

# **NHRC DEPARTMENT OF RESPIRATORY DISEASES RESEARCH**

## **Biological Substance Category B Specimens: How to Package, Label and Ship**

### **1. PURPOSE**

To provide a procedure for packing, labeling and shipping preserved Category B specimens to be delivered via courier to or from any collaborating study site.

### **2. SCOPE**

The scope of this procedure is to provide instructions on how to package, label and ship specimens that will be delivered to or from NHRC by any applicable courier, in compliance with applicable regulations.

### **3. GENERAL CONSIDERATIONS**

In accordance with changes in IATA and FedEx<sup>®</sup> shipping regulations, all domestic and international specimens routinely shipped and received by the Naval Health Research Center Department of Respiratory Diseases Research (NHRC DRDR), are now classified as Biological Substances, Category B (IATA Code UN3373). This document is provided as a guideline for the packaging, labeling, and shipping of Category B specimens. For a list of infectious substances forbidden as Category B specimens, please see Table 7.5 - HHS and USDA Select Agents and Toxins, 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

Before a new collaborating laboratory elects to ship specimens to NHRC DRDR, it must first be determined if the laboratory has adequate shipping materials to prepare specimen shipments. All Shipping materials shown in section 7 of this SOP can be provided by the NHRC DRDR shipping department, if requested.

#### **3.1. PPE**

Laboratory Biosafety Level 2 PPE, at a minimum, requires non-latex gloves, clean laboratory coats and safety glasses or face shield if not working in a BSC. Refer to HMIG decals and/or MSDS for additional PPE requirements for chemicals.

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### **4. DEFINITIONS**

**Biological Substance, Category B:** Any specimen type that does not fall under 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. See Attachment following this SOP.

**CFR:** Code of Federal Regulations

**Courier:** FedEx<sup>®</sup>, DHL, UPS, World Courier, USPS, other transport carriers as applicable.

**DOT:** Department of Transportation

**g:** gram

**IATA:** International Air Transport Association

**kg:** kilogram

**L:** Liter

**ml:** milliliter

**NHRC DRDR:** Naval Health Research Center Department of Respiratory Diseases Research

**SOP:** Standard Operating Procedure

**UN:** United Nations

### **5. RESPONSIBILITIES**

#### **5.1. LABORATORY SUPERVISOR**

Distributes the SOP to all collaborating sections for compliance.

Ensures that the Shipper is appropriately qualified and trained to safely and properly handle specimens for shipping purposes.

#### **5.2. SHIPPER**

Ensures that the proper procedures are followed when packing, labeling and shipping specimens.

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### **5.3. COURIER/TRANSPORTER**

Ensures that samples are properly packed and labeled prior to acceptance for transport.

Ensures that samples are stored in a suitable secondary container while in transport.

Ensures that secondary containers are adequately secured while in a transport vehicle.

## **6. PROCEDURE**

### **6.1. PACKAGING CATEGORY B SPECIMENS**

Proper packaging of Category B specimens includes four basic requirements: watertight primary containers, absorbent material, watertight secondary containers, and sturdy outer packaging. Please see the attachments section of this SOP.

#### **6.1.1. USE WATERTIGHT PRIMARY CONTAINERS**

All primary containers must have positive closures (such as screw-on, snap-on, or push-on lids) and must be reinforced by adhesive tape.

To prevent contact between multiple fragile primary containers, each primary unit should be individually wrapped.

Primary containers must be leak proof (liquid specimens) or sift proof (solid specimens).

Primary containers cannot contain more than 500ml or 500g of liquid or solid specimens, respectively.

When determining the volume of Category B specimens, be sure to include any transport media as well. The entire contents of the primary containers are considered the Category B specimen.

Primary containers may be made of plastic or metal.

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### **6.1.2. USE ABSORBENT MATERIAL**

Place absorbent material between the primary and secondary containers, making sure that multiple primary containers are individually wrapped to prevent contact.

Use enough absorbent material to absorb the entire content of all primary containers.

Absorbent material may include paper towels, cotton balls or absorbent pads.

### **6.1.3. USE WATERTIGHT SECONDARY CONTAINERS**

Secondary containers can be any watertight packaging.

### **6.1.4. USE STURDY OUTER PACKAGING**

Sturdy outer packaging must consist of corrugated fiberboard, wood, metal, or rigid plastic and be appropriately sized for content.

The outer packaging cannot contain more than 4L or 4Kg for liquid or solid shipments, respectively.

The minimum package size that FedEx<sup>®</sup> can accept is 7" x 4" x 2". For smaller packages that do not contain dry ice, insert entire package (meeting all 4 basic requirements) into a FedEx<sup>®</sup> Clinical Pak.

Each completed package must be able to withstand a 4' drop (as outlined in IATA 6.6.1.).

Some examples of unacceptable forms of outer packaging are Styrofoam<sup>™</sup> boxes, plastic bags, paper envelopes, and FedEx<sup>®</sup> boxes, tubes, packs, or envelopes.

## **6.2. FILL OUT A LABORATORY REQUISITION FORM**

A Laboratory Requisition Form and Specimen Log should be filled out, per SOP # G-0.315, Preparation of Laboratory Requisition Forms. The Specimen Log should contain an accurate description of each specimen within the shipment.

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Each specimen will have a label that matches the description written in the Specimen Log, per the SOP # G-0.315, Preparation of Laboratory Requisition Forms.

This Laboratory Requisition Form should be placed inside the shipment between the watertight secondary container and the sturdy outer packaging.

### **6.3. LABEL THE OUTER BOX OF THE CATEGORY B SPECIMEN SHIPMENT**

To avoid delays of shipments, all packages must be labeled correctly. Category B specimen shipments should have the following labels securely affixed to the outer packaging:

- Temperature Requirements: For specimens that need to be stored in specific temperature conditions, dry ice or ice gel packs may be placed within the watertight secondary container.
- Temperature specification will be determined based on the requirements of the laboratory test protocol. “Dry Ice Label (Class 9 / UN1845)” may not be required for shipments, when applicable.
- “INNER PACKAGING COMPLIES WITH PRESCRIBED SPECIFICATIONS” should only be used if the inner packaging actually does include all four of the basic requirements (watertight primary container, absorbent material, watertight secondary container, and sturdy outer packaging).
- The outer shipping box must be labeled with the name and 24 hr phone number of the person shipping the package, as well as the name and 24 hr phone number of the person receiving the package.
- The “Biological Substance Category B UN3373” label must be affixed to the outer shipping box.

### **6.4. PREPARING AN AIR WAYBILL VIA FEDEX**

Go online to website [www.fedex.com](http://www.fedex.com).

Click on the “Ship” tab at the top of the page.

Click on “Prepare Shipments”.

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Complete the “From” section accordingly. If shipping from NHRC, the shipping address is:

Naval Health Research Center

US Military Base, Point Loma

ATTN: Laboratory

McClelland Rd. & Patterson Rd.

Gate 4, Barracks Building 330/ SHED

San Diego, CA 92152

Complete the “To” section with the receiver’s contact information.

Complete the “Package & Shipment Details” section, by selecting the appropriate package and shipment details. Please note that Category B specimens must always be shipped via “Priority Overnight” delivery. Generally, the ship date is “today” however, you may select a different day if you plan to ship later.

Complete the “Billing Details” section, as appropriate. If shipping to NHRC, choose bill to recipient.

If another party requests to be billed for a shipment, that party must provide their account number to NHRC, and billing options adjusted when appropriate.

Under the “Special Services” section, select the Edit button. Click on the box labeled “Dangerous Goods”.

Dangerous goods are classified as “Accessible” or “Inaccessible” on the FedEx<sup>®</sup> website. Infections substances fall under the “Inaccessible” genre. Category B Substances are not considered Dangerous Goods. Dry Ice is considered a dangerous good, but does not require a shipper’s declaration form.

If dry ice is being used in the package, also click on the box labeled “dry ice”. This will prompt you to enter the total dry ice weight.

Also, select “Adult Signature Required” from the signature menu.

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## **Biological Substance Category B Specimens: How to Package, Label and Ship**

Complete the "Pickup/Drop Off" section by either scheduling a pickup or choosing to drop the package off. Please note that not all FedEx<sup>®</sup> drop off locations accept dangerous goods. Please plan accordingly.

Click "Ship".

Print 2 copies of the air waybill – one to send and one for the shipper to file for reference purposes in the designated filing area.

### **6.5. ACCEPTANCE AND TRANSPORT OF CATEGORY B SPECIMENS**

Transport personnel are responsible for ensuring that Category B specimen shipments meet all packing and documentation requirements prior to accepting and transporting a package.

While in transit, all packages are subject to random inspection at any time.

If a package is suspected of not meeting the above requirements, the courier or transport personnel must reject the package and notify the shipper of the error. The package should not be accepted or transported until all errors and missing information have been corrected.

Specimens must be secured in a secondary container and held in the designated areas of the transport vehicle while in transit.

In the event of an accident while in transit, the courier must notify the shipper and the consignee. In the event of a biological spill, special handling precautions must be taken, per IATA and DOT regulations.

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## **Biological Substance Category B Specimens: How to Package, Label and Ship**

### **7. ATTACHMENTS**

#### **7.1. EXAMPLES OF PRIMARY CONTAINERS**

#### **7.2. EXAMPLES OF ABSORBENT MATERIAL**

#### **7.3. EXAMPLES OF SECONDARY CONTAINERS**

#### **7.4. EXAMPLES OF OUTER FIBERBOARD LABELS**

### **8. REFERENCES**

Federal Express. Pointers on shipping: clinical samples, diagnostic specimens, and environmental test samples. Available at [http://fedex.com/us/services/pdf/PKG\\_Pointers\\_Specimens.pdf?link=4](http://fedex.com/us/services/pdf/PKG_Pointers_Specimens.pdf?link=4). Accessed April 21, 2004.

Consignment of diagnostic specimens. Available at [http://www.iata.org/NR/ContentConnector/CS2000/SiteInterface/pdf/cargo/dg/Consignment\\_diagnostic\\_specimens\\_2003.pdf](http://www.iata.org/NR/ContentConnector/CS2000/SiteInterface/pdf/cargo/dg/Consignment_diagnostic_specimens_2003.pdf). Accessed April 23, 2004.

CRF Part 331, 9 CFR Part 121, 42 CFR part 73 list of HHS and USDA Select agents and Toxins.

SOP # G-0.315 Preparation of Laboratory Requisition Forms

### **9. REVISION HISTORY**

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## Biological Substance Category B Specimens: How to Package, Label and Ship

Version	Brief general description and justification of changes	Effective Date
A-B	No revision history logged/documented.	N/A
C	Updated format and added new procedures.	08/25/2006
D	Added Contact list, new section to 6.4 and added section 6.5.	2/7/07
E	Updated format and added new procedures to 6.3 and 6.4	3/5/2007
F	Added new responsibility section for couriers, added new procedures for accepting specimen shipments	1/23/2008
G	Updated Fedex account information. Replaced "Diagnostic Specimen" terminology with "Biological Substance, Category B", updated SOP template, updated laboratory director name and QA POC on header. Added SOP # 0.315 Preparation of Laboratory Requisition Forms.	11.03.2009
H	Remove all caps on title name. Change 'NDRDR' to 'NHRC DRDR' throughout SOP. Corrected spelling, punctuation and grammatical errors throughout SOP. Corrected 'SOP # 0.315' to 'SOP # G-0.315' throughout SOP. 6.4.: Revised instructions on how to prepare airway bill via FedEx®. Placed attachments at the end of the document instead of attachment section.	10.22.2010
I	6.5.: Added bullets on the requirements for the outer packaging. Removed user and account information throughout SOP. Do not add anymore for security purposes. Changed from building 315 to building 330 and shed. Corrected spelling, grammatical and punctuation errors throughout SOP.	03.17.2011

### 7.1. EXAMPLES OF PRIMARY CONTAINERS



Sealed Plastic Bag



Plastic canister



Glass/Plastic Vial



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\* Used sealed sterile plastic bags as primary containers for tissues only.

### 7.2. EXAMPLES OF ABSORBENT MATERIAL

### 7.3. EXAMPLES OF SECONDARY CONTAINERS



### 7.4. EXAMPLES OF

#### OUTER FIBERBOARD LABELS

