LSUHSC are shipped domestically by ground/air and must follow DOT and IATA regulations.
- Additional regulations apply to shipments of extremely infectious Select Agents, international shipments, and materials shipped by rail or vessel.
- **Import permits** may be required for the importation of etiologic agents of humans, animals, and plants.
- The Department of Commerce regulates **exports** of etiologic agents. Consult the **Commerce Control List** (CCL) and coordinate with EH&S prior to any international shipments.
- Failure to comply with regulations can result in refusal of the shipment by the airline, penalties or fines, and/or jail.

Roles & Responsibilities

Personnel who ship Biological Materials shall:

- Complete this or equivalent training every two years.
- Maintain copies of shipping records for two years after material is accepted by initial carrier.
- Ensure all hazardous materials are properly identified, classified, packaged, marked, labeled, and documented.

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



Roles & Responsibilities



- Packages containing biological materials shall not be left unattended (e.g., left outside the FEDEX drop-off box or on a loading dock) or placed inside the FEDEX drop-off box.
- Contact the carrier (e.g., FEDEX and UPS) to schedule a pickup directly from laboratory or clinic.
- A dangerous goods account be established with FEDEX prior to shipping dangerous goods. Proof of dangerous goods training is required. Contact FEDEX at 1-800-463-3339 to establish a dangerous goods account.

Shipment of Biological Materials

The steps to properly ship biological materials include:

Classification



Packaging



Marking and Labeling



Documentation

The shipper is responsible for proper classification, identification, packaging, marking and labeling, and documentation of the material they wish to ship.

Several commercial vendors manufacture shipping systems. Click [here](#) for a representative vendor list.⁷



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 can spread disease when exposure occurs.

Classifying Biological Materials for Shipment



Biological materials are classified for transportation under the following categories:

- Category A Infectious Substances
 - Category B Biological Substances
 - Exempt Human and Exempt Animal Specimens
 - Genetically Modified Microorganisms (GMMOs) and Genetically Modified Organisms (GMOs)
 - Non-Regulated Biological Materials
-
1. The classification flow chart on next slide guides you on selecting appropriate material classification.
 2. After determining category, slides 11 – 28 guide you through proper material packaging & labeling.
 3. Slides 29 – 36 provide guidance on shipment documentation.

CLASSIFICATION FLOW CHART

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

Biological Material for Classification¹

- Are all microorganisms present in shipment non-pathogenic to humans and animals?
- Are the present pathogens neutralized or inactivated as to no longer pose a health risk?
- Are the materials a dried bloodspot, fecal occult blood, intended for transplant/transfusion?
- Is material known NOT to contain an infectious substance?

YES

NO OR UNKNOWN

- Is material on list of the examples of Category A infectious substances?
- Or is material capable of causing permanent disability, life-threatening or fatal disease in otherwise health humans or animals?

Is material a non-pathogenic GMMO or GMO?

YES

NO

Does material affect humans only?

Is material a direct patient specimen for which a professional judgment has determined it has a minimal likelihood of containing a pathogen? ²

YES

NO

YES

NO

NO OR UNKNOWN

YES

Then UN 2814
Infectious substance,
affecting humans
PI 620

Then UN 2900
Infectious substance,
affecting animals
PI 620

Then UN 3373
Biological substance,
Category B
PI 650

Exempt human specimen OR
Exempt animal specimen
(PI 650 recommended)

Then UN 3245
Genetically modified organisms and micro-organisms
PI 959

Not Regulated

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.

Preparing Biological Shipments

Category A Infectious Substances



Category A Infectious Substance are those capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. They have two shipping names:

- "Infectious substances, affecting humans" (UN 2814) or "Infectious substances, affecting animals" (UN 2900).
- Examples of include:
 - Cultures (laboratory stocks) of pathogens such as *Coxiella burnetii* (UN 2814) or *Vesicular stomatitis virus* (UN 2900).
 - Human blood or tissue known to contain or suspected of containing Ebola virus (UN 2814).
 - For a more detailed list of examples click [here](#).
- Always confirm with the carrier prior to pick-up that they are able to transport a Category A infectious substance.
- FedEx and World Courier will transport Category A infectious substances.

Preparing Biological Shipments

Category A Infectious Substances – Package Preparation



Package using a triple packaging system according to packing instructions 620 described below:

- Place material inside a leak proof primary receptacle (e.g., Vacutainertm).
- Place the primary receptacle into a leak-proof secondary receptacle (e.g., certain polyethylene bags). Either the primary or secondary receptacle must be able to with stand 95 kPa of pressure and temperatures from -40C to 55C.
- Place the secondary container inside an outer container and secured so it does not shift during transport. An itemized list of contents must be placed between the secondary and outer container. Do not mix unrelated materials in package.
- Outer container must meet specific quality tests and bear a printed UN specific markings which confirms requirements met. Maximum amount per outer package is 4kg / 4L.
- No other dangerous goods are allowed inside the outer package unless they are necessary for maintaining viability of material.

Preparing Biological Shipments

Category A Infectious Substances – Labeling

Shipments must have a class 6.2 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.
- 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 **Infectious substance, affecting humans, UN2814, ___ mL/ kg or 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 (e.g., dry ice) contained in package with the proper labels and markings on the box.

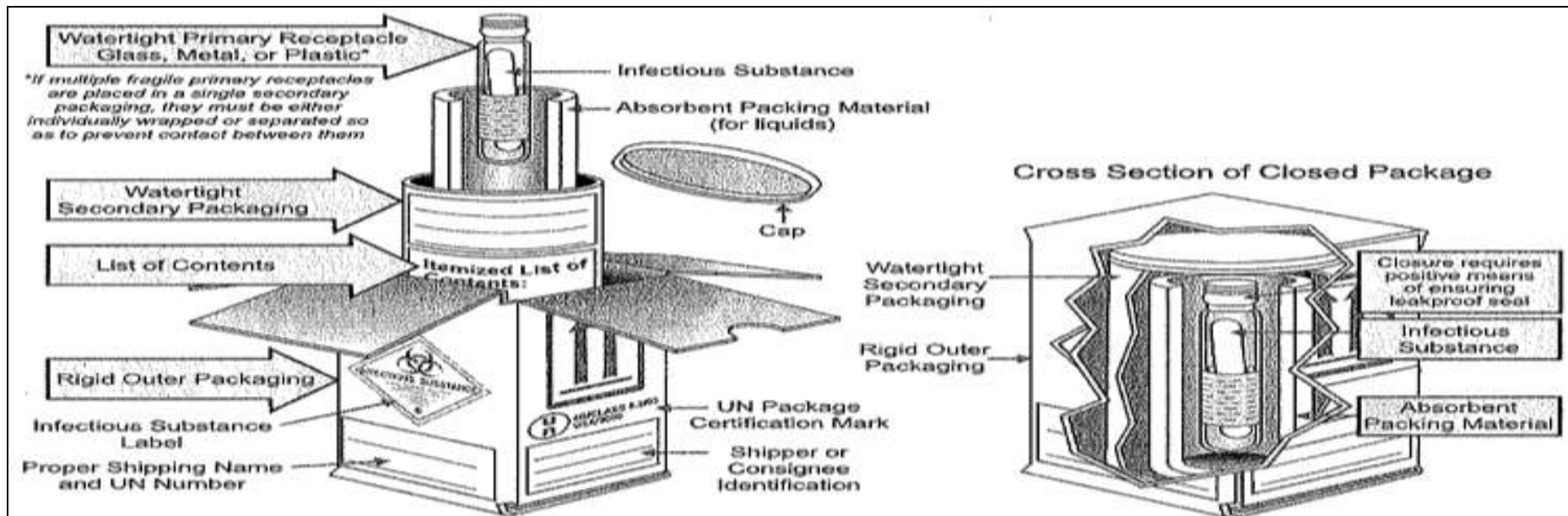
Preparing Biological Shipments

Category A Infectious Substances – Package Preparation

Example of outer container UN marking:



Example of completed package:



Preparing Biological Shipments

Category B Biological Substances



- **Category B Biological Substance** are those not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. This includes substances transported for diagnostic or investigational purposes. Additional **examples** include:
 - Hepatitis B infected blood, adenoviral vectors, or body fluids 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.

Preparing Biological Shipments

Category B Biological Substances – Packaging Preparation

Prepare the package according packing instructions 650 of the IATA DGR described below:

- Place material inside a leak proof primary receptacle which must be placed in a leak proof secondary receptacle. The primary or secondary receptacle must be able to withstand 95 kPa and temperatures from – 40° C to 55° C.
- Place the secondary container inside of an outer container and secured so it does not shift during transport. Place an itemized list of contents between the secondary and outer container.
- Outer container must be of good quality and able to withstand the shocks and pressures of transit. The outer container does not need the specific UN markings like on a Category A box.
- **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).



Preparing Biological Shipments

Category B Biological Substances – Labeling



Shipment must have the below label on the outside of the outer package. The label (at least 2" X 2") must be of a contrasting color to the package, clearly visible and legible.

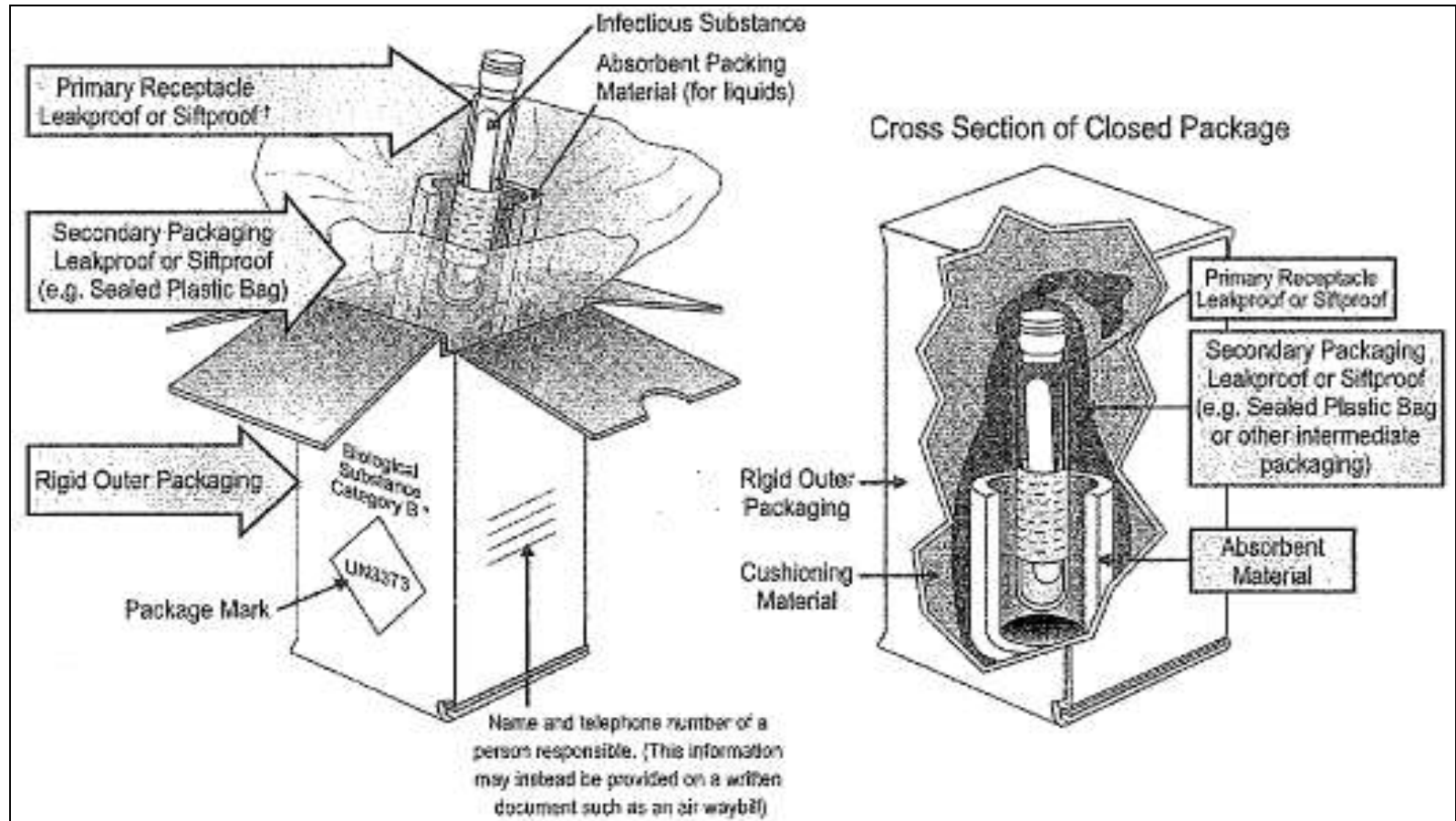


- All labels must be flat on one side of the package.
- Mark the proper shipping name: "**Biological Substance, Category B**" on the outer packaging adjacent to this label.
- Write or attach a label with the shipper's name, address, and telephone number and the consignee's name and address on the outside 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.

Preparing Biological Shipments

Category B Biological Substances – Labeling

Below illustrates a complete Category B package:





Preparing Biological Shipments

Exempt Human and Exempt Animal Specimens

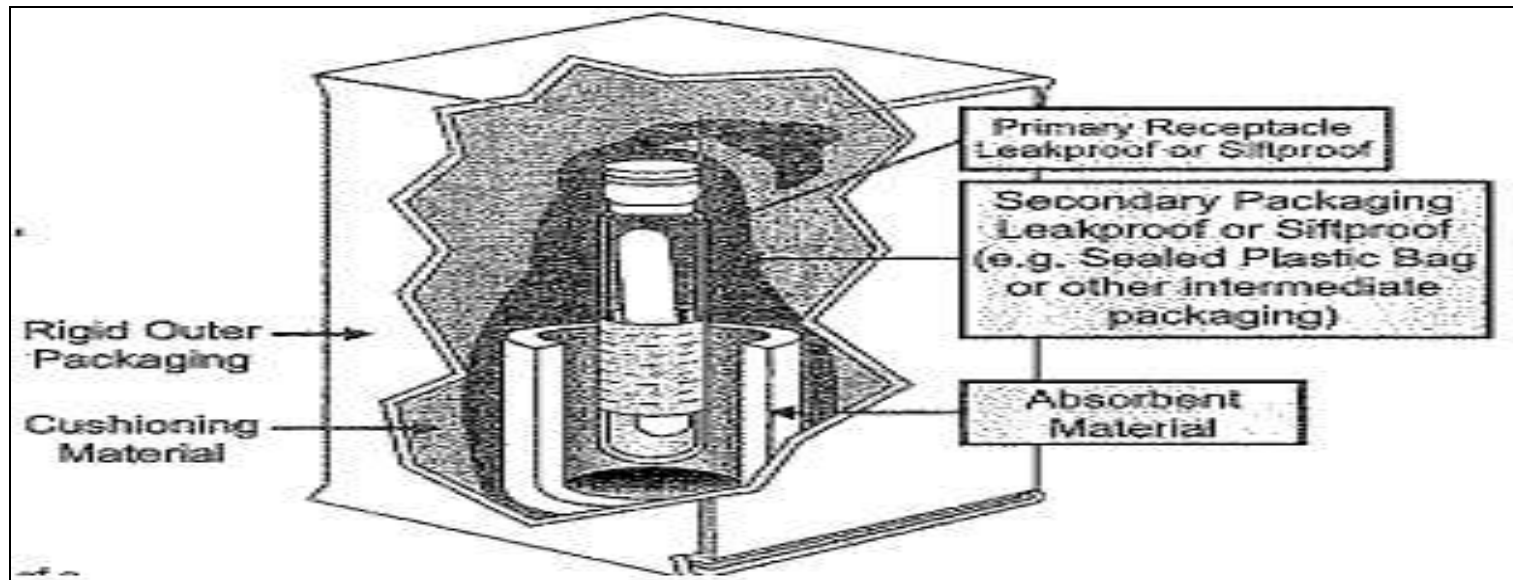
- Exempt specimens are taken directly from a human or animal subject and transported for research, diagnosis, investigational activities, or disease treatment or prevention and have a minimal likelihood of containing pathogens.
- Professional judgment is critical in determining the probability of pathogens being present in a specimen. The judgment should be based on medical history, symptoms and circumstances of the source, and endemic conditions of the local area.
- Patient specimens **examples** include excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media.
- **Additional examples** include blood or urine tests to monitor cholesterol, glucose, or hormone levels; testing to monitor organ functions such as heart, liver, or kidney for humans or animals with non-infectious diseases; also included are specimens for drug monitoring purposes, pregnancy tests, and biopsies for cancer detection or antibody detection.

Preparing Biological Shipments

Exempt Specimens – Package Preparation & Documentation

- Exempt specimens are packed according to the basic triple packing method, similar to Category B, Biological substances which includes a leak proof primary receptacle, leak proof secondary receptacle, and a rigid outer container
- The outer package must be marked with the words “EXEMPT HUMAN SPECIMEN” or “EXEMPT ANIMAL SPECIMEN”.

Example of Exempt Specimen Package:



Preparing Biological Shipments

GMMOs & GMOs

- Genetically Modified Micro-Organisms (GMMOs) and Genetically Modified Organisms (GMOs) 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.
- Classify GMMOs and GMOs that pose a risk of infection as Category A or Category B substances as appropriate. These materials must be assigned to UN 3245.



Preparing Biological Shipments

GMMOs & GMOs – Packaging Preparation



Follow packing instruction 959 of IATA DGR described below:

- Place material inside a leak proof primary receptacle. Place primary receptacle in a leak-proof secondary receptacle. 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. The secondary container is placed inside of an outer container and secured so that it does not shift during transport.
- 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).

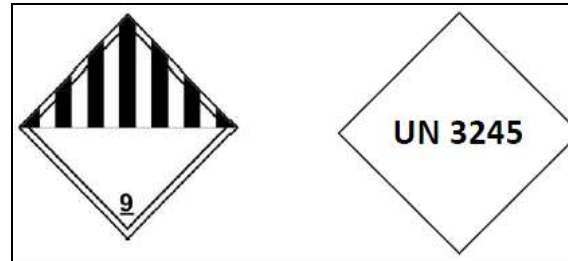
Preparing Biological Shipments

GMMOs & GMOs – Labeling & Documentation



Labeling:

- Use 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 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 (e.g., dry ice) contained in package with proper labels and markings on box.

Preparing Biological Shipments

Non-Regulated Biological Materials



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 (complete list found [here](#)):

- 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 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 and fecal occult blood screening tests.
- Blood or blood components collected for the purposes of transfusion or 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.



Preparing Biological Shipments

Other Regulated Materials

- Dry ice is often packaged with infectious substances and diagnostic specimens. Dry ice falls into hazard class 9.
- Liquid nitrogen is classified as a non flammable gas and cryogenic liquid. Liquid nitrogen falls into hazard class 2.2.
- 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 are 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 options are not subject to 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.

Preparing Biological Shipments

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 biological material 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.



Preparing Biological Shipments

Dry Ice – Packaging Preparation & Labeling

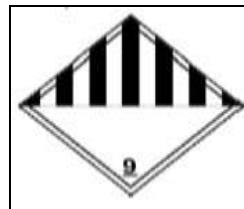


Pack according to packing instructions 954 in the IATA DGR described below:

- 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 CO₂ 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.

Labeling:

- Outer packages need a class 9 (miscellaneous) label.





Preparing Biological Shipments

Liquid Nitrogen – Packaging Preparation

- Liquid nitrogen is classified as a non flammable gas and cryogenic liquid.
- 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, closed cryogenic receptacle, or as a vapor shipper, contact EH&S for details on packing, labeling, and documenting.

Documentation

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.
- If the shipment does not require a shipper's declaration, the information must be included on the waybill.
- Category A infectious substances and GMMO/GMOs require a Declaration for Dangerous Goods for each shipment.
- Shipments containing Category B and Exempt Human/Animal Specimens do not require a shipper's declaration. If applicable, the "Nature and Quantity of Goods" section of the air waybill must be marked with "BIOLOGICAL SUBSTANCE, CATEGORY B" and "UN 3373".
- 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.
- 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>.



Documentation

Shipper's Declaration for Dangerous Goods

Below is an example shipper's declaration form, descriptions below:

SHIPPER'S DECLARATION FOR DANGEROUS GOODS						
Shipper LSU Health Sciences Center Jon Doe 123 Paved Avenue New Orleans, LA USA Tel: 5045681234				(A)	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				(B)		
Two completed and signed copies of this Declaration must be handed to the operator.				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.		
TRANSPORT DETAILS						
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>			Airport of Departure			
<input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT		<input checked="" type="checkbox"/> CARGO AIRCRAFT ONLY		(C)		
Airport of Destination				(D)	Shipment Type <i>(delete non-applicable)</i> NON-RADIOACTIVE - <input checked="" type="checkbox"/> EXTREMELY	
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 kgs All packed in one Fiberboard box.	904	
Additional Handling Information						
Emergency Telephone Number: 504-111-1111				(F)		
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:		
				(G)		

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.

Documentation

Shipper's Declaration for Dangerous Goods



- 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.



Documentation

Category A Infectious Substances

Use the information from the IATA table to fill out the Nature and Quantity section of the Dangerous Goods Declaration. Below is an **example** declaration for Category A infectious substances:

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 the proper shipping name must be supplemented with technical name in parentheses on the Declaration. 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 to check on the side of the document.
- If applicable, the **Nature and Quantity** box on the air waybill should read: *Infectious substance affecting humans or animals*.

Documentation

GMMO/GMOs & Dry Ice



- GMMOs and GMOs require a Declaration, **example** below:

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.
- If applicable, the Nature and Quantity box should read: *Genetically Modified Organisms* or *Genetically Modified Microorganisms*.
- If dry ice is the only hazardous item in the package then a Declaration 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 other dangerous goods are in package, complete Declaration as such:

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 All packed in one fibreboard box	954	

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 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 package must be able to pass the **drop, load, and puncture tests** described [here](#) 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.

Limited and Excepted Quantities



Limited Quantities:

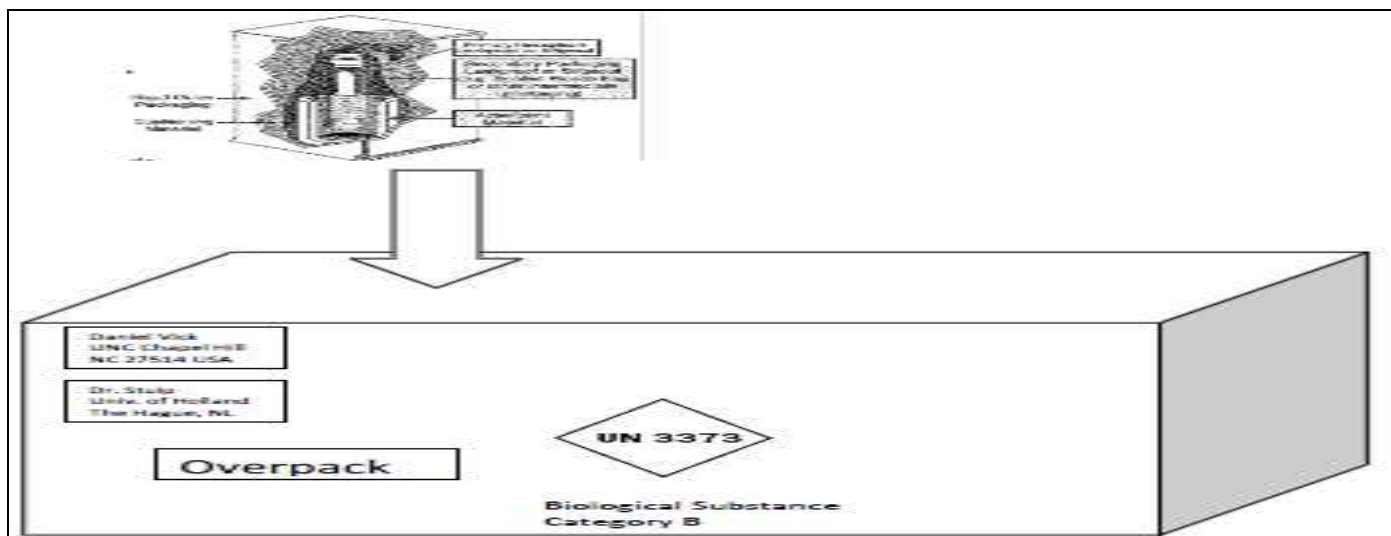
Other dangerous goods (e.g., dry ice) shipped with infectious substances that exceed the 30 mL limit may be shipped as a “Limited Quantity.” The quantity of the material determines whether it can be shipped as a limited quantity. Packing instructions for limited quantities have a prefix “Y” (e.g., Y305) for designation. Contact EH&S for more information if dangerous goods in excess of 30 mL.

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. A description of the EQ codes can be found [here](#).

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 to ship multiple dangerous goods packages as one piece to save money.
- 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.



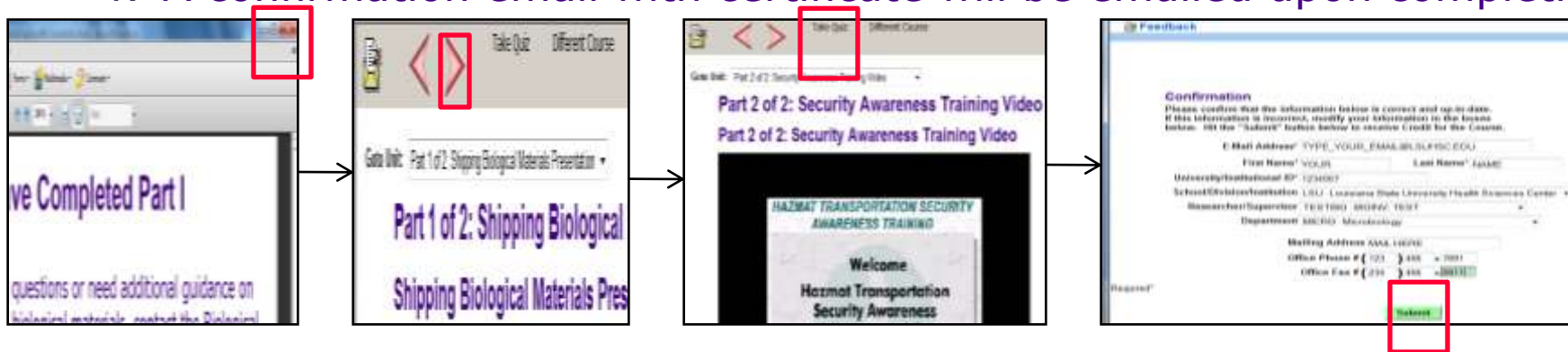
You Have Completed Part I



- If you have any questions or need additional guidance on the shipment of biological materials, contact the Biological Safety Officer, Aaron Pourciau, at 504-568-6586.
- In order to complete this Shipping Biological Materials Training, you must also complete:
 - **PART II VIDEO – SECURITY AWARENESS TRAINING**
 - **SHIPPING BIOLOGICAL MATERIALS QUIZ (80% required to pass)**

TO PROCEED:

1. Minimize or close this PDF training presentation.
2. Navigate to the Security Awareness video by selecting the 'next' red arrow.
3. After video, navigate to quiz by selecting 'next' arrow or 'Take Quiz'.
4. A confirmation email with certificate will be emailed upon completion.





REFERENCE SLIDES

Listing of Regulations page 1/5



- **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 up to 5 years (49 CFR 107.329 & 107.333). Penalties double when 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.

[Click to Return](#)

Listing of Regulations page 2/5



- **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>.

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IMPORTATION OF ETIOLOGICAL 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.
- **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.
- **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>.

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EXPORTATION

- **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.
- **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.

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Complete Listing of Regulations page 5/5



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.

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

Examples of Category A Infectious Substances

UN 2814 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, verotoxigenic</i> (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) Click to Return ⁵¹	

Examples of Category A Infectious Substances

UN 2900 Affecting Animals page 2/2



- 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)

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Items Exempt From Infectious Substance Shipping Regulations page 1/7



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.

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Exempt Items page 2/7



- 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.

Exempt Items page 3/7



- 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.

Exempt Items page 4/7



- 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.

Exempt Items page 5/7



- 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".

Exempt Items page 6/7



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.

Exempt Items page 7/7



- 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.

Packaging Test Requirements for Infectious Substances



Drop Test: Before the drop tests can be performed, the completed package must be preconditioned. 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.



Packaging Test Requirements for Infectious Substances

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.

○ 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.



Limited and Excepted Quantities

Excepted Quantities IATA Table:

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 Code 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.”