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.

Per CDC guidance, all applicable requirements of the US Hazardous Materials Regulations issued by the US Department of Transportation (DOT) can be found on the DOT website.

3. GENERAL CONSIDERATIONS

In accordance with changes in shipping regulations, all domestic and international specimens routinely shipped and received by the Naval Health Research Center (NHRC) Operational Infectious Diseases are classified as Biological Substances, Category B (Code UN3373). This document is provided as a guideline for the packaging, labeling, and shipping of Category B specimens only.

Before a new collaborating laboratory elects to ship specimens to NHRC Operational Infectious Diseases, it must first be determined if the laboratory has adequate shipping materials to prepare specimen shipments.
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 SDS for additional PPE requirements for chemicals.

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.

CDC: Center for Disease Control and Prevention

CFR: Code of Federal Regulations

Courier: FedEx®, DHL, UPS, World Courier, USPS, other transport carriers as applicable.

DOT: Department of Transportation

g: gram

HMIG: hazardous material identification guide

IATA: International Air Transport Association

kg: kilogram

L: Liter

ml: milliliter

NHRC: Naval Health Research Center Department

PPE: personal protective equipment

SDS: safety data sheet

SOP: standard operating procedure
5. RESPONSIBILITIES

5.1. LABORATORY SUPERVISOR

Distributes this SOP to all collaborating sections for compliance.

5.2. SHIPPER

- Ensures that the proper procedures are followed when packing, labeling and shipping specimens.
- Must be qualified and trained to safely and properly handle specimens for shipping purposes.

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.

- Using the appropriate disinfectant, specimens should be thoroughly cleaned on the outside with the lid on securely to reduce the risk of contamination while in transit.
- Refer to current CDC guidance for packaging material related to ongoing outbreaks.
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. Glass containers are not recommended.

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® 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® Clinical Pak.

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

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

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

A Laboratory Requisition Form and Specimen Log should be completed. The Specimen Log should contain an accurate description of each specimen within the shipment. Each specimen will have a label that matches the description written in the Specimen Log.

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 hour phone number of the person shipping the package, as well as the name and 24 hour 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.

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

Click on “Prepare Shipments”.

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 Road
Gate 4, Barracks Building 313
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.

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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® website. Infectious substances fall under the “Inaccessible” genre. However, 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.

Complete the “Pickup/Drop Off” section by either scheduling a pickup or choosing to drop the package off. Please note that not all FedEx® 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.

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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.

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

Title 49, Part 173.196, Transportation


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

<table>
<thead>
<tr>
<th>Version</th>
<th>Brief general description and justification of changes</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-B</td>
<td>No revision history logged/docuemented.</td>
<td>N/A</td>
</tr>
<tr>
<td>C</td>
<td>Updated format and added new procedures.</td>
<td>08/25/2006</td>
</tr>
<tr>
<td>D</td>
<td>Added Contact list, new section to 6.4 and added section 6.5.</td>
<td>2/7/07</td>
</tr>
<tr>
<td>E</td>
<td>Updated format and added new procedures to 6.3 and 6.4</td>
<td>3/5/2007</td>
</tr>
<tr>
<td>F</td>
<td>Added new responsibility section for couriers, added new procedures for accepting specimen shipments</td>
<td>1/23/2008</td>
</tr>
<tr>
<td>G</td>
<td>Updated Fedex account information. Replaced “Diagnostic Specimen” terminology with &quot;Biological Substance, Category B&quot;, updated SOP template, updated laboratory director name and QA POC on header. Added SOP # 0.315 Preparation of Laboratory Requisition Forms.</td>
<td>11.03.2009</td>
</tr>
<tr>
<td>H</td>
<td>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.</td>
<td>10.22.2010</td>
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<td>I</td>
<td>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.</td>
<td>03.17.2011</td>
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<td>K</td>
<td>Header/footer: New dates and version Global: Changed “MSDS” to SDS in anticipation of 2015 ICH guidelines. Restored approved template 3.: 1st paragraph, removed “now” from before “classified”. Deleted “Operational Infectious Diseases are classified as Biological Substances, Category B (IATA Code UN3373” 2nd paragraph: Deleted last sentence. 4.: Added PPE, HMIG, SDS, CDC. Deleted MSDS, UN 5.1.: Deleted 2nd sentence. 5.2.: Added 2nd sentence. 6.1.: Added two bullet points. 6.1.1.: Added “Glass containers are not recommended. Deleted “shed” from address. Corrected typo: Changed “infection” to “infectious” Added “However” to paragraph 10. New revision history</td>
<td>10.22.2014</td>
</tr>
<tr>
<td>L</td>
<td>Header/footer: New dates and version. Section 2: Added caveat. Section 8: SOP # BSL3 Intra-Entity and Inter-Entity Transfer of Biological Select Agents and Toxins; DOT Title 49.</td>
<td>10.29.2014</td>
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7.1. ATTACHMENT: EXAMPLES OF PRIMARY CONTAINERS

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

7.2. ATTACHMENT: EXAMPLES OF ABSORBENT MATERIAL
7.3. ATTACHMENT: EXAMPLES OF SECONDARY CONTAINERS

- Screw-Cap Can Container
- Sealed Styrofoam™ Container (minimum of 1” thick)
- Sealed Plastic Bag
- Plastic

7.4. ATTACHMENT: EXAMPLES OF OUTER FIBERBOARD LABELS

- BIOLOGICAL SUBSTANCE CATEGORY B
- UN3373