


Title:	ACTG/IMPAACT Network Guidelines for Shipping and Receiving Biological Substance, Category B specimens		
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1 Purpose

This Standard Operating Procedure (SOP) describes procedures for the shipping and receiving of Biological Substance, Category B specimens.

2 Scope

This SOP is part of the ACTG/IMPAACT Laboratory Manual:
(<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>).

3 Background

International Air Transport Association (IATA)/ International Civil Aviation Organization (ICAO) and US Department of Transportation (DOT) regulations (for incoming and outgoing US shipments) must be followed for the shipping of all biological specimens. The ACTG and IMPAACT clinical trial networks have additional requirements for the shipping of clinical trial specimens for testing or storage in the designated specimen Repository. This SOP includes both the IATA/ICAO regulations as well as network-mandated requirements for shipping and receiving Biological Substance, Category B specimens.

Note: shippers must be aware of local shipping requirements and must follow the more stringent requirements across all regulations.

4 Authority and Responsibility

- 4.1 The Network Laboratory Directors (or his/her designee) have the authority to establish, review and update this procedure.
- 4.2 The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is responsible for the maintenance and control of SOP documentation.
- 4.3 The Laboratory Director is responsible for the implementation of this LTC SOP or laboratory-specific SOP and for ensuring that all appropriate personnel are trained. A laboratory SOP must:
 - 4.3.1 Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory.
 - 4.3.2 Reference the current version of the LTC SOP.
- 4.4 All laboratory technicians are responsible for reading and understanding this SOP prior to performing the shipping and receiving of Biological Substance, Category B specimens procedures described herein.
- 4.5 The site Principal Investigator and designees are responsible for understanding and adhering to the participant preparation and specimen collection components.

5 General information and packaging details

- 5.1 Proper organization, packaging, shipping and handling of human pathogens insure the sample integrity while maintaining timely and safe transfer of specimens. Specific packaging and shipping procedures must be followed in accordance with federal regulations.

- 5.2 ACTG/IMPAACT laboratories should check and update holiday restrictions annually via the [HANC website](#) to ensure proper specimen collection and timely shipment delivery.
- 5.3 It is the responsibility of the shipper to comply with the protocol Laboratory Processing Chart (LPC) shipping instructions and to confirm with the courier that the shipment will be received by the consignee during operating hours, on the required day of delivery. Recommended USA shipping days are Monday, Tuesday, and Wednesday. For other shipping days (holidays and weekends), check with the receiving facility to ensure coverage
- 5.4 Around any holiday, call the receiving laboratory to check their holiday schedule. Remember that couriers often have difficulty meeting delivery schedules around holidays. ACTG/IMPAACT Holidays are posted on HANC Public Site:
<https://www.hanc.info/labs/labresources/procedures/Pages/actnShippingDemo.aspx>
- 5.5 IATA/ICAO regulations state that any individual who handles, offers for transport, or transports dangerous goods must be formally trained and certified in Biological Substance, Category B specimen shipping. IATA/ICAO training and certification must be renewed every two years (24 months) or whenever the regulations change and prior to the expiration date of the previous certification. Each site must be able to produce documentation of current personnel training upon request. Training records must be retained for 36 months following the last training. The DOT 49 CFR states this record must be retained by the employer for the duration of employment, and for 90 days thereafter.
- 5.6 Label protocol specimens per instructions provided in the LPC. Specimens being shipped to the Repository must comply with [ACTG SOP144](https://actgnetwork.org/node/430) (<https://actgnetwork.org/node/430>).
- 5.7 Verify the information on each specimen label to ensure it complies with the requirements defined in the LPC/LDMS prior to packaging.
- 5.8 For shipments requested by the DMC, carefully follow shipping instructions provided. These instructions are customized for each request, providing valuable information regarding the specimens needed, volume required, appropriate anticoagulant, days to ship, and date specimens are due. Questions should be directed to the contact cited on the shipping request.
- 5.9 ACTG/IMPAACT network-specific shipping requirements
 - 5.9.1 All shipments must include the LDMS-generated Manifest Report and Shipping Container Report in printed hardcopy as well as the electronic LDMS shipping file. Refer to the LPC for specific shipping instructions.
 - 5.9.2 LDMS-generated electronic shipping files may be shipped on diskettes, CDs or USB storage drives. Protect the device during transit (e.g., by placing in a diskette/CD mailer or placing the USB storage drive in a watertight enclosure, i.e. zip closure bag or plastic container).

Note: electronic files may be emailed if pre-approved by the receiving laboratory as defined in the LPC.
 - 5.9.3 Arrange aliquot vials in each freezer box to correspond with the LDMS-generated shipping Manifest Report. The order on the Manifest Report and the order in the

freezer boxes must match. Include the Manifest Report and Shipping Container Report, which indicates positions for each specimen in every shipment.

Note: Do not combine the records of frozen, refrigerated, and ambient specimens in the same shipping batch, diskette or CD, or manifest.

- 5.9.4 A 100% QC must be performed to ensure the vials in the box match the Manifest Report and Shipping Container Report generated by LDMS.
- 5.9.5 The box lid and bottom must be labeled with the Batch # and Shipping Laboratory LDMS #.
- 5.9.6 Correct any database errors BEFORE generating the Manifest Report and Shipping Container Report. If an error is noticed after the diskette or CD is made, then the laboratory must “unship” the batch, fix the error, and “reship” the batch, re-creating a corrected Manifest Report, Shipping Container Report, and shipping file. Assistance may be requested from the LDMS User Support staff at the DMC (phone 716-834-0900, ext 7311 or e-mail: LDMSHelp@fstrf.org).
- 5.9.7 Place rubber bands and absorbent material around all storage boxes prior to placing them into the secondary leak-proof container. PBMCs must be shipped in an LN2-rated fibreboard storage container with vents. Indicate the number 1 position on the box.
- 5.9.8 Shipments of 25 vials or fewer can be shipped in small 5 X 5 grid boxes (2x2x2”). Specimens that don’t fit into the standardized cryo-storage containers (e.g., 50mL conical tubes, 15mL conical tubes, etc.) must be secured with plastic paraffin film (e.g. Parafilm M®) and wrapped securely with bubble wrap and absorbent material prior to placing into an appropriate secondary container.

Note: small 2.88 x 2.88 x 2 inches (75 x 75 x 52mm) cryoboxes may not be used for Repository shipments.

Individual vials or tubes (primary containers) should be physically separated. Ambient blood tubes should be placed in small individual plastic zip closure bags, with absorbent material included. Frozen cryovials should be separated in small 5 X 5 grid boxes or placed in sleeves of bubble wrap packaging and then into appropriate secondary container. (See the insert diagram for SAF-T-Pak shippers, packing direction D.)

- 5.9.9 Avoid secondary containers with smaller openings. While specimens can easily be loaded in these containers, it may be difficult to remove the tubes safely.
- 5.9.10 Include sufficient dry ice to last at least 48 hours when shipping frozen samples. Do not partially fill the shipper with other materials such as Styrofoam or refrigerated / frozen gel packs.
- 5.9.11 Specimens that contain more than 30ml of preservative or fixative must be shipped as a toxic substance. Refer to each protocol LPC for specific instructions

Specimens containing less than 30 mls fixative or preservative per primary container may be shipped as Category B or A according to packing instructions for either Category B (PI 650) or A (PI 620) as required.

- 5.9.12 Always ship by recommended courier service (FedEx for US sites and World Courier for International Sites). Designate FedEx shipments as "Priority Overnight" to ensure morning delivery. Follow the instructions if the protocol or the DMC specifies the use of a specific courier service. Call the receiving laboratory if there are difficulties complying with those instructions.

Note: During winter and summer months, protect all ambient specimens from temperature extremes by packing the approved safety shippers inside Styrofoam-lined boxes. Fill excess space with insulating material (e.g. ambient temperature gel packs with bubble wrap).

6 Post-packaging details:

- 6.1 The ACTG shipping regulations require that the sender notify the recipient of the dangerous goods shipment prior to the shipment being sent (on the day of shipment). This alerts the receiving party that the shipment is coming and ensures that arrangements have been made for someone to receive the shipment at delivery time.
- 6.2 Use the appropriate (Ambient, Refrigerated, Frozen) ACTG/IMPAACT Specimen Shipment Notice Form to contact the recipient, providing the air bill number; courier company name; date of the expected shipment; name, location, phone and fax numbers of the shipper; name, phone and fax number of the person receiving the results (if applicable); the contents of the shipment; and which assay is to be performed on the specimens. This form is available on the HANC website, ACTG/IMPAACT Laboratory Manual:
<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>.
Specify on the form if the shipment is frozen, refrigerated, or ambient.
- 6.3 If several attempts to notify by fax or e-mail, as appropriate, have failed, phone the recipient with the information. Use of E-mail, alone, must be pre-approved by the recipient prior to shipment. The e-mail recipient may be out of the laboratory for several days and their coworkers will not know a shipment is being sent.
- 6.4 The sender should track their shipments via the courier web site to be sure their packages are not delayed. The sender MUST and the recipient should check with the courier if the package has not arrived by the designated schedule. Notify the recipient of any known problems (for example, airplane delay, returned to sender) or any missing shipments.

7 International and US Dangerous Goods Shipping Regulations

- 7.1 The IATA implements updated regulations governing the identification, packaging and shipping of Dangerous Goods via air transport on January 1st of each year. These regulations reflect the changes incorporated into the current edition of the Recommendations on the Transportation of Dangerous Goods, and adopted by the ICAO in the Technical Instructions for the Safe Transport of Dangerous Goods by Air. These regulations are published by the IATA Dangerous Goods Board and must be followed by all IATA member airlines. Thus, freight carriers such as FedEx, Airborne/DHL Express and others who are members of IATA must adhere to these regulations as well as ensure that all customers using their services comply.

- 7.2 This procedure document will outline the necessary regulations a laboratory must follow in order to safely and correctly transport items that have been identified as Biological Substance, Category B specimens. Included in this procedure are explanations of the labels and airbill information to be used for both US and International shipments of Biological Substance, Category B specimens. A checklist can be found in the ACTG/IMPAACT Laboratory Manual: <https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>. If there is a need for more detailed instructions, refer to the latest IATA Dangerous Goods Regulations.
- 7.3 IATA has stated that anyone shipping Biological Substance, Category B specimens must have current documented formal training or they may incur a fine. Most courier companies and packaging companies offer training courses. The CDC and NLTN offer a training course. This training may be available at some ACTG/IMPAACT meetings; confirm the schedule with the Laboratory Technologist Committee. Some universities and institutions of higher learning include this training in their array of clinical/laboratory safety and hazardous materials/waste disposal classes.
- 7.4 Definition: IATA regulations **3.6.2.1.1** define Infectious Substance as Substance which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.
- 7.5 Classification: IATA regulations 3.6.2.2.1 define Category A, An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. See Table 3.6.D in IATA manual for indicative examples of Substance that meet these criteria. Biological Substance, Category B specimens are defined as any infectious Substance which does not meet the criteria found under Category A. Dried Blood Spots are exempt from both groups and are not classified as Dangerous Goods.
- 7.5.1 IATA 3.6.2.1.3 Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in IATA 3.6.2.1.4 as specimens collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention. Culture supernatants, cells or other amplified stocks are the end products of a culture maintained for growth or storage of an organism. (This does NOT refer to a primary specimen that is sent for the purpose of having a culture performed). When shipped, culture products and viral stocks must be packaged in accordance with Division 6.2 guidelines, which require UN rated packaging, a shippers' declaration and training every 2 years for those involved with the packaging. Follow the ACTG/IMPAACT Guide for Shipping Biological Substance, Category A (Infectious Substance) instructions when transporting culture harvests and cultured stocks.
- 7.5.2 Biologic products are defined as materials that are prepared and manufactured for the prevention, treatment or diagnosis of disease, such as test kits or vaccines.
- 7.5.3 Biological Substance, Category B specimens are exempt from the strict packaging and labeling requirement of Division 6.2 Biological Substance, Category A (infectious Substance), but must be packaged according to IATA Packing instructions 650 that

requires triple packaging and specific labeling as described below in Section 8 Packaging Material.

- 7.5.4 Another class of dangerous goods identified by the IATA/ICAO regulations is Class 9 "Miscellaneous Dangerous Goods" defined as "Articles and Substances which during air transport, present a danger not covered by other classes". The only miscellaneous article and or substance an ACTG/IMPAACT laboratory will likely be responsible for shipping is dry ice. The IATA regulations state that when dry ice is used as a coolant for Biological Substance, Category B specimens a Shippers Declaration for Dangerous Goods is not required provided that the total weight of the dry ice does not exceed 200kg. A Miscellaneous (Class 9) label and UN 1845 (Carbon Dioxide, solid [or "Dry Ice"], weight in kg, "Packing Instruction 954", "Packing Group III") label are required. Packaging must be designed and constructed to permit the release of carbon dioxide gas and to prevent the build-up of pressure that could rupture the packaging. Dry ice should never be placed in a sealed container. Do not tape the packaging such that carbon dioxide cannot be vented.
- 7.5.5 Occasionally, liquid nitrogen (LN₂) may be the required refrigerant for a shipment. When fully absorbed in a porous insulated shipper ("dry shipper") as the refrigerant for Biological Substance, Category B specimens, IATA regulations for packing instruction 202 do not apply under special provision A152. The insulated packaging must be designed to prevent build-up of pressure within the container and not permit release of any refrigerated liquid nitrogen irrespective of the orientation of the insulated packaging. LN₂ dry shippers require a label with the words "Dry Shipper, Not Restricted" and "A152, Not Restricted" must be written on the airway bill. "Keep Upright" or package orientation labels placed on all outer sides of the packaging are recommended.

8 Packaging Material

IATA General Requirements for packaging shipping Biological Substance, Category B state that the packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport. Packaging must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport. The packaging must consist of three components: (a) a primary receptacle(s); (b) a secondary packaging; and (c) a rigid outer packaging. Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

- 8.1 Each manufacturer is responsible for complying with IATA/ICAO regulations concerning package testing and certification (drop test at a height of 1.2 m at various temperatures, angles, dry and wet conditions etc.) Each manufacturer must provide detailed packing instructions (enclosed or printed on packaging) as tested and approved. These instructions must be retained by the shipper for a period of 90 days from the time of the shipment. Individual components of different manufacturers' packaging cannot be combined as this creates a new, non-tested configuration, and will result in a non-compliant package.
- 8.2 The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa in the range of -40°C to 55°C (-40°F to 130°F). See IATA PI 650 for specific testing

- 8.3 Packaging must not be reused if it is in anyway damaged. All packaging must be disinfected before reuse.

Note: An easy way to extend the life of a shipping carton is to cover a new outer packaging completely with clear shipping tape or laminated sheets.

9 Packing

- 9.1 For liquid substance:
- 9.1.1 The primary receptacle(s) must be leak-proof and must not contain more than 1 L.
 - 9.1.2 The secondary packaging must be leak-proof (e.g. o-ringed plastic jar or rated sealed plastic bag with Tyvek outer bag).
 - 9.1.3 If multiple fragile primary receptacles are placed in a single secondary packaging; they must be either individually wrapped or separated to prevent contact between them.
- 9.2 Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent 650 material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging. When multiple primary containers (i.e. centrifuge tubes or vacutainers) are placed in secondary packaging, the containers must be wrapped individually to prevent contact between them. Ideally, cryovials should be placed in a grid box to maintain the required physical separation.
- 9.3 The outer packaging must not contain more than 4 L. This quantity excludes refrigerated gel packs, dry ice or liquid nitrogen when used to keep specimens cold.
- 9.4 For solid substance:
- 9.4.1 The primary receptacle(s) must be sift-proof (so as not to move during transit) and must not exceed the outer packaging weight limit.
 - 9.4.2 The secondary packaging must be sift-proof.
 - 9.4.3 If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.
 - 9.4.4 Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes refrigerated gel packs, dry ice or liquid nitrogen when used to keep specimens cold.
 - 9.4.5 If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then packaging suitable for liquids, including absorbent materials, must be used.
- 9.5 At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm (4 in × 4 in).
- 9.6 Packing Specification and Performance Testing

The following performance test must be done by the packaging manufacturer:

- 9.6.1 The height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

Note: Do not rubber band specimens together or place specimens in plastic bags directly on the dry ice. Dry ice will crack the rubber bands and certain types of plastic bags.

- 9.7 All packages containing Biological Substance, Category B specimens must be accompanied by an itemized list of contents enclosed BETWEEN the secondary packaging and the outer packaging (taping on top of the secondary packaging is recommended). Do NOT put the paper work or shipping diskette or CD on the dry ice or down the sides of the boxes. Protect the diskette or CD by placing inside a mailing carton.
- 9.8 Shipments of ACTG/IMPAACT Biological Substance, Category B specimens require the shipper to make ADVANCE arrangements with the consignee to ensure that the shipment can be transported and delivered without unnecessary delay.

10 Special Requirements

- 10.1 Substances shipped at ambient temperatures: Primary receptacles may be glass, metal or plastic. The receptacle must have a positive means of ensuring a leak proof seal, such as heat seal, skirted stopper, or metal crimps. If screw caps are used these must be reinforced with paraffin film (e.g. Parafilm M®).
- 10.2 Substances shipped refrigerated or frozen (using refrigerated or frozen gel packs or dry ice): Dry ice must be placed outside the secondary packaging. The secondary packaging containing the primary receptacle (specimens) must be secured inside by some measure of interior support (i.e. preformed indentations in Styrofoam or a cardboard support form). This will ensure that the secondary packaging remains in place after the dry ice has dissipated. If dry ice is being used, the outer container must permit the expansion of and subsequent release of carbon dioxide gas (i.e., the lid of the insulating Styrofoam container should not be sealed w/tape).
- 10.3 Wet ice is not acceptable.
- 10.4 Other dangerous goods, such as preservatives, must not be packed in the same packaging as Division 6.2 Infectious Substance unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substance. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided they meet the requirements of 2.6. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these regulations are necessary.

11 Marking and Labeling

- 11.1 The shipping laboratory (shipper) is responsible for all necessary marking and labeling of each package of Biological Substance, Category B, specimens. Each package must be large enough

to accommodate all required markings and labels (dimensions of one side must be a minimum of 4in x 4in or 100mm x 100mm)

- 11.2 The shipper must make sure all relevant markings and labels are in the correct location and any irrelevant markings and labels are removed.
- 11.3 Two types of labels are required for shipment:
 - 11.3.1 Hazard Labels. The Hazard Label identifies the class of dangerous goods. For Biological Substance, Category B specimens a UN3373 Biological Substance, Category B label must be used.
 - 11.3.2 Handling Labels. The Handling Label identifies any special handling instructions pertinent to the class of dangerous goods (none required for shipping Biological Substance, Category B specimens).
 - 11.3.3 The following labels, required for the ambient and frozen shipment of Biological Substance, Category B specimens must be marked, durably and legibly, on the outside of the package and all the labels must be on the same side of the box:
 - 11.3.4 A “UN3373 Biological Substance, Category B” label must be placed on the outer box for both ambient and frozen shipments.
 - 11.3.5 MISCELLANEOUS DANGEROUS GOODS Hazard Label. For frozen shipments using dry ice (DRY ICE # 9 label) the net weight of the dry ice (in kilograms) and “Packing Instruction 954” must be stated on the label. There is a maximum of 200 kg per package for both passenger and cargo aircraft.
 - 11.3.6 A Responsible Person label with name and phone number of person responsible for the shipment must be placed on the outside of the box.
 - 11.4 No label should wrap around the edge of the box or overlap any other label. Even very small overlaps have been grounds for returning packages.
 - 11.5 Shipper’s Declaration for Dangerous Goods is NOT required for Biological Substance, Category B specimens shipments

12 Shipper’s and Receiver’s Responsibilities

- 12.1 The shipper must notify the recipient using the [ACTG/IMPAACT Shipment Notification Form](#) that a shipment is being sent.
- 12.2 The shipper must and the recipient should track the shipment. Shippers must track their shipments and inform the recipient if their package has been delayed or returned.
- 12.3 The ACTG/IMPAACT networks require that a shipping evaluation form be filled out for each shipment received at the Repository. Use of the form by any other recipients is optional. This form is faxed to the shipping laboratory so that corrections and rebuttal, if applicable, can be made and send to the DMC once finalized. All shipments are tracked by the ACTG-PEC and included in the Site Evaluation Report. Additional information on the shipment evaluation proceed can be found in the Shipment Evaluation SOP on the [HANC website, ACTG/IMPAACT](#)

[Lab Manual](#)

(<https://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx>)

- 12.4 If the shipper wants to have the empty box returned, a completed air bill (billed to the shipper's account) or other pre-paid return document must be included with the original shipment. When the receiver returns the boxes to the shipper, the secondary container must be disinfected. All hazard labels must be covered and the box labeled as "EMPTY". It is not sufficient to cover the labels with brown paper or tape paper or to black out the labels. Secure the label to assure that it does not tear during transport. If the hazard label is exposed, then the courier will not know that the package is empty and will treat it as "Dangerous Goods" without proper paperwork.

13 International Shipments

- 13.1 CDC regulates importation of all etiologic agents and hosts and vectors of human disease. Failure to have an appropriate import permit may result in confiscation of a shipment at a port of entry.
- 13.2 Other countries often require similar documents. Check with the recipient for any documentation needs and regulations specific to their country before sending the package. Many international shipments also require a Customs Declaration of Value. Couriers are a resource for documentation required by each country.
- 13.3 Many international shipments require several days (including transit time and importation/customs inspections). Verify with your courier that packages will arrive at their destination on a weekday or that the courier will maintain cold chain custody until the package can be delivered. Packages of frozen specimens should be packed with sufficient dry ice to last at least 72 hours.

Note: When using a LN2 Shipper, follow manufacturer's instructions to ensure that the shipper is fully charged and contains no free liquid nitrogen prior to shipping.

- 13.4 Recipients of Infectious Substance from outside of the United States must obtain an Importation Permit from the Biosafety Branch, Office of Health and Safety, Centers for Disease Control and Prevention. The regulation, application, and instructions can be found at the CDC website. (<http://www.cdc.gov>).

Note: Use the search field to enter "Import Permit" for information and forms.

- 13.5 Refer to the CDC website for the required time to process import permit applications and renewals.
- 13.6 Incoming foreign Diagnostic Specimen shipments must bear labels provided to the importer by the CDC along with the importation permit. These labels display the address of the importer, the permit number, and the expiration date. A copy of the importation permit must also be attached outside of the package.
- 13.7 The receiving lab bears the responsibility for importation documents.

14 Limitations

- 14.1 This document is not intended to replace the complete IATA/ICAO regulations. It has been designed to function as a reference tool for the necessary components required to ship

dangerous goods under IATA/ICAO regulations. All specific questions or concerns relating to shipping need to be referred to the official IATA/ICAO regulations guide.

15 Literature References

15.1 IATA Dangerous Goods Regulations

www.iata.org

International Air Transport Association

33,Route de l'Aéroport , 1215 Geneva 15 Airport, Switzerland

E-mail: dangood@iata.org

15.2 Annex 18 to the Chicago Convention on International Civil Aviation- The Safe Transport of Dangerous Goods by Air

International Civil Aviation Organization (ICAO)

999 University Street , Montreal , Quebec, Canada H3C 5H7

16 Acknowledgments

16.1 LTC SOP editing working group:

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