

## **SHIPPING SOP**

### **Purpose & Scope**

The purpose of this SOP is to define and outline the shipping of specimens from collection sites within the United States to the GAPPS main repository in Seattle. It does not cover requirements for shipping specimens from international sites to the GAPPS main repository or transport of specimens within institutions. The GAPPS project does not intend to collect or ship specimens that fall under the category “Infectious Substance UN2814 or UN2900”, therefore the focus of this SOP will be aimed at the “Human Exempt” and “Biological Substance Category B” shipping classifications.

\*Please note, this SOP may be used as a guide, but it is not the final authority for shipping regulations or a substitute for certified training on shipping hazardous goods.

### **Authority Source**

IATA regulations are the most widely accepted authority worldwide for shipping specimens and are the regulation accepted internationally for air transport of specimens. GAPPS specimen shipments will be packaged under IATA guidelines and should meet shipping requirements at collection sites. Please notify the GAPPS Repository if guidelines within this SOP do not meet the guidelines at your institution.

### **Delivery Options:**

There are two primary means to deliver collected specimens to the GAPPS Repository Coordinating Center.

- 1) Courier/personal delivery
- 2) Conventional shipping using Federal Express overnight

Courier/personal delivery is preferred by GAPPS Repository, but for sites outside of the Seattle Metropolitan area, conventional shipping may be used. Please reference appendix C for the site shipping schedule.

### **Courier/Personal Delivery:**

1. The DOT does not regulate specimens transported via dedicated couriers in dedicated motor vehicles, including private or contracted couriers. Examples include transporters who carry specimens within a building, or GAPPS/Seattle Children’s-sponsored couriers transporting specimens in vehicles owned by GAPPS/Seattle Children’s. It does not include taxi, commercial shipping companies, US Mail or employees transporting specimens in their private vehicle.

2. The primary specimen container (i.e. vacutainer, urine cup) must be leakproof, and tightly closed. It must be recognizable as containing specimen so that all personnel handling it will practice Universal Precautions.

3. Primary containers must be placed within a watertight secondary container. For example, seal the test tube in a leakproof plastic bag. It is good practice to place absorbent material between the bag and the tube to cushion the tube and absorb leakage from improperly sealed tubes. Contact the GAPPS Repository for supplies of specimen bags.

4. Couriers should transport specimen containers in secure, crush-resistant outer carriers as described in the IATA section below. There may be more than one secondary package, but no more than 4 liters of liquid or 4 kg of solids per outer package.

5. The specimen transporter should carry an itemized manifest of shipment contents (see section below for further details) and potential hazards should be documented on overpack. Contact the GAPPS Repository for shipping supplies.

### **Conventional Shipping:**

All specimens that are shipped using conventional shipping should be packed according to IATA guidelines as outlined below:

### **Specimen Classifications**

There are 3 official categories of specimens:

1. **Infectious Substance:** Substances containing or suspected to contain highly pathogenic agents referred to as Category A infectious substances.
  - **UN 2814** Infectious substances affecting humans
  - **UN 2900** Infectious substances affecting animals
2. **Biological Substance, Category B: (UN 3373)** Substances containing or suspected to contain infectious substances that do not meet Category A criteria.
3. **Exempt Human Specimens:** Minimal likelihood that pathogens are present (non-infectious) *Patient specimens* (collected from human or animals for research, diagnosis, etc) must be assigned to one of the three above classifications as appropriate. GAPPS specimens will predominately fall under the classification of “Exempt”, and occasionally specimens that are identified as infectious may fall under “Biological Substance Category B” in cases where HIV or other Category B substances are known to be present in specimens.

### **Packing Instructions 650**

Packaging requirements for “Biological Substance Category B” and “Exempt” specimens are very similar except for classification markings on the outside of the shipper container. GAPPS will ask sites to follow IATA packing instructions 650 for shipments, making sure to apply the correct classification labeling listed above and documentation for each shipment type on the exterior of every shipment. See shipment packaging diagram appendices.

#### **1. Liquids**

- a) Leak-proof primary receptacle and must not contain more than 500 mL.
- b) Leak-proof secondary packaging. Absorbent material must be placed between the primary and secondary packaging and be able to absorb all liquid material inside secondary packaging.
- c) Outer packaging of adequate strength for its capacity and intended use and able to withstand a pressure differential of 95 kPa and temperatures of -40°C to 55°C (-40°F to 130°F) without leaking.

- d) At least one side of the packaging must have a minimum dimension of 100 mm x 100 mm.
- e) The outer packaging must not contain more than 4 L.

## 2. Solids

- a) Primary receptacles must be sift proof and contain no more than 500g.
- b) If more than one fragile or breakable primary receptacle is packaged together they must be wrapped or separated to prevent contact. Multiple primary receptacles must be placed in secondary packaging that is leak or sift proof.
- c) The outer packaging must not contain more than 4 kg.

## Hazardous Materials

Materials sometimes used to maintain a stable environment for specimens during shipping are classified as "hazardous materials". The materials listed below are substances that may be used in shipping frozen specimens or tissues.

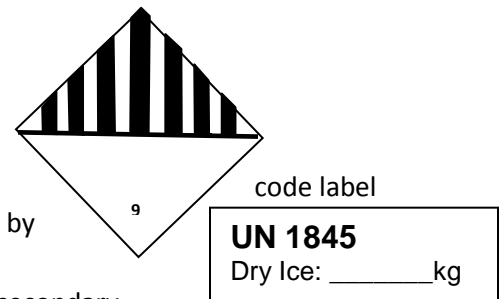
### 1. Dry Ice

#### a. **Hazard:**

- Dry ice is a substance that gives off CO<sub>2</sub> gases as it sublimates. CO<sub>2</sub> gases can build up in confined spaces and cause asphyxia. Proper ventilation should always be present when working with or storing dry ice. Also, if dry ice is kept in air tight conditions these gases can build up enough pressure and become explosive. Therefore dry ice should always be stored and shipped in containers that allow venting.

#### b. **Shipping:**

- Dry ice is a class 9 hazardous substance and requires a Miscellaneous Class 9 hazard label on the outer packaging.
- Dry ice also requires a specific UN 1845, identification on the outer packaging that lists the quantity of dry ice by weight within the container.
- Dry ice must be shipped in insulated containers with a secondary fiberboard over pack. Do not tape



### 2. Formalin

#### a. **Hazard:**

- Formalin or Formaldehyde is a colorless gas with a strong odor that is sold commercially in a methanol and water solution. It is used as a preservative of biological tissue as well as in other industrial processes. Formalin in high concentrations is considered a carcinogen, mutagen and is flammable. It can irritate the lungs when inhaled and can be absorbed through the skin; therefore it should be handled with gloves in properly ventilated locations and stored in leak proof containers.
- Formalin used for the fixing of GAPPS tissues is at a < 10% solution in a neutralized buffer and falls under a non-regulated category for shipping at this concentration.

b. **Shipping < 10% Formalin:**

- GAPPS specimen shipments that contain tissues in 10% formalin do not require special labels on the exterior of the package specific to formalin. Other labeling for tissues or dry ice may apply, see specimen classifications.

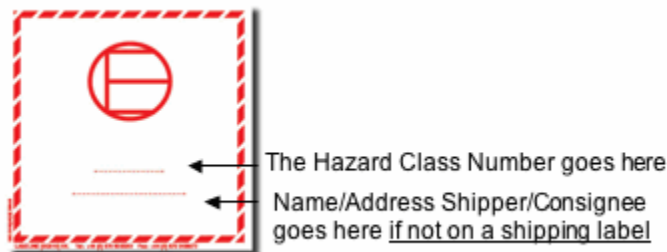
3. **Ethanol**

a. **Hazard:**

- Ethanol is a flammable substance and produces explosive fumes.

b. **Shipping Ethanol Solutions:**

- Ethanol may be shipped by air when in limited quantities, no more than 30ml EtOH per primary container and a maximum of 500ml per package.
- No shipping papers are required; however, a “Dangerous Goods in Limited Quantities” sticker must be affixed to the outside of the box. Ethanol’s Hazard Class = 3. Other useful numbers: UN Number = UN1170 and US DOT Packing Group = II



“Dangerous Goods in Limited Quantities” sticker

**Shipping Paper Work**

1. A printed manifest should accompany all GAPPS shipments. An itemized list of contents and quantities must be enclosed between the secondary packaging and the outer packaging of each shipment. If multiple outer boxes are part of one shipment job or tracking event then a single manifest will suffice for the entire shipment.
2. All shipments of hazardous materials must describe any hazardous materials on applicable shipping papers (e.g., waybill) as required by the IATA regulations.
3. Each person who provides a shipping paper must retain a copy of the shipping paper, or an electronic image thereof, such that it is accessible at or through its principal place of business and available, upon request, to an authorized official of a Federal, State, or local government agency at reasonable times and locations.
4. For all hazardous materials, the shipping paper must be retained for two (2) years after the material is accepted by the initial carrier. Each shipping paper copy must include the date of acceptance by the initial carrier (e.g., the date on the shipment waybill, Airbill, or bill of lading may be used in place of the date of acceptance by the initial carrier).

Special labeling and documentation is required when shipments will or might go via aircraft, and contain more than 30 ml of 10% formalin. Package must bear a “Class 9” hazardous materials diamond-shaped label, and the words “Aviation regulated liquid, n.o.s (10% formalin) UN3334”. See page 8 for a printable version of this label.

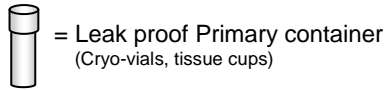
The package must be accompanied by a Shipper's Declaration for Dangerous Goods which provides the name, address and phone number of the shipper and consignee, the proper shipping name, class, UN number, quantity and description of packing, the statement "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations." It must have a statement with an emergency phone number of the shipper. It must bear a signature of the person responsible for shipping the package.

The original and 2 copies (color copies may be required) are placed in an unsealed pouch on the outside of the package. Some carriers may require prior arrangements or the use of their own version of the form. For an example and a partially completed printable version of the Shipper's Declaration of Dangerous Goods, see page 9. UPS will not accept these packages. Links to additional materials:

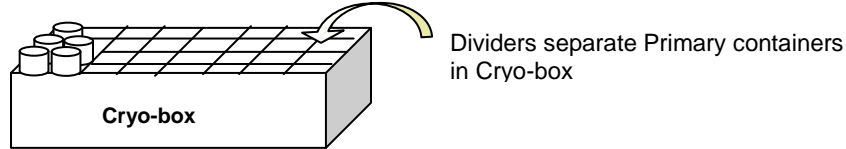
- DOT Final Rule: <http://hazmat.dot.gov/regs/notices/rulemake.htm>
- DOT Hazmat Regulations: <http://www.myregs.com/dotrspa/>
- International Air Transportation Association: <http://www.iata.org/dgr>
- Excellent shipping support materials: <http://www.unh.edu/research/shipping-hazardous-materials>

## Shipment Packaging Diagram - Human Exempt w/Dry Ice

1. Specimens are placed in Leak proof primary containers



2. Multiple Primary containers are placed into cryo-boxes with dividers to prevent contact.

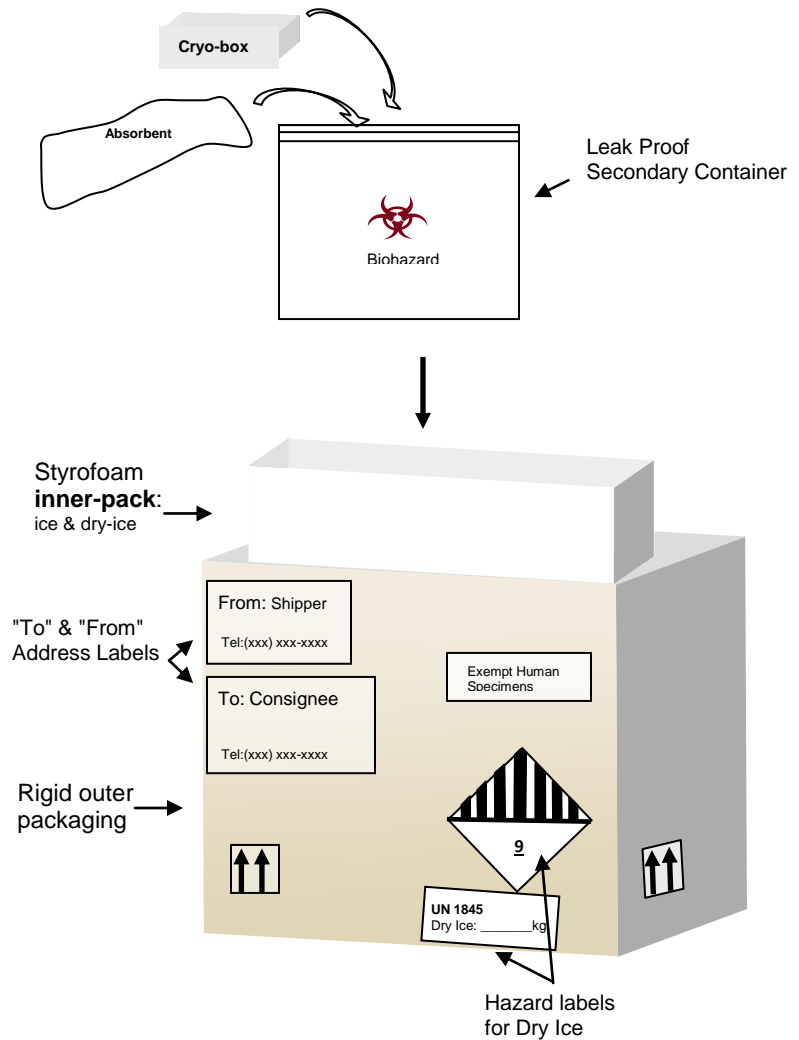


3. Cryo-box with lid and rubber band holding lid on are placed into a leak proof biohazard bag with absorbent material. Absorbent material must be able to absorb all of the liquid in case of leak.

1. **Create manifest:**
  - Line list of each specimen type and volume.
  - Contact information for shipper and consignee.
  - Classification (Human Exempt Specimens)
  - Completed manifest is placed on lid of inner pack.
2. **Package specimens:**
  - Primary containers with barcoded labels should be placed in cryo-boxes with dividers.
  - Rubber band should be placed around cryo-boxes to keep lid secure.
  - Absorbent & cryo-box are placed in secondary container.
  - Place package in shipment in the middle of or below dry ice.
3. **Shipping labels:**

(Apply all on single side)

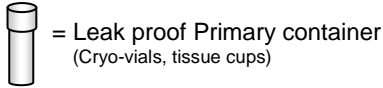
  - Contact labels for **Shipper** and **Consignee** should be legible and accurate.
  - Apply "Exempt Human Specimens" label.
  - Apply "Miscellaneous Hazard Class 9" label.
  - Apply "UN 1845 Dry Ice" label listing quantity of dry ice in shipment. 15lbs minimum.
4. **Close shipment:**
  - Make sure inner pack lid is in place but not taped or air tight.
  - Add completed manifest on top of Styrofoam lid.
  - Make sure outer package is securely taped but not air tight.



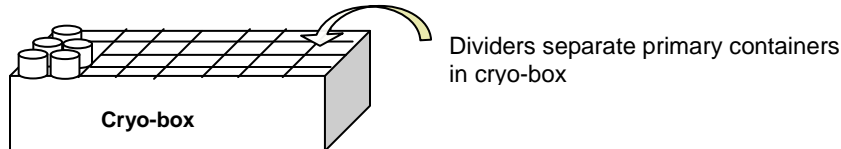
## Shipment Packaging Diagram – “Biological Substance Category B” w/Dry Ice

If a single specimen in a shipment contains a substance that falls under the list of Biological Substance Category B then the shipment must be properly packaged and labeled as per IATA guidelines.

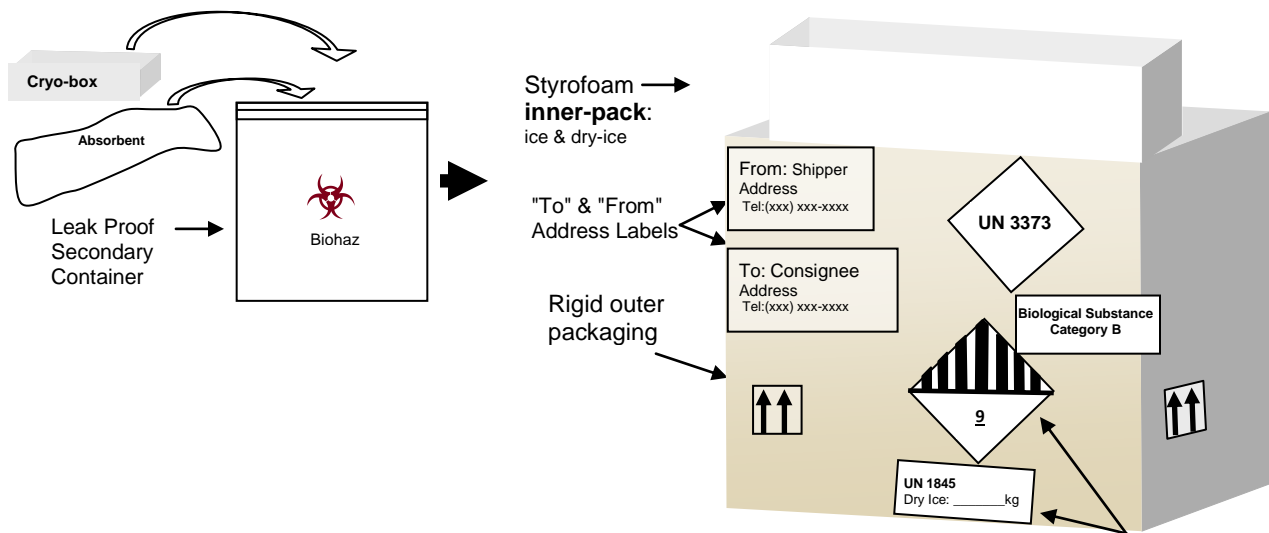
4. Specimens are placed in Leak proof primary containers



5. Multiple Primary containers are placed into cryo-boxes with dividers to prevent contact.



Secure cryo-box with lid and rubber band and place into a leak proof biohazard bag with absorbent material. Absorbent material must be able to absorb all of the liquid in case of leak.



Hazard labels for Dry Ice

### 7. Create manifest:

- Line list of each specimen type and volume.
- Contact information for shipper and consignee.
- Classification UN3373 “Biological Substance Category B” and name of infectious substance (ex: Human Immunodeficiency Virus, Hepatis B)
- Place completed manifest on lid of Styrofoam inner pack and keep a copy for your records.

### 8. Package specimens:

- Primary containers with bar coded labels should be placed in cryo-boxes with dividers and lid.
- Rubber band should be placed around transported cryo-boxes to keep lid secure.
- Absorbent & completed Cryo-box are placed in a leak proof secondary container.
- Place packaged secondary container below dry ice in shipper.
- Place Styrofoam lid on inner pack. DO NOT TAPE shut. Dry ice must be allowed to vent and not build up pressure.

### 5. Shipping labels:

(Apply all on single side)

- Contact labels for **Shipper** and **Consignee** should be legible and accurate.
- Apply “UN 3373” diamond label
- Apply “Biological Substance Category B” label next to UN 3373 label if it is not part of the UN 3373 label.
- Apply “Miscellaneous Hazard Class 9” label.
- Apply “UN 1845 Dry Ice” label listing quantity of dry ice in shipment. There is a 20 lbs minimum for GAPPS Overnight shipments.

### 6. Close shipment:

- Make sure outer package is securely taped but not air tight.
- Contact shipping company, receiving lab and complete shipping waybill invoice.

