

APPENDIX A

GUIDELINES FOR TRANSPORT OF SPECIMENS

UNITED STATES POSTAL SERVICE  
DEPARTMENT OF TRANSPORTATION  
INTERNATIONAL CIVIL AVIATION ORGANIZATION

**Packaging and shipping of Infectious substances (Division 6.2 materials) is dependent on a few important steps:**

1. **Identification-** Identify that what you are attempting to send is a hazardous substance. An infectious substance is defined as a material known or reasonably expected to contain a pathogen that is likely to cause disease in humans or animals. It is also important to identify any additional hazardous materials that may be included with your sample/package such as dry ice.
2. **Classification-** If it has been determined that this is an infectious substance, the next step is classifying the hazard. There are two categories within the infectious substance classification: Category A and Category B. Category A infectious substances are defined as infectious substances transported in a form that when exposure occurs is capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals. A list of indicative agents for Category A classification is provided below. It is important to note that this list is non-inclusive, and may not contain new or emerging pathogens.

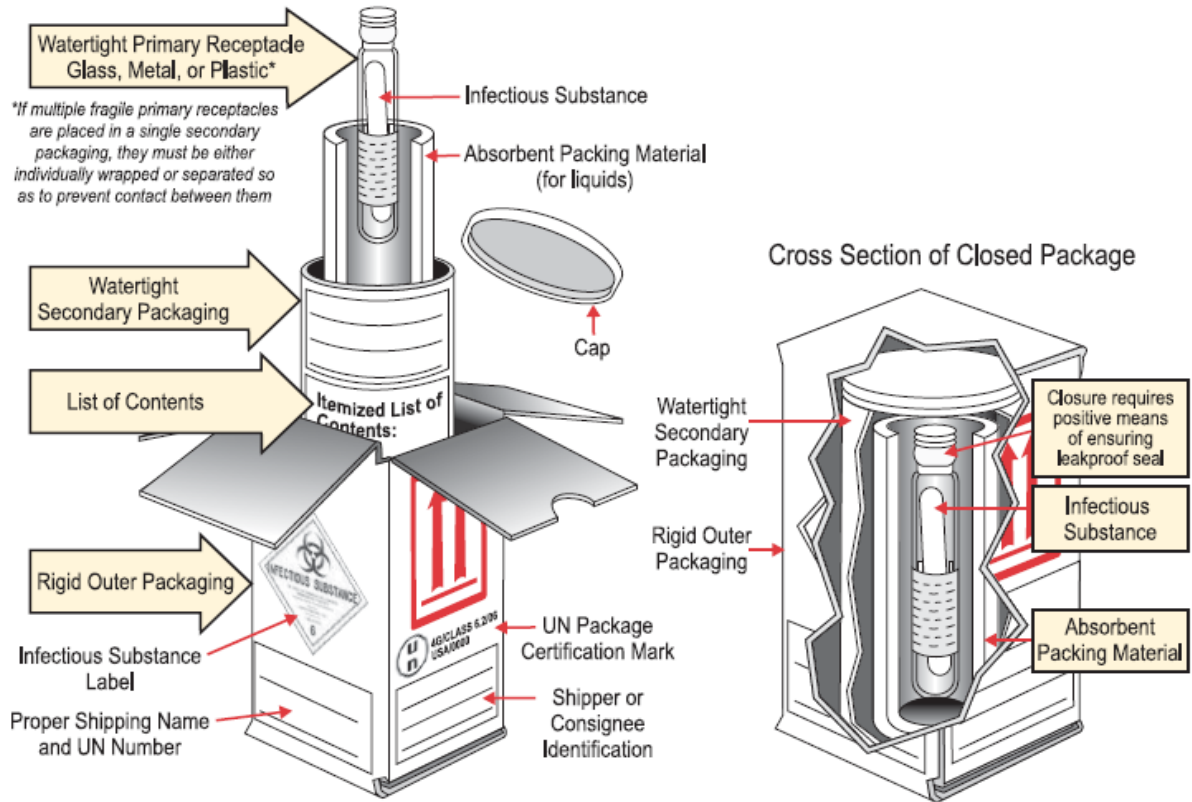
Bacillus anthracis (cultures only)	Lassa virus
Brucella abortus (cultures only)	Machupo virus
Brucella melitensis (cultures only)	Marburg virus
Brucella suis (cultures only)	Monkeypox virus
Burkholderia mallei (cultures only)	Mycobacterium tuberculosis (cultures only)
Burkholderia pseudomallei—(cultures only)	Nipah virus
Chlamydia psittaci-avian strains—(cultures only)	Omsk hemorrhagic fever virus
Clostridium botulinum (cultures only)	Poliovirus (cultures only)
Coccidioides immitis (cultures only)	Rabies and other lyssaviruses (cultures only)
Coxiella burnetti (cultures only)	Rickettsia prowazekii (cultures only)
Crimean-Congo hemorrhagic fever virus	Rickettsia rickettsia (cultures only)
Dengue virus (cultures only)	Rift Valley fever virus (cultures only)
Eastern equine encephalitis virus (cultures only)	Russian spring-summer encephalitis virus (cultures only)
Escherichia coli, verotoxigenic (cultures only)	Sabia virus
Ebola virus	Shigella dysenteriae type I (cultures only)
Flexal virus	Tick-borne encephalitis virus (cultures only)
Francisella tularensis (cultures only)	Variola virus
Guanarito virus	Venezuelan equine encephalitis virus (cultures only)
Hantaan virus	Vesicular stomatitis virus (cultures only)
Hantaviruses causing hemorrhagic fever with renal syndrome	West Nile virus (cultures only)
Hendra virus	Yellow fever virus (cultures only)
Junin virus	Yersinia pestis (cultures only)
Kyasanur forest disease virus	

Category B Infectious substances are defined as infectious substances that do not meet the criteria of a Category A infectious substance. Category B specimens can include both patient specimens and cultures.

- 3. Method of transport-**The next step is to identify the method of transport. This will determine the regulating agency and governing regulations. If you are sending it through the mail then the USPS/Domestic Mail manual regulations apply, surface transportation/vessel/rail/air are regulated by Department of Transportation/Hazardous Material Regulations. Air transport through International Air Transport Association (IATA) air carriers is regulated by the International Civil Aviation Organization/ International Air Transport Association (IATA) Dangerous Goods Regulations. It is important to note that the United States Postal Service will not accept Category A infectious substances.

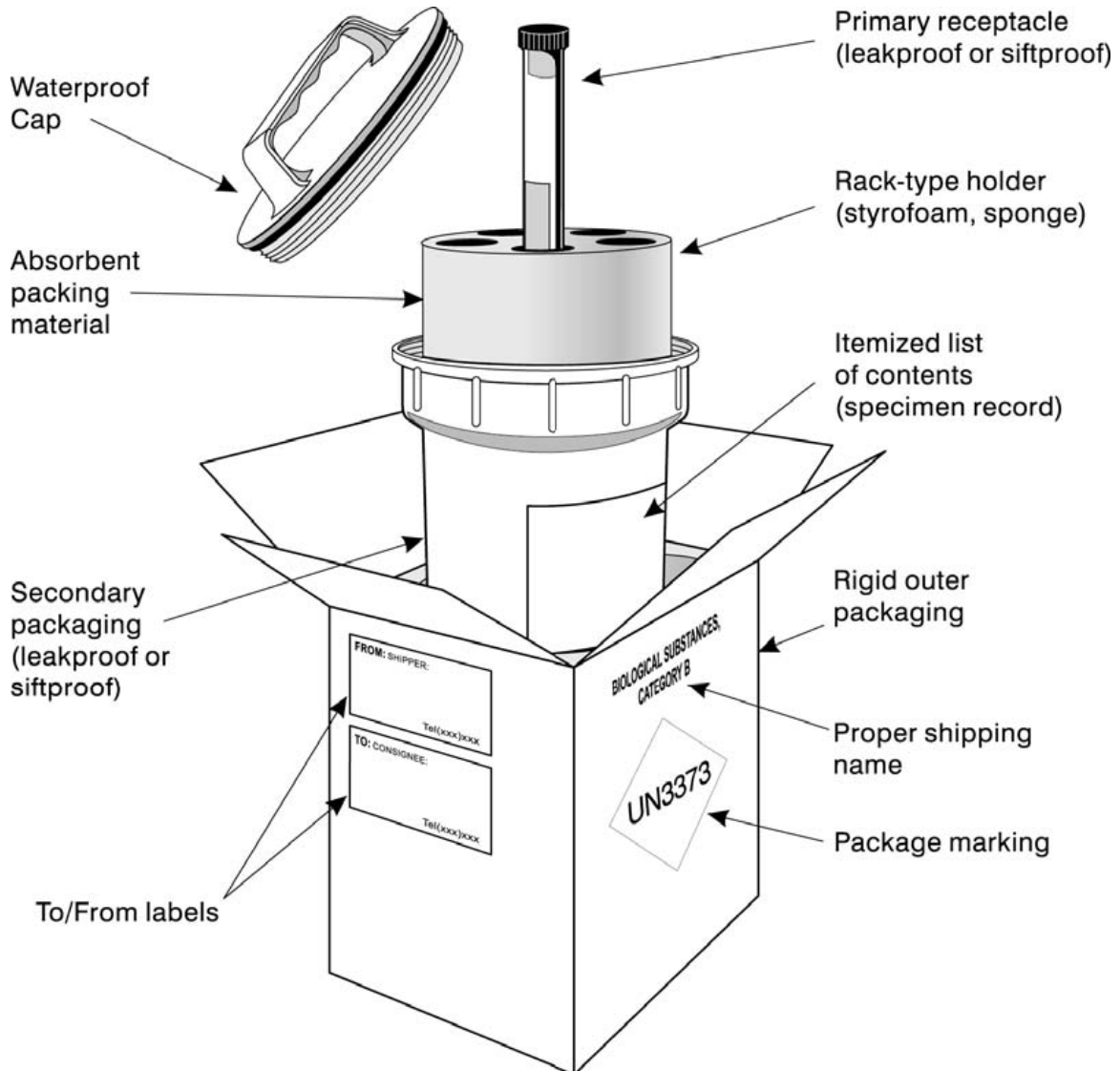
**4a. Package, Mark, and Label** -Example of Packing and Marking for Category A infectious substances

# Infectious Substances



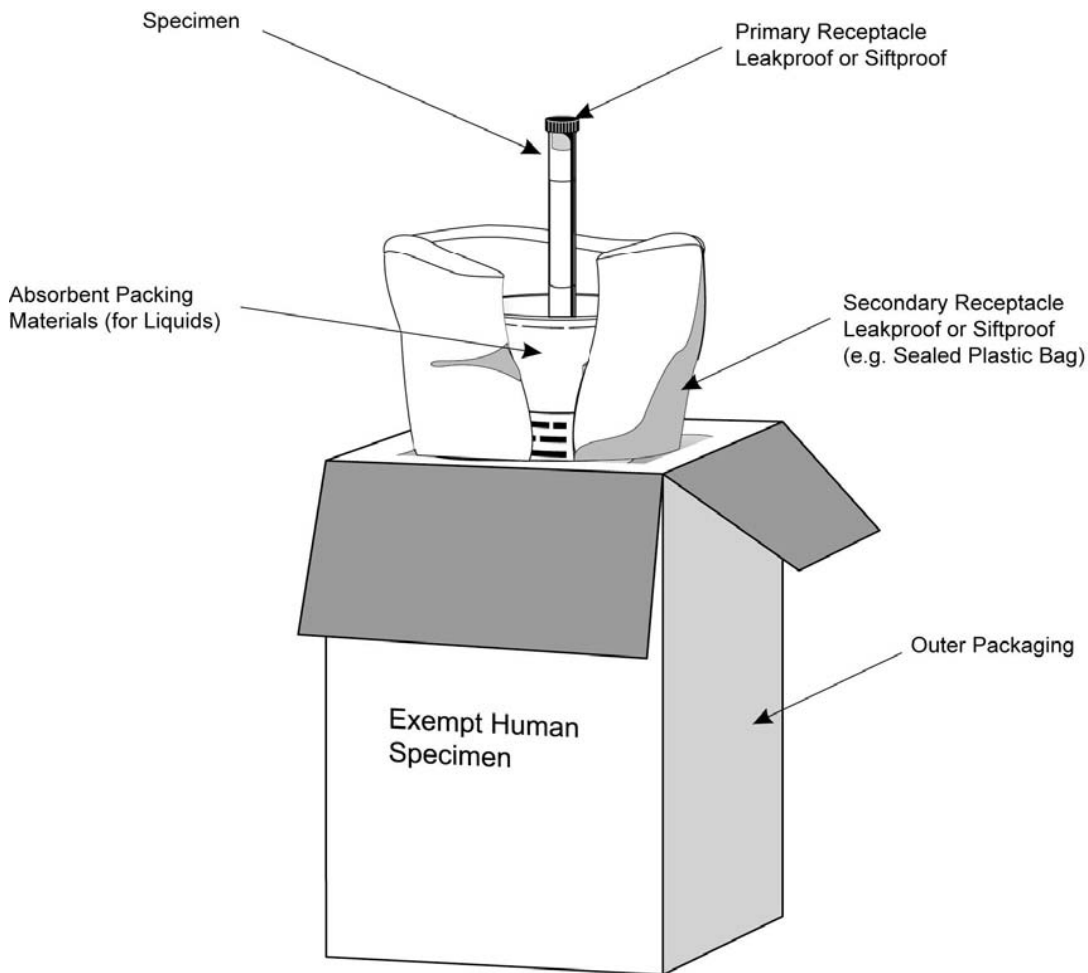
- Note 1:** The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)
- Note 2:** The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa
- Note 3:** Follow package manufacturer's closure instructions

**4b. Package, Mark, and Label** -Example of Packing and Marking for Category B infectious substances



1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The outer packaging must be of adequate strength for its capacity, mass and intended use.

4c. Package, mark, and label -Example of packing and marking for exempt specimens. This category includes human or animal specimens that are being transported for routine testing not related to an infectious disease. These specimens include those in which there is a low probability of the sample being infectious as determined through professional judgment taking into consideration known medical history, symptoms and source information, human or animal, and local endemic local condition. This category is used only when shipping through an IATA member carrier or through USPS.



1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The outer packaging must be of adequate strength for its capacity, mass and intended use.

- 5. Documentation** -The documentation required is dependent on the classification and the method of shipping. Both DOT And IATA require that a shipper's declaration form be completed when shipping Category A agents. The IATA dangerous goods form is a red candy striped form that must include shipper's and consignee's name and address and a 24/7 emergency phone number. This form must also contain the proper shipping name and UN number, the quantity, the packaging instructions followed and a detailed description of the contents and packaging. The form's declaration statement must also be signed. It is important to note that anyone packaging and shipping Category A agents **must** have documentation of appropriate training. For DOT, Category A infectious substances may be documented on the IATA form or on a separate form generated that contains the information in Section 172.202 of 49 CFR. Category B shipments being sent by air require an airway bill. Please note that pursuant to the 2010 IATA updates, the wording for the information to be included on the Air Waybill has been revised to include the number of packages.
- 6. Guidance**-The following sections provide additional guidance for each of the regulating agencies and their respective regulations.

## **United State Postal Service Division 6.2 Infectious Substance (Domestic Mail Manual)**

### **Category A Infectious Substances**

Under the domestic mail manual regulations Category A Infectious substances cannot be mailed.

### **Category B Infectious Substances**

#### ***Proper Shipping Name and ID Number***

All Category B infectious substances must meet the triple packaging requirements of 49 CFR 173.199 and be sent as Express Mail, Priority Mail, or First-Class Mail service. The proper shipping name Category B infectious substances is Biological substance, Category B and packages must be marked with the UN3373 identification number.

#### ***Required Packaging***

##### ***Primary Receptacle***

- The specimen material must be packaged in a durable and securely sealed primary receptacle.
- If the primary container contains a solid it must be sift proof.
- The volume in a single primary receptacle may not exceed 1 liter.
- Two or more primary receptacles whose total volume does not exceed 4L or 4kg may be enclosed in a secondary container.

##### ***Absorbent and Cushioning Material***

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

##### ***Secondary Packaging***

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- Either the secondary or primary container must be capable of withstanding an internal pressure differential of not less than 95kPa pressure without leakage.
- The secondary packaging must be marked with the international biohazard symbol.

*Outer Packaging (referenced from 49CFR 173.199)*

- The outer package must be sturdy and rigid so that the entire package is able to withstand normal transportation and handling without release of hazardous material into the environment.
- The packaging must be capable of successfully passing the drop tests of at least 1.2 meters (3.9 feet) without leakage from the primary receptacle.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

### Markings

- The address side of the mail piece must be clearly marked Biological Substance Category B and must be marked with the correct UN number (UN3373).
- Orientation arrows may be used but are not required.
- A name and phone number of a responsible person familiar with the contents and having emergency response information must be included on the outside of the package.

### **Exempt human/animal specimens**

This category includes human or animal specimen that are being transported for routine testing not related to an infectious disease. These specimens include those in which there is a low probability of the sample being infectious. These samples are not subject to hazardous material regulations but must meet packaging requirements found in 10.17.10.

### Required packaging

#### *Primary Receptacle*

- The specimen material must be packaged in a durable and securely sealed primary receptacle. If the primary container contains a solid it must be sift proof.
- The volume in a single primary receptacle may not exceed 500mL or 500g if a solid.
- Two or more primary receptacles whose total volume does not exceed 500mL or 500g may be enclosed in a secondary container.

#### *Absorbent and Cushioning Material*

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

#### *Secondary Packaging*

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.

- The secondary packaging must be marked with the international biohazard symbol.

#### *Outer packaging*

- The secondary packaging must fit securely in a rigid outer container such as a fireboard box not less than 3.9x3.9" in dimension.
- The outer container must be marked Exempt human or Exempt animal specimen.

#### **Not Regulated**

Specimens defined as not regulated under the Domestic mail manual 601 10.17.3 include: transfusion/transplant material, dried specimens including blood spots and feces, biological product, agricultural product, or forensic material containing a biological material not expected to contain a Category A or Category B infectious substance transported on behalf of a U.S. Government agency or a state, local, or Indian tribal government agency.

#### **Dry Ice-Carbon Dioxide Solid**

Dry ice shipped by air transport must be packaged according to domestic mail manual 10.20.4. In general, dry ice must be packaged in container that is designed and constructed to permit the release of carbon dioxide gas and prevent pressure build up within the package. Containers must conform to 49 CFR 173.217 and 175.10. In addition, air transport requires that each mail piece not contain more than 5 pounds of dry ice.

#### Proper Shipping Name and UN Number

The proper shipping name Dry ice or Carbon Dioxide solid along with the proper UN number UN1845 must be used with packages.

#### Markings (air transport)

- The outer container must have the following labels and markings: UN 1845
- Class 9 hazards label
- The net quantity of dry ice in each package
- Name and address of submitter and consignee.

#### Documentation (air transport)

- A shipper's dangerous goods declaration filled out in triplicate
- Proper shipping name of Dry Ice or Carbon Dioxide Solid
- Class 9 label
- The net quantity of dry ice in each package
- The number of packages

For surface transportation, the amount of dry ice per mail piece may exceed 5 pounds.

Markings (surface transportation)

- "Carbon Dioxide Solid" or "Dry Ice"
- "Surface Only" or "Surface Mail Only"
- The net weight of the dry ice and the identity of the contents being cooled.
- A shipper's declaration and a DOT Class 9 warning label are not required for surface transport of dry ice.

**Department of Transportation (DOT) –Hazardous Materials Regulations**

**Category A Infectious substances**

Proper Shipping Name and UN Number

All Category A infectious substances must meet the triple packaging requirements of 173.196. The proper shipping name if it is infectious for humans or humans and animals is Category A infectious substance infecting humans and is designated with a UN number of UN2814. If it is infectious for animals only, the proper shipping name is Category A infectious substance affecting animals with a UN number of UN 2900.

Required Packaging

Primary Receptacle

- The specimen material must be packaged in a leak proof securely sealed primary receptacle.
- If the primary container contains a solid it must be sift proof.

Absorbent and Cushioning Material

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

Secondary Packaging

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- Either the secondary or primary container must be capable of withstanding an internal pressure differential of not less than 95kPa pressure without leakage.
- The secondary packaging must be marked with the international biohazard symbol.

Itemized List of Contents

An itemized list of contents must be included between the secondary and outer packaging.

### *Outer Packaging*

- The packaging must be capable of successfully passing the drop tests of at least 35 ft and must meet UN 6.2 certification.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

### Markings

- Category A Infectious substance label
- U.N. specification certification
- Class 6.2 Infectious substance diamond
- Orientation arrows (if greater than 50mL)
- Name and 24/7 contact number of responsible person
- Shipper and Consignee name and address

### Documentation

DOT does not require a specific type of shipping paper. The IATA dangerous goods form may be used or a shipping paper may be developed. Section 172.202 of 49 CFR contains type & sequence of required information.

## **Category B Infectious substances**

### Proper Shipping Name and ID Number

All Category B infectious substances must meet the triple packaging requirements of 49 CFR 173.199. The proper shipping name Category B infectious substances is Biological substance, Category B and packages must be marked with the UN3373 identification number.

### Required Packaging

#### *Primary Receptacle:*

- The specimen material must be packaged in a leak proof primary receptacle.
- If the primary container contains a solid it must be sift proof.
- The volume in a single primary receptacle may not exceed 1 liter.
- Two or more primary receptacles whose total volume does not exceed 4L or 4kg may be enclosed in a secondary container.

#### *Absorbent and Cushioning Material*

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

#### *Secondary Packaging*

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing

- the failure of the secondary packaging should there be leakage from the primary receptacle.
- Either the secondary or primary container must be capable of withstanding an internal pressure differential of not less than 95kPa pressure without leakage.
  - The secondary packaging must be marked with the international biohazard symbol.

*Outer Packaging (referenced from 49CFR 173.199):*

- The outer package must be sturdy and rigid so that the entire package is able to withstand normal transportation and handling without release of hazardous material into the environment.
- The packaging must be capable of successfully passing the drop tests of at least 1.2 meters (3.9 feet) without leakage from the primary receptacle.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

Markings

- The address side of the mail piece must be clearly marked Biological Substance Category B and must be marked with the correct UN number (UN3373).
- Orientation arrows may be used but are not required.
- A name and phone number of a responsible person familiar with the contents and having emergency response information must be included on the outside of the package.
- Shipper and Consignee name and address

**Not Regulated**

This category Includes human or animal specimen that are being transported for routine testing not related to an infectious disease. These specimens include those which there is a low probability of the sample being infectious. These samples are not subject to hazardous material regulations.

**Dry Ice-Carbon Dioxide Solid**

Dry ice shipped by air transport must be packaged according to Packing Instructions 954. In general, dry ice must be packaged in container that is designed and constructed to permit the release of carbon dioxide gas and prevent pressure build up within the package.

Proper Shipping Name and UN Number

The proper shipping name Dry ice or Carbon Dioxide solid along with the proper UN number UN1845 must be used with packages submitted for air transport

Markings

- The outer container must have the following labels and markings:
- UN 1845

- Class 9 hazard label
- The net quantity of dry ice in each package
- Name and address of submitter and consignee.

### Documentation

Documentation on a Dangerous Goods Form is required only when used as a refrigerant for other Dangerous Goods. Otherwise, the airway bill must contain the following information:

- The proper UN number (UN1845)
- Proper shipping name of Dry Ice or Carbon Dioxide Solid
- Class 9
- The net quantity of dry ice in each package
- The number of packages

## **International Civil Aviation Organization (ICAO)** **International Air Transport Association (IATA)-Dangerous Goods** **Regulations**

### **Category A Infectious substances**

#### Proper Shipping Name and UN Number

All Category A infectious substances must meet the triple packaging requirements of Packing Instructions 620. The proper shipping name if it is infectious for humans or humans and animals is Category A infectious substance infecting humans and is designated with a UN number of UN2814. If it is infectious for animals only, the proper shipping name is Category A infectious substance affecting animals with a UN number of UN 2900.

#### Required Packaging

##### Primary Receptacle

- The specimen material must be packaged in a leak proof securely sealed primary receptacle.
- If the primary container contains a solid it must be sift proof.

##### Absorbent and Cushioning Material

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

##### Secondary Packaging

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing

- the failure of the secondary packaging should there be leakage from the primary receptacle.
- Either the secondary or primary container must be capable of withstanding an internal pressure differential of not less than 95kPa pressure without leakage.
  - The secondary packaging must be marked with the international biohazard symbol.

#### *Itemized List of Contents*

An itemized list of contents must be included between the secondary and outer packaging.

#### *Outer Packaging*

- The packaging must be capable of successfully passing the drop tests of at least 35 ft and must meet UN 6.2 certification.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (4"x4").

#### Markings

- The outer container must have the following labels and markings:
- Shipper and Consignee name and address
- Category A Infectious substance label
- U.N. specification certification
- Class 6.2 Infectious substance diamond
- Orientation arrows (if greater than 50mL)
- Name and 24/7 contact number of responsible person

#### Documentation

- The Shipper's Declaration Form must be filled out completely and accurately.
- The form must have a red border and must be submitted on the outside of the package. The shipper must always keep at least one copy of the form.
- Shippers such as Fed-Ex may have additional requirements including that the form must be typed and the number of copies required for shipment. These shippers should be consulted prior to submitting dangerous goods for shipping.

### **Category B Infectious substances**

#### Proper Shipping Name and ID Number

All Category B infectious substances must meet the triple packaging requirements of Packing Instructions 650. The proper shipping name Category B infectious substances is Biological substance, Category B and must be marked with the UN3373 identification number.

### Required Packaging

#### *Primary Receptacle*

- The specimen material must be packaged in a leak proof primary receptacle.
- If the primary container contains a solid it must be sift proof.
- The volume in a single primary receptacle may not exceed 1 liter.
- Two or more primary receptacles whose total volume does not exceed 4L or 4kg may be enclosed in a secondary container.

#### *Absorbent and Cushioning Material*

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

#### *Secondary Packaging*

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- Either the secondary or primary container must be capable of withstanding an internal pressure differential of not less than 95kPa pressure without leakage.
- The secondary packaging must be marked with the international biohazard symbol.

#### *Itemized List of Contents*

An itemized list of contents must be included between the secondary and outer packaging.

#### *Outer Packaging*

- The outer package must be sturdy and rigid so that the entire package is able to withstand normal transportation and handling without release of hazardous material into the environment.
- The packaging must be capable of successfully passing the drop tests of at least 1.2 meters (3.9 feet) without leakage from the primary receptacle.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (4"x4").

### **Exempt human/animal specimens**

This category includes human or animal specimen that are being transported for routine testing not related to an infectious disease. These specimens include those in which there is a low probability of the sample being infectious as determined through professional judgment taking into consideration known medical history, symptoms and source information, human or animal and local

endemic local conditions. These samples are not subject to hazardous material regulations but must meet packaging requirements found in IATA 3.6.2.2.3.6.

### Required packaging

#### *Primary Receptacle*

- The specimen material must be packaged in a durable and securely sealed primary receptacle. If the primary container contains a solid it must be sift proof.
- The volume in a single primary receptacle may not exceed 500mL or 500g if a solid.
- Two or more primary receptacles whose total volume does not exceed 500mL or 500g may be enclosed in a secondary container.

#### *Absorbent and Cushioning Material*

Absorbent material must surround the primary receptacle or be otherwise configured to take up all of the liquid content in the primary receptacle in case of leakage. Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.

#### *Secondary Packaging*

- The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging that has a leak proof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- The secondary packaging must be marked with the international biohazard symbol.

#### *Outer packaging*

- The secondary packaging must fit securely in a rigid outer container such as a fireboard box not less than 4x4" in dimension.
- The outer container must be marked Exempt human or Exempt animal specimen.

### **Not Regulated**

Specimens defined as not regulated under IATA dangerous goods regulations include: samples that are sterile/killed or inactivated, organisms that are non-pathogenic for humans/animals, environmental samples, transfusion/transplant material, dried specimens including blood spots and feces, biological product, agricultural product, or contaminated materials such as laundry or medical equipment.

### **Dry Ice-Carbon Dioxide Solid**

Dry ice shipped by air transport must be packaged according to Packing Instructions 954. In general, dry ice must be packaged in container that is

designed and constructed to permit the release of carbon dioxide gas and prevent pressure build up within the package.

Proper Shipping Name and UN Number

The proper shipping name Dry ice or Carbon Dioxide solid along with the proper UN number UN1845 must be used with packages submitted for air transport

Markings

The outer container must have the following labels and markings:

- UN 1845
- Class 9 hazards label
- The net quantity of dry ice in each package

Documentation

Documentation on a Dangerous Goods Form is required only when used as a refrigerant for other Dangerous Goods. Otherwise, the airway bill must contain the following information.

- The proper UN number (UN1845)
- Proper shipping name of Dry Ice or Carbon Dioxide Solid
- Class 9
- The net quantity of dry ice in each package
- The number of packages

**Federal Express**

For additional guidance using Federal Express please consult the Fed-Ex Website

<http://www.fedalexpress.com/us/services/options/index.html>

[http://images.fedex.com/us/packaging/guides/UN3373\\_fxcom.pdf](http://images.fedex.com/us/packaging/guides/UN3373_fxcom.pdf)