AIDS CLINICAL TRIALS NETWORK* (ACTN) GUIDELINES FOR SHIPMENT AND RECEIPT OF CATEGORY A INFECTIOUS SPECIMENS AND OTHER DANGEROUS GOODS

ACTN-Specific Instructions and Information

1.0 General information and packaging details

1.1 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.

1.2 ACTN labs that receive specimens from other sites should announce their holiday restrictions annually via the ACTG website (https://www.actgnetwork.org/lab_resources/lab_closures.aspx), so clinics have time to schedule patients accordingly

1.3 Recommended shipping days are Monday, Tuesday, and Wednesday. For Thursday shipments, check with the receiving facility to ensure coverage on Saturday in case a shipment is delayed. *Do not ship on Fridays, weekends, or the day before a holiday.*

1.4 Around any holiday, call the receiving lab to check their holiday schedule. Remember that couriers often have difficulty meeting delivery schedules around holidays**.**

1.5 IATA requires that any individual handling (packing, unpacking, signing for receipt or shipping out) a Category A Infectious Substance shipment be formally trained. This training is to be updated every other year. Each site must be able to produce documentation of current personnel training if requested by an inspector.

1.6 Label specimen aliquot vials with the unique LDMS-generated specimen number (Spec. I.D.), Global Specimen Identifier (GSID), patient identifier (PID), sample collection date, specimen type/anticoagulant, visit identifier (VID), and protocol, as well as any protocol specified information such as time of collection. Pharmacokinetic samples should also have the collection time documented. Specimens being shipped directly from the clinic without LDMS data entry should be labeled with all of the above identifiers except the LDMS-generated specimen number.

1.7 Before shipping the specimens, verify the Spec. I.D., GSID, PID, VID, specimen number, date, protocol, anticoagulant and specimen type on tubes to eliminate corrections and confusion on specimen identification.

1.8 For shipments requested by the DMC, carefully follow shipping instructions provided by Frontier Science and Technology Foundation (FSTRF). 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. If there are questions, call the DMC/FSTRF contact cited on the Shipping Request for clarification.

1.9 Arrange aliquot vials in each freezer box to correspond with the LDMS-generated

shipping manifest. The order on the shipping diskette and the order in the freezer boxes must match. Include the manifest and box map indicating positions for each specimen. The top and bottom of the box must be labeled with the Batch # and Shipping Lab #.

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

1.10 All frozen shipments must include the LDMS diskette. Many large shipments may be received on a given day and the receiving lab will be overburdened hand-entering the data for multiple shippers. Additionally, the receiving lab will not be able to enter your unique specimen ID numbers into their lab software, which will complicate specimen tracking and resulting.

1.11 Always use a new disk for each shipping diskette. Protect the diskette during transit by placing in a diskette mailer.

1.11.1 Specimen information MUST accompany every shipment. For ACTG shipments, use the LDMS software to create a shipping diskette, specimen manifest, and box map (when packaged in a box). It is optional to log whole blood AMBIENT shipments into the LDMS at the originating laboratory. *If the LDMS is not used at the shipping site, the ambient shipment MUST include a tracking form.*

1.12 Make sure that the information on the tubes and vials matches the data on the manifest (which will also be contained in the shipping diskette). Correct errors BEFORE making the shipping diskette. If an error is noticed after the diskette is made, *do not try to go back into the shipping diskette using a word processing or spreadsheet program*. This changes all the formatting of the diskette and the receiving lab will not be able to use it.

1.13.1 Note: All corrections must be made in accordance with the SOP for LDMS Changes found at https://www.actgnetwork.org/lab_resources/specimen management.aspx

1.12.1 Shipments of greater than 15 vials must be organized as described above and placed in a cryovial box. Bind the cryovial box with laboratory tape or rubber bands. If rubber bands are used, be sure they can withstand the dry ice temperature. PBMCs from LN2 storage must be shipped in an LN2-rated cryovial box. (Rubber bands should not be used if the shipment is coming in LN2.) Indicate the number 1 position on the box and the box lid and label the box with the Batch # and Shipping Lab #.

1.12.1.1 Shipments of less than 15 specimens can be shipped in the small red or orange screw cap containers. Keep the PIDs and protocols together, but do not tape the tubes to bubble wrap or a plastic bag, because the tape may pull the label off the tubes and leave the tubes unidentifiable.

1.13 Individual vials or tubes (primary containers) should be physically separated. Ambient blood tubes should be placed in small individual zip lock bags, with absorbent material in each zip lock bag. Frozen cryovials should be separated and organized by using a grid insert in the plastic orange screw cap containers. (See the insert diagram for SAF-T-Pak shippers, packing direction D.)

1.14 Avoid shipping jars with smaller mouths. While specimens can easily be loaded in these containers, it may be difficult to remove the tubes safely.

1.15 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, "kool packs", or wet ice.

1.16 Note: An easy way to extend the life of a shipping carton is to cover a new package completely with clear shipping tape.

1.17 Specimens that are collected in guanidinium or preserved in formalin will also need Toxic Substance (#6, skull & crossbones) labels, UN# 3071 on the box. That information must also be listed on the Dangerous Goods Declaration. (Beta-mercaptoethanol is the toxic component in guanidinium.)

1.17.1 Always ship by overnight courier service such as Federal Express or Airborne. Designate shipments as "Priority Overnight" to ensure morning delivery. Follow the instructions if the protocol or FSTRF specify the use of a specific courier service. Call the receiving lab if there are difficulties complying with those instructions.

2.0 Post –packaging details:

2.1 The International Air Transport Association (IATA) 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.

2.2 Use the ACTN 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 AACTG Laboratory web page: https://www.actgnetwork.org/pub/download/ACTN-Frozen-Specimen-Shipment-Notice.doc. Specify on the form if the shipment is frozen or ambient.

2.3 If several attempts to notify by fax have failed, call the recipient with the information. E-mail, alone, is not acceptable for shipment notification. The e-mail recipient may be out of the lab for several days and their coworkers will not know a shipment is being sent.

2.4 The sender should track their shipments via the FED EX 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 at the designated time (10 a.m. for Federal Express Priority Overnight shipments). Notify the recipient of any known problems (for example, airplane delay, returned to sender) or any missing shipments.

Federal Dangerous Goods Shipping Regulations

3.0 Background

3.1 As of January 1, 1995, the "International Air Transport Association" (IATA) implemented updated regulations governing the identification, packaging and shipping of Dangerous Goods via air transport. On January 1, 2001, the 42nd Edition of the IATA Dangerous Goods Regulations came into effect. This update reflects the changes incorporated in the Edition on the UN Recommendations on the Transportation of Dangerous Goods, published in the summer of 1995 and adopted by the ICAO in the Technical Instructions for the Safe Transport of Dangerous Goods by Air in 1997-1998. These regulations are published by the IATA Dangerous Goods Board and must be followed by all IATA member airlines. Thus, freight carriers such as Federal Express, DHL, World Courier and others who are members of IATA must adhere to these regulations as well as ensure that all customers using their services comply.

3.2 Dangerous Goods Regulations, 48th Edition, includes amendments that re-defined Dangerous Goods Infectious Substances categories into Category A and Category B Biological Substances.

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3.3 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 “Category B biological Substance specimens.” Included in this procedure are explanations of the labels and airbill information to be used for both US shipments and International shipments of Category B biological Substance specimens. A checklist for shipment of ACTN Category B biological Substance specimens can be found in the ACTG Laboratory Manual https://www.actgnetwork.org/pub/download/labmanual/ACTN_Guidelines_Ship_Cat B.doc. If there is a need for more detailed instructions, refer to the latest IATA Dangerous Goods Regulations manual.

3.3 As a reminder, IATA has stated that anyone shipping Dangerous Goods must have current documented formal training or they may incur a $25,000 fine. Most courier companies and packaging companies offer training courses. The CDC and NLTN also offer a training course. This training may be offered at some ACTG meetings; confirm the schedule with the Laboratory Technologist Committee.

.34 Definition: IATA regulations define Category A, Infectious Substances as an infectious substance which is shipped in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease to humans or animals. Category B biological Substance specimens are defined as any infectious substance which does not meet the criteria found under Category A. Dried Blood Spots are exempted from both groups and are not classified as Infectious Substances.

3.5 Classification: Dangerous goods are further defined as those goods which meet criteria of one or more of the nine United Nations (UN) hazard classes ("type of hazard").

3.6.1 Cultures and stocks are the end product of a culture maintained for growth or storage of an organism. When shipped commercially, these materials 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 Guide for Shipping Category A Infectious Substances instructions when transporting culture harvests and stocks.*

3.6.2 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.

3.7 Another class of dangerous goods identified by the IATA regulations is Class 9 "Miscellaneous Dangerous Goods". This class is defined as follows: "Substances and articles which during air transportation present a danger not covered by other classes". Included in this class are "Other regulated substances, magnetized material and miscellaneous articles and substances". The only miscellaneous article and or substance an ACTG laboratory will likely be responsible for shipping is DRY ICE. The IATA regulations state that when dry ice is used as a coolant for dangerous goods it must be documented on the Shippers Declaration for Dangerous Goods.

3.8 Occasionally, liquid nitrogen (LN2) may be the required refrigerant for a shipment. LN2 shipping containers are very expensive and may be provided on loan from the ACTG. Dry LN2 shipments do not require a Non Flammable Gas label (#2). LN2 is a class 2 substance, UN ID number 1977, and the packing instruction code is "202". 50 Kg is the maximum allowed for passenger aircraft; up to 500Kg may be shipped on cargo aircraft. Package orientation arrows and the words "Keep Upright" must be placed on every side of the package. The package must also be labeled "Do Not Drop - Handle With Care" and with instructions to be followed if an emergency or transport delay occurs or if the shipment is unclaimed.

4.0 **Packaging Material:**

4.1 IATA regulations also oversee the use and identification of appropriate packaging materials.

4.2 Packaging materials must pass specified quality documentation tests, including free drop, soak, and puncture tests. Once a manufacturer's packaging material passes the necessary testing, it is assigned a package marking, consisting of :

- 4.2.1 A United Nations packaging symbol,
- 4.2.2 The test "Class 6.2",
- 4.2.3 The last two digits of the year of the manufacture of the packaging material,
- 4.2.4 The country (i.e. USA) authorizing the allocation of the mark,
- 4.2.5 The name of the manufacturer or other identification of the packaging specified by the appropriate national authority.
- 4.2.6 Rating codes “4G” or “4GU”.
  4.2.6.1Any packaging container used for shipping Dangerous Goods must have this package marking displayed on the container. When investigating commercial vendors for dangerous goods shipping containers, make sure that their products have met the IATA criteria and display appropriate UN specification markings.

4.3 Packaging must not be reused if it is in anyway damaged. The UN rating symbols on the packaging must not be defaced.

5.0 **Packing:**

5.1 In general, the approved package must include the following:

5.1.1 Watertight primary receptacle (vacutainer, cryovial).

5.1.2 IATA approved watertight secondary packaging, for example: o-ringed plastic jar, rated sealed bag (Tyvek), sealed approved Styrofoam container. *Note: a cryovial box may be sealed in a rated sealed bag.*

5.1.3 An absorbent material placed between the primary receptacle and secondary packaging. (The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.)

5.1.4 Sturdy outside packaging container constructed of corrugated fiberboard, wood, metal or rigid plastic. The minimal acceptable size is 7" x 4"x 2". (Styrofoam, plastic bags, and paper envelopes are NOT ACCEPTABLE outer packaging.)

5.1.5 The tested packaging must bear the UN specification markings as required by the IATA regulation outlined above in 4.2.

5.2 When multiple primary containers (e.g. cryovials or tubes) are placed in secondary packaging, the containers must be wrapped individually to prevent contact between them. Alternatively, primary containers may be placed in a grid box to maintain the required physical separation.

5.3 All packages containing Category A Infectious Substances must contain 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 on the dry ice or down the sides of the boxes.* Protect the diskette by placing inside a mailing carton.

5.4 All packages containing Category A Infectious Substances must be marked durably and legibly on the outside of the packaging with the name and telephone number of a person responsible for the shipment.

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

5.6 An emergency contact phone number must be included on the Dangerous Goods Declaration. *This number must be answerable 24 hours a day by a person who can provide instructions should the package be damaged, leaking, etc.* Pagers and hospital answering services do NOT meet the expectation for the emergency contact. This phone number must be from the shipper's site or a service the shipper has contracted for this purpose, not the recipient's phone number. The ACTG has contracted the

services of Chemtrec to fill this function. Contact the ACTG operations office if your site needs to be added to the Chemtrec contract for coverage.

5.6.1 Shipments of Category A Infectious Substances of Division 6.2 require the shipper to make ADVANCE arrangements with the consignee to ensure that the shipment can be transported and delivered without unnecessary delay.

6.0 **Special Requirements:**

6.1 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 (with no o-ring), these must be reinforced with adhesive tape or Para film.

6.2 Substances shipped refrigerated or frozen (pre-frozen ice packs, dry ice): Dry ice must be placed outside the secondary packaging. The secondary packaging containing the primary receptacle (specimens) must be secure 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.*

6.3 *Wet ice is not recommended*. If wet ice is being used, the outer container must be leak proof.

6.4 The primary receptacle must maintain its containment integrity during possible extreme changes in temperature and pressure.

7.0 **Marking and Labeling:**

7.1 The shipping laboratory (shipper) is responsible for all necessary marking and labeling of each package of dangerous goods. Each package must be large enough to accommodate all required markings and labels.

7.2 The shipper must make sure all relevant markings and labels are in the correct location and any irrelevant markings and labels are removed.

7.3 Two types of labels are required for shipment:

7.3.1 Hazard Labels. The Hazard Label identifies the class of dangerous goods and must bear the class or division number in the bottom corner of the label.

7.3.2 Handling Labels. The Handling Label identifies any special handling instructions pertinent to the class of dangerous goods.

7.4 The following labels, required for the ambient and frozen shipment of dangerous goods must be marked, durably and legibly, on the outside of the package:

7.4.1 INFECTIOUS SUBSTANCES Affecting Humans UN2814 Hazard Label, with the amount in ml.

7.4.2 CARGO AIRCRAFT Handling Label, if applicable. If the total volume of Category A Infectious Substances is greater than 50mL **, the package must be shipped on a cargo (non-passenger) aircraft only. Do NOT put the CARGO AIRCRAFT handling Label on packages containing less than 50 mL of Category A Infectious Substances.

*7.4.2.1 **IATA regulations allow a Special Provision relating to Category A Infectious Substances (A81). This allows the quantity limits for bodily fluids to be raised to 1000ml per primary container (effective July 1, 2001) and 4 L net per package on both passenger and cargo aircraft. You MUST reference "Special authorization A81" in the Nature & Quantity of Dangerous Goods Section on the Dangerous Goods paperwork. (Reminder: you must have the proper size shipping container for this provision..)*

7.4.3 MISCELLANEOUS DANGEROUS GOODS Hazard Label. For frozen shipments using dry ice (DRY ICE # 9 label), the net weight of the dry ice (in kilograms) must be stated on the label. There is a maximum of 200kg per package for both passenger and cargo aircraft.

7.4.4 NAME and TELEPHONE NUMBER of the Responsible Person (shipper) for the shipment.

7.4.6 "OVERPACK USED" label, when an overpack is used. *(Remember: a non class 6.2 box can be used as an overpack, however the inner box must be an approved 6.2 test box with all proper markings and labels.)*

7.4 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.

8.0 **Dangerous Goods Declaration:**

8.1 The shipper is responsible for the completion of the "Shippers Declaration of Dangerous Goods form" for each shipment containing dangerous goods as defined in the IATA regulations. The declaration form may be printed in black and red on white paper or it may be printed in red only on white paper. The diagonal hatchings in the left and right margins MUST be printed in red. Federal Express, DHL, World Courier and other Dangerous Goods Declarations meet these regulations and are available at no charge to the shipper.
Shippers can get forms on lines from FED EX
http://www.fedex.com/us/services/options/express/dangerousgoods/declarationforms.html or from IATA
http://www.iata.org/whatwedo/cargo/dangerous_goods/download.htm

8.2 Any corrections that need to be made to the form must have a line drawn through them, the correction written, signed (complete signature) and dated by the person responsible

for the shipment. It is recommended to fill out a new DG Declaration if there are errors.

8.3 A copy of the Dangerous Goods Declaration must be kept by the shipper for two full years from the ship date.

8.4 Completion of the form must be as follows:

8.4.1 The declaration must be completed in English. The English wording may be accompanied by an accurate translation into another language.

8.4.2 Two-Four copies of the declaration must be presented to the shipping carrier. Check with your courier for the number of copies of the DG Declaration that they need. One or more copies are kept by the carrier and the other is forwarded with the shipment to its destination.

8.4.3 The Shipper must SIGN the declaration. The signature may be written by hand or it may be in the form of a facsimile reproduced by printing or stamping. A typewritten signature is NOT ACCEPTABLE.

8.4.4 Note: It is helpful to have a correctly filled out sample form, laminated, to use as a reference. A programmable typewriter or computer can be used to fill out batches of forms with the frequently used and type-required information. This both saves time and reduces mistakes/avoidable omissions significantly.

8.5 Note: Effective June 1, 2001, Fed Ex requires several components of the Dangerous Goods Declaration to be typewritten:

8.5.1 Nature and Quantity of Dangerous Goods (actual volume or weight may be handwritten.)

8.5.2 Additional Handling Information

8.6 Shipment Type (delete non-applicable): Strike or cross out the type of shipment that does not apply. For almost all Category A Infectious Substance shipments, the word "RADIOACTIVE" is struck out, leaving the words "NON-RADIOACTIVE" displayed.

8.7 Nature and Quantity of Dangerous Goods: This section of the declaration properly identifies the type and quantity of the dangerous goods that are being shipped. The example that is included below is for a shipment for dangerous goods that is classified as a Category A Infectious Substance:

8.7.1 Proper Shipping Name: This section must properly identify the substance that is being shipped as dangerous goods. The use of dry ice as a refrigerant for dangerous goods must also be identified in this section of the declaration.

8.7.2 Class or Division: This section identifies the United Nations hazard class for each specific dangerous good. (HIV is classified as 6.2; DRY ICE is classified as 9.0).

8.7.3 UN or ID number: This section is an additional code that identifies the type of dangerous goods being shipped. (HIV has UN number "UN 2814"; DRY ICE has UN number "UN1845").

8.7.4 Quantity and type of packing: This section identifies the type of outer packing used. As mentioned above, certain types of outer containers are approved by IATA (fiberboard box, wood, metal or rigid plastic). This section must reflect the actual type of container used. The volume or weight of specimens must be entered in this section. The IATA regulations state that a maximum volume of 50mL of Category A Infectious Substance can be packaged and shipped via passenger aircraft. If the volume exceeds this, the package must be transported via cargo aircraft and requires a Cargo Aircraft label on the package, unless the *Special Provision A81 for bodily fluids* (volumes up to 1000ml) is used. The volume maximum on cargo aircraft is 4 liters. If a larger non-UN rated container is used to hold the dry ice around the 6.2 shipping box, the words "Overpack used" must also be written in this section.

8.7.5 Packaging Instructions: This section identifies the specific regulations that have been provided by IATA for packaging dangerous goods. The instruction code for Category A Infectious Substances (HIV) is identified as "602". The instructions for dry ice are “904, packing group III”.

8.7.6 Additional Handling Information: IATA regulations **NO longer** state that this section must be filled in with the following statement: "*Prior Arrangements as required by IATA Dangerous Goods Regulations 1.3.3.1 have been made*". But Dangerous Goods Regulation 1.3.3.1 still requires the shipper to notify the recipient, in advance, that a dangerous goods package is being shipped.

8.7.7 Checkmark the box indicating that the shipment is “Prepared for AIR TRANSPORT according to ICAO/IATA requirements”. If the airbill does not provide a space indicating whether ICAO/IATA or CRF49 guidelines were used to prepare the shipment, then handwrite "ICAO/IATA used" in the Additional Handling Information box.

8.7.8 Emergency Telephone Number: The shipper must provide a telephone number that can be answered 24 hours a day in case of an emergency regarding the packages being shipped. This will be the Chemtrec number if your site is contracted for their coverage. The name and phone number of the responsible person (same as the label on the outside of box) is required in this section of the Dangerous Goods Declaration.

8.7.9 Name and Title of the Signatory: This must identify the name and title of the individual that is responsible for signing the declaration. This information may be printed or stamped.

8.7.10 Place and Date: The date and place the declaration has been signed by the above mentioned individual must be filled in. This also may be printed or stamped.

8.7.11 Signature: The signature must be that of the individual for the declaration. It may be written or reproduced by printing or stamping. A typewritten signature is NOT acceptable. This is a legal document.

9.0 **Shipper’s and Receiver’s Responsibilities**:

9.1 The shipper must notify the recipient that a shipment is coming, providing the Airbill number, the courier used, the date and contents of the shipment.

9.2 The shipper and receiver must track the shipment. Shippers must track their shipments and let the recipient know if their package has been delayed or returned.

9.3 The receiver should notify the shipper if a package has not arrived and relay any information that they have discovered concerning the delay, e.g. returned to sender, delayed by courier. The receiver should notify the shipper when the delayed package finally arrives and the condition of the package.

9.4 The ACTG and IMPAACT require that a shipping form be filled out for any problem shipments. This form is faxed to the DMC as well as to the shipping lab so that corrections can be made.
The study coordinator at the shipping site should be notified of any problems that have occurred. It is not necessary to contact the Principal Investigator unless the problems are ongoing or if there was a major rule violation.

9.5 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. (These can be ripped in shipping. The courier (Fed Ex, DHL, UPS, US mail) will not know that the package is empty and will treat it as "Dangerous Goods" without proper paperwork.) It is also not sufficient to just black out the labels.

10.0 **International Shipments**

10.1 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.

10.2 Other countries often require similar documents. Check with the recipient on any regulations in their country before sending the package. Many international shipments also require a Customs Declaration of Value. Federal Express provides an excellent resource for the documentation required by each country.

10.3 Many international shipments require more than a couple days. Packages of frozen specimens should be packed with sufficient dry ice to last at least 72 hours, and the use of a courier that will add dry ice as needed may be required (i.e. World Courier). Scheduling of shipments should be carefully monitored to ensure delivery during operation hours of the receiving laboratory.

10.4 Recipients of Category A Infectious Substances 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. Applications may be requested from the CDC (404-718-2077 FAX 404-718-2093, or obtained on the CDC website **http://www.cdc.gov/od/eaipp/ and the apps at http://www.cdc.gov/od/eaipp/importApplicationForms.htm**

10.5 Importation Permit applications must be filed at least 10 working days prior to any foreign Category A Infectious Substance shipment being sent to the U.S.

10.6 Detailed instructions for filling out the importation permit application are available on the web (**http://www.cdc.gov/od/eaipp/ and the apps at http://www.cdc.gov/od/eaipp/importApplicationForms.htm** .

10.7 Incoming foreign Category A Infectious Substance shipments must bear labels provided to the importer by the CDC along with the importation permit. These labels display the universal biohazard symbol, the address of the importer, the permit number, and the expiration date. A copy of the importation permit must also be attached to the package.

10.8 *"The importer bears the responsibility for assuring that the foreign shipping personnel pack and label the infectious materials according to the USPHS regulations."* The importer should provide the foreign shipper detailed packing instructions plus the appropriate labels and copy of the importation permit. It would be advisable to also supply the completed airbill(s) or a sample airbill at the minimum.

11.0 **Limitations**:

This document is not meant as a replacement for the complete IATA regulations. It has been designed to function as a reference tool for the necessary components required to ship dangerous goods under IATA regulations. All specific questions or concerns relating to shipping need to be referred to the official IATA regulations guide, by calling

DG Support Service
Tel: +1 (514) 390 6770
Fax: +1 (514) 874 2660
dangood@iata.org.

Procedure: ACTG Lab Man ACTG Guidelines for Shipping Category A Infectious Substances

Prepared by: ACTG Laboratory Technologist Committee

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Date Implemented into the Laboratory: _____

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Supersedes Archived Manual: DAIDS Virology Manual for HIV Laboratories, Version January 1997