1. PURPOSE

Provide guidance for receiving and transporting specimens from hospitals or clinics, which may potentially contain high-risk infectious agents.

To provide a procedure for classifying, packaging, labeling and shipping infectious agents to be delivered via courier to or from any study site that collaborates with NHRC.

2. SCOPE

This SOP is intended for shipping and laboratory personnel within the Operational Infectious Diseases department, for shipping presumptive positive samples for confirmation testing of pathogens, including but not limited to: Ebola virus, MERS CoV, Influenza A/H5 and A/H7.

3. GENERAL CONSIDERATIONS

This document is provided as a guideline for the classification, packaging, labeling, and shipping Category A infectious specimens. For a list of infectious substances, please reference the HHS and USDA Select Agents and Toxins website, 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. Penalties for non-compliance are significant and could result in fines or imprisonment.

Before a collaborating laboratory elects to ship specimens to NHRC OID, it must first be determined if the laboratory has adequate shipping materials to prepare specimen shipments. Refer to supplement for suggested shipping systems to use.
3.1. **PPE**

BSL-3 level PPE is required to perform these procedures. Refer to applicable procedures for donning and doffing this type of PPE.

3.2. **MATERIALS AND SUPPLIES**

Absorbent pad, soaked with Wescodyne (to be placed in the biosafety cabinet).

Bleach wipes, 10% bleach spray

Box cutter

Category A Shipping System (DOT/IATA approved)

Lab tape, 4 strips

Parafilm

Specimen holding rack

Small-medium sized biohazard bags, minimum quantity 2

Small biohazard container

3.3. **EQUIPMENT**

Biological safety cabinet, type II A2

4. **DEFINITIONS / ACRONYMS**

**BSC:** Biological safety cabinet

**BSL:** Biological safety level

**CFR:** Code of Federal Regulations

**Consignee:** The person who is receiving a specimen shipment.

**Courier:** FedEx, DHL, UPS, World Courier, USPS

**Don:** To put on

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Doff: To take off

DOT: Department of Transportation

IATA: International Air Transport Association

ID: Identification (number)


NHRC: Naval Health Research Center

PPE: Personal Protective Equipment

SDS: Safety data sheet

SOP: Standard Operating Procedure

QA: Quality Assurance

UN (numbers): United Nations (Committee of Experts on the Transport of Dangerous Goods)

5. RESPONSIBILITIES

5.1. LABORATORY STAFF AND SHIPPING PERSONNEL

Performs all procedures safely.

Complies with this SOP and ensuring they meet shipment training requirements, including but not limited to bloodborne pathogen training certification.

Ensuring that the proper procedures are followed when classifying, identifying, packing, labeling and shipping infectious specimens.

Ensures that specimens for confirmation testing are properly secured, tracked and package according to this SOP and all other applicable SOPs.

Works with laboratory supervisor for questions or concerns relating to specimen handling.

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5.2. LABORATORY DIRECTOR

Ensures that specimen transfer paperwork is complete with all necessary patient information and approvals, prior to release from NHRC.

6. SPECIMEN RECEIPT PROCEDURE

Don PPE according to SOP# S-0.70 “Personal Protective Equipment for Outbreak Surveillance”, and set up the receiving area for laboratory processing.

While still outside of the containment area, open the outer packaging of the shipment with a box cutter. Search for associated specimen paperwork with demographic data. Keep this separate from the specimen container.

Examine the inner contents of the package. If inner contents appear intact (no leaks or breaks), take the inner packaging inside the laboratory containment area for further processing.

Open the inner package inside the biosafety cabinet.

Examine the contents of the inner packaging, and remove the specimen tube from plastic container.

Surface-decontaminate the specimen tube with bleach wipes or 10% bleach spray.

Verify specimen identification information. Once verified, place specimen in the holding rack provided.

While still in the biosafety cabinet, prepare to discard the inner shipping container and remaining contents. Surface-decontaminate the items with bleach wipes or 10% bleach spray.

Place the items to discard in a small-medium sized biohazard bag. Seal and surface decontaminate again the outside of the bag with bleach wipes.

Decontaminate the hands with bleach and remove the sealed bag from the biosafety cabinet.

Place bag in a second red biohazard bag. Seal closed and label appropriately for waste disposal.

Clean work area to prepare for laboratory processing.
Decontaminate hands, remove Tyvek sleeves and outer gloves and discard in the small biohazard container inside the BSC.

Proceed with decontamination procedures to cross to the designated clean area of the laboratory.

6.1. GENERAL PREPARATION FOR OUTGOING TRANSPORT OF PRESumptive positive Specimens

Prepare materials for inner container of the Category A Shipping System.

The white plastic container, absorbent material and padding should be inside the biosafety cabinet.

The inner shipping container should be on the clean side of the containment area.

The outer shipping container, shipping labels and packing tape can remain outside of the containment area for final packaging.

6.2. PACKAGING THE OUTGOING SPECIMEN

Remove specimen to be shipped from the refrigerator or freezer.

Verify ID on specimen tube. Surface-decontaminate the specimen tube. Secure lid of tube with parafilm.

Wrap specimen in absorbent material and padding provided with the inner shipping container. Place specimen in white plastic container.

Secure and seal white plastic container.

Decontaminate hands, decontaminate the outside of the white plastic container and remove from the BSC.

6.3. TRANSFER OUT OF CONTAINMENT

Transfer the white plastic container to the clean side of the containment area, to be packaged in the inner shipping container by a 2nd laboratory member.
Clean laboratory area, doff BSL-3 level PPE. Place any remaining specimens not being shipped back in the refrigerator or freeze. Update storage information on internal tracking forms as needed.

Don BSL-2 enhanced PPE, take inner packaging outside the containment area and place in the outer packaging of the category A shipping system.

Do not leave package unattended once it has left the containment area.

6.4. DOCUMENTATION

Place all necessary paperwork inside the plastic sheet that also holds the shipping airwaybill. Work with the local chain of command to obtain patient information for necessary paperwork requirements.

6.5. PACKAGING INFECTIOUS SPECIMEN SHIPMENT

Proper packaging of infectious specimens includes four basic requirements: watertight primary containers, absorbent material, watertight secondary containers, and sturdy outer packaging. These requirements must meet the standards for packaging instruction 602 under 49 CFR 173.196 and 49 CFR 137.199.

6.5.1. 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 with absorbent material. Do not use primary containers made of glass.

Primary containers must be leak proof to accommodate liquid specimens or sift proof to accommodate solid specimens.

Depending on the type of infectious substance, it must first be determined whether it is permissible to ship the substance by “Passenger and Cargo Aircraft” or by “Cargo Aircraft” only.

For shipping liquid or solid infectious substances by Passenger and Cargo Aircraft, primary containers should contain no more than 50ml or 50g, respectively.

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For shipping liquid or solid infectious substances by Cargo Aircraft Only, primary containers should contain no more than 4L or 4Kg, respectively.

When determining the volume of infectious specimens, be sure to include any transport media to the total volume of the specimen. The entire contents of the primary containers are considered the infectious specimen.

Primary containers may be made of plastic or metal.

6.5.2. **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.

6.5.3. **USE WATERTIGHT SECONDARY CONTAINERS**

Secondary containers can be any watertight packaging.

6.5.4. **USE STURDY OUTER PACKAGING**

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

The minimum package size that couriers will accept is 7” x 4” x 2”. For smaller packages that do not contain dry ice, insert the entire package (meeting all 4 basic requirements) into an appropriate clinical shipping pack.

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 boxes, plastic bags, paper envelopes, banker’s boxes, tubes, packs, or envelopes.
6.6. **LABEL THE OUTER BOX OF THE INFECTIOUS SPECIMEN SHIPMENT**

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

Package must have the Proper Shipping Name(s) of the inner contents, supplemented with the technical name(s) if appropriate, and the corresponding UN number(s) or ID number(s) preceded by the letters “UN” or “ID” as applicable. Following the UN number or ID number, it must be specified in parenthesis whether the specimen is a solid or a liquid.

- Fully infectious specimens (liquid or solid) that affect humans shall be designated UN2814.
- Fully infectious specimens (liquid or solid) that affect animals shall be designated UN2900.

Full name and address of the shipper and consignee.

Net quantity and gross weight (in metric units) of dangerous goods contained in each package must be shown, affixed next to the label with the Proper Shipping name* of the inner contents.

For certain agents, it is advised to only indicate “Suspected Category A infectious substance” as the technical name on shipping documentation, rather than the actual name. Verify current requirements for the agent being shipped to ensure compliance.

Name and telephone number of a responsible person, listed for emergencies.

Complete Shipper and Consignee information.

6.7. **COMPLETE A SHIPPER’S DECLARATION FOR DANGEROUS GOODS**

A Shipper’s Declaration for Dangerous Goods must be completed when shipping a category A infectious substance with UN2814 or UN2900. A declaration is not required for shipments when dry ice is the only hazardous material in the package.

Declarations must be typewritten or computer-generated. Handwritten declarations are not acceptable.
Declarations must be printed in color to show the red-striped border.

Blank Declaration forms can be found on the internet. Complete the required information on the Shipper’s Declaration form:

- **Shipper**: Enter full name, address and telephone number.
- **Consignee**: Enter full name and address of recipient. When shipping infectious substances, include the phone number of a responsible point of contact.
- **Air waybill No.**: This number will be the same as your tracking number. See section 6.5. to generate a tracking number.
- **Pages**: Enter the total number of pages of the shipper’s declaration.
- **Transport Details**: Indicate whether the shipment is restricted to “Cargo Aircraft Only” or “Passenger and Cargo”.
- **Airport of Departure**: If shipping infectious specimens from NHRC OID, type in “San Diego, CA”. If shipping infectious specimens to NHRC OID, type in the city where the nearest airport is located.
- **Shipment Type**: Cross out the word “radioactive”.
- **UN or ID Number**: Enter appropriate UN number as found in section 6.3.
- **Proper Shipping Name**: Enter the proper shipping name of the infectious pathogen (scientific name).
- **Class or Division**: Enter hazard class 6.2 in this section.
- **Packing Group**: For dry ice, enter “III” in this section. Biological materials are not assigned packing group numbers.
- **Quantity and Type of Packaging**: Enter the number of packages and what the package is made of (ex: 1 fiberboard box).
- **Packing Instruction**: Enter instruction “602” in this section.
- **Emergency Telephone Number**: Enter the name and telephone number of an emergency contact who can be reached 24 hours a day.
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- Name/Title of Signatory: Enter the name of the document preparer. Note: This person must be trained to ship infectious substances prior to preparing a shipment.

- Place and Date: Enter the consignee information and date the shipment was prepared.

- Signature: An original signature in black ink is required for all Shipper’s Declarations.

If an error is made, cross out the error with a straight line and write the correct information in the appropriate section. All corrections must be in black ink and followed with an original signature from the person who prepared the declaration.

Print out at least 4 copies of the shipper’s declaration: 3 copies for the courier, 1 copy for the shipper’s records.

It is required that all shipper’s declaration records be maintained for a minimum of 2 years.

6.8. PREPARING SHIPMENT DOCUMENTS/TO SCHEDULE PACKAGE PICK UP (FEDEX)

Note: FedEx will NOT ship a Category A risk group 4 infectious substance. In the US, World Courier is the only commercial cargo carrier that will ship Category A risk group 4 agents, but is not available in all geographic regions. Verify that a commercial carrier will accept your infectious material in advance.

Go online to the website www.fedex.com.

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

Click on “Create Shipments”.

Enter User ID and password to login. To obtain this information, please contact the NHRC OID designated shipping technician.

Complete recipient/consignee information.

Shipments should be billed to NHRC. To obtain account information, please contact the NHRC OID designated shipping technician.

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- If shipping from NHRC, choose bill to sender.
- If shipping to NHRC, choose bill to recipient.

Select appropriate package and shipment details. Always ship infectious specimens for “Priority Overnight” delivery.

Complete the FedEx ShipAlert® as necessary.

Enter ship date (this will usually be “today”).

Under “Shipment Details”, click on the “Go To Options” button.

Under “Special Services” click on the box labeled “Dangerous Goods”.

- A Disclaimer screen will appear describing the marking and labeling requirements for Dangerous Goods/Hazardous Material. After reading, click OK to select the class of your Dangerous Good.

- Dangerous goods are classified as “Accessible” or “Inaccessible” on the FedEx website. Infectious substances fall under the “Inaccessible” genre.

Click “Continue”.

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

Click “Go To Next Steps”.

Click “Schedule a pickup”.

Follow the instructions to schedule a pickup.

Use ship to address:

Naval Health Research Center
US Military Base, Point Loma
ATTN: Laboratory/619-553-9105
McClelland Rd. & Patterson Rd.
Gate 4, Barracks Building 313
6.9. PREPARING SHIPMENT DOCUMENTS/TO SCHEDULE A PACKAGE PICK-UP (WORLD COURIER)

Call 1-800-221-6600 to schedule a shipment pick-up appointment in advance. Afternoon appointments will require notification in the morning, at minimum. NHRC will provide an account number for payment reference, if necessary.

Airwaybills shall be completed by hand, using the hard copy templates provided by the courier. All information on the airwaybill must match what is written on the shipper’s declaration form.

All documentation and packaging must be completed prior to the package pick-up time. A carbon copy of the airwaybill must be maintained for reference, after the courier has signed for the package for transport.

6.10. SHIPMENT EXCEPTIONS

Commercial couriers generally cannot pick up or deliver shipments directly to or from shipboard locations.

Shipboard sites that wish to ship specimens to NHRC OID must first determine their domestic shipping point from where all shipboard packages are routed.

The shipper can send the specimens to their domestic shipping point and arrange for a pick up at that location using the NHRC OID account. Shipments intended for ships can be arranged by an NHRC OID Shipboard Study Coordinator.

The NHRC OID FedEx account cannot be used for importing or exporting specimens from other countries. Shipping requirements vary from country to country.

NHRC OID uses a World Courier account to accommodate international shipping and handling requirements.

All required documentation for shipping infectious specimens still applies when using the World Courier account.
6.11. INFECTIOUS SHIPPING TRAINING (FOR NHRC STAFF ONLY)

All sites that intend to ship specimens to NHRC OID are responsible for properly packaging and labeling their infectious shipments.

NHRC OID uses the SafTPak training program to properly train employees on how to ship infectious specimens.

The SafTPak training program includes a comprehensive test after all training modules are complete. The passing score for this comprehensive test is 80% or higher.

NHRC OID employees are not permitted to ship infectious specimens until SafTPak training and tests are complete.

Upon completion of the comprehensive exam, a certificate will be automatically generated, as proof of training. This record of training will be signed and maintained by Safety and Logistics.

Refresher training for shipping infectious specimens is provided and maintained by NHRC OID on an annual basis. Please contact Safety and Logistics to obtain annual refresher training or to begin new training or certification.

7. REFERENCES

SOP # S-0.70, Personal Protective Equipment for Outbreak Surveillance

SUP-G-0.326, Supplement for Category A Infectious Shipping Systems.


IATA Dangerous Goods Regulations

Part 602 under 49 CFR 173.196 and 49 CFR 137.199

Select Agent regulations 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73
### 8. REVISION HISTORY

<table>
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<tr>
<th>Version</th>
<th>Brief general description and justification of changes</th>
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<tr>
<td>A</td>
<td>New SOP.</td>
<td>02.11.2015</td>
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<td>B</td>
<td>Header: Replaced Delacruz with Falaminiano. Changed Ellorin to Reyes as QA Approver. Changed Brice to Myers as OID Director. Added Graf as Medical Director. Global: Combined SOP S-0.72 with S-0.73 and G-0.326 - new sections: 6.1 - 6.11. 3.2: Added 10% bleach spray, Category A shipping system, and parafilm. 4.: Added new definitions and acronyms. 6.: Added title of SOP S-0.70</td>
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