SAMPLE PACKAGING AND SHIPPING OF INFECTIOUS SUBSTANCE SAMPLES

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SAMPLE PACKAGING AND SHIPPING OF INFECTIOUS SUBSTANCE SAMPLES

1.0 OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to provide guidance for the packaging, marking/labeling, notifying and shipping of samples classified as Infectious Substances, Class 6.2, and assigned United Nations (UN) numbers 2814 or 2900.

2.0 APPLICABILITY

This SOP is applicable to samples shipped by Scientific, Engineering Response, and Analytical Services (SERAS) personnel and classified as Infectious Substances by the regulations stipulated in Title 49 Code of Federal Regulations Parts 171 through 177 (49CFR171-177) and International Air Transport Association (IATA) Dangerous Goods Regulations. This SOP is also applicable to the shipping of certain samples classified as Biological Products.

3.0 DESCRIPTION

3.1 General Information for Infectious Substance Samples

Samples collected by SERAS personnel are typically shipped to the SERAS Laboratory in Edison, New Jersey or a subcontract laboratory for analysis. Samples must be packaged and transported in a manner that will ensure their integrity, guard the samples from the detrimental effects of sample leakage or breakage, and protect the health and safety of shipping/receiving personnel. Regulations for packaging, marking/labeling, notifying and shipping samples containing Biological Products or Infectious Substances are promulgated by the United States Department of Transportation (U.S. DOT). Air Carriers (e.g., Federal Express) that transport samples containing Infectious Substances and certain Biological Products require compliance with the current edition of the IATA Dangerous Goods Regulations. Following current IATA regulations will ensure compliance with the U.S. DOT.

3.2 Definition of Infectious Substance Samples

Division 6.2 includes substances that are infectious to humans and or animals, genetically modified microorganisms and organisms, biological products, diagnostic specimens and clinical and medical waste.

Infectious Substances are substances known to contain, or reasonably expected to contain, pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant microorganisms (hybrid or mutant) that are known or reasonably expected to cause infectious disease in humans or animals. Infectious Substance samples are to be shipped as Hazardous Materials, only if they are capable of spreading disease when exposure occurs.

3.3 Classification of Infectious Substance Samples

Infectious substances must be classified in Division 6.2 and assigned to UN2814 or UN2900, as appropriate, on the basis of whether the samples fall within one of the three risk groups. A fourth group is included to classify limited or non-pathogenic organisms. The risk groups are

characterized by the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to an individual and community, and the reversibility of disease through the availability of known and effective agents and treatment. Description of the four risk groups are as follows:

3.3.1 Risk Group 4

This group contains pathogens that are considered a high individual and community risk. These pathogens usually cause serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventative measures are not usually available.

3.3.2 Risk Group 3

This group contains pathogens that are considered a high individual risk and a low community risk. These pathogens usually cause serious human or animal disease and do not ordinarily spread from one infected individual to another. Effective treatment and preventative measures are available.

3.3.3 Risk Group 2

This group contains pathogens that are considered a moderate individual risk and a low community risk. These pathogens can cause human or animal disease but are unlikely to be a serious hazard, and are capable of causing serious infection upon exposure to the pathogen. Effective treatment and preventative measures are available. The risk of the spread of infection is limited.

3.3.4 Risk Group 1

This group contains micro-organisms that are considered to pose no or very low individual and community risk. They are unlikely to cause human or animal disease.

Refer to Table 1, Appendix A for the IATA List of Dangerous Goods specific to Infectious Substances.

3.4 Biological Products as Infectious Substance Samples

3.4.1 Definition of Biological Products

Biological products are derived from living organisms that are manufactured and distributed in accordance with the requirements of national governmental authorities, which may have special licensing requirements. These products are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto.

3.4.2 Classification of Biological Products

For the purposes of IATA regulations, Biological Products are defined and divided into the following groups:

- those which contain microorganisms in Risk Group 1; those which contain pathogens under such conditions that their ability to produce disease is very low to none; and those known not to contain pathogens. Substances in this group are not considered Infectious Substances and are not subject to the requirements for Division 6.2 and therefore would not have to be shipped as an Infectious Substance sample.

- those manufactured and packaged in accordance with the requirements of national government health authorities. Substances in this group are not subject to the requirements for Division 6.2 and are not Infectious Substance samples.

- those known or reasonably expected to contain pathogens in Risk Groups 2, 3 or 4 (refer to section 3.3). Substances in this group must be classified in Division 6.2 under UN2814 (affecting humans) or UN2900 (affecting animals), as appropriate. (Table 1, Appendix A)

3.5 Infectious Substance Sample Considerations

The following are examples of the types of information that a SERAS Task Leader may use to determine if a matrix should be considered an Infectious Substance sample.

- Proximity of the sampling location to the suspected source of contamination
- Field screening results
- Environmental indicators such as living biota (human, animal)
- Type of site and activities conducted on the site

Distinctions must be made between a non-infectious and an infectious substance sample. Determine the IATA requirement for the transportation of Infectious Substance samples. If there is any doubt, a sample should be considered hazardous and shipped accordingly. Special precautions are necessary when shipping Infectious Substance samples to protect the health and safety of shipping and sample receiving personnel.

3.6 Packaging of Samples

Infectious Substance samples must be packaged as follows:

- A watertight primary receptacle(s)

- Watertight secondary packaging

- Absorbent material must be place between the primary receptacle(s) and the secondary packaging. Absorbent material is not required for solid substances.

- Wet ice, dry ice, frozen packs or other refrigerant must be placed outside the secondary packaging(s) or, alternatively, in an overpack with one or more complete packages, showing

the markings "**4G/Class 6.2/YY/USA+------**", where 4G is a fiberboard box, Class 6.2 refers infectious substance, YY/USA refers to the year when the package was manufactured in the US and the lab that tested the package.

- When solid dry ice is used, a Miscellaneous Label - Class 9 (Figure 1, Appendix B) must be attached to the outer carton.

3.6.1 Multiple Primary Containers

Multiple primary receptacles placed in single secondary packaging must be wrapped individually, separated and supported to ensure that contact between them is prevented.

- Authorized primary receptacles are those of glass, metal or plastic, and ensure a leak proof seal be provided, such as heat seal, skirted stopper or metal crimp seal. If screw caps are used, these must be reinforced with adhesive tape.
- Ullage (expansion) must be allowed for.
- Sufficient absorption material must be used so the entire contents of the primary receptacle(s) are absorbed.

3.6.2 Outer Packaging

The outer package must be of sufficient strength to meet the design type test found in IATA, along with the required markings. If a fiberboard box is used, the appropriate markings "4G/Class 6.2/YY/USA/------" must appear on the outer packaging. A cooler may be used as an overpack only and show all markings as the outer package along with the label.

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging. Each container must have a separate chain of custody record (COC) detailing the contents of the package. Refer to SERAS SOP #4005, *Chain of Custody Procedures* for detailed instructions.
- A label "Inner Packages Comply With Prescribed Specifications" must be present on the outer packaging (Figure 2, Appendix B)
- The outer package must be sealed completely with clear packing tape. If a cooler is used as an overpack, duct tape should be used.

3.7 Marking/Labeling of Shipping Containers and Shipping Papers.

- All sample jars must have completed sample labels. When liquid samples are shipped, two sides of the shipping container must be marked "This End Up" or arrow labels (Figure 3, Appendix B) may be affixed. The shipping container must be marked with the name and address of both the shipper and receiver, name and telephone number of both the shipper and receiver, the name and telephone number of the person responsible for the shipment and

Infectious Substance affecting humans, including a technical name, UN2814, if applicable.

- An Infectious Substance label (Figure 4, Appendix B) must be affixed to the shipping container, along with any other labels needed, when shipping under DOT or IATA regulations.

- At least two custody seals must be placed across the shipping container openings as per SERAS SOP # 4005, Chain of Custody Procedures.

- Starting in January 2004, an Air Eligible label will also have to be affixed to the outer package. (Figure 5, Appendix B).

3.8 Transportation

The restrictions listed in section 4.2 of the IATA List of Dangerous Goods (Table 1, Appendix A) for either Passenger Aircraft, columns I & J, or Cargo Aircraft only, columns K & L. If columns K & L are exceeded, a Danger label must be affixed to the outer package (Figure 6, Appendix B). Typically, Federal Express is used for all overnight sample shipments. If service is not available via Federal Express, the SERAS shipping/receiving department must be contacted to determine the appropriate overnight carrier and make arrangements for shipping. Due to holding time constraints, this is highly recommended unless the samples can be transported by person to the appropriate laboratory for analysis.

Prior to shipping samples classified as Infectious Substances, advance arrangements must be made between the shipper, operator and consignee. A shipper's "Declaration for Dangerous Goods" (Figure 7, Appendix B) must be completed along with the shipper's Airbill (Figure 8, Appendix B).

3.9 Training Requirements

SERAS employees should be aware that the Hazardous Material training is applicable for the packaging, marking/labeling and documentation of Infectious Substance samples. All personnel responsible for packing and shipping Infectious Substance samples shall be trained as required by 49 CFR parts 171 through 177 as follows:

3.9.1 Initial Training Requirements

- Training for employees employed after November 15, 1992 shall be completed within 90 days of their employment.

- Employees who change job functions shall complete training within 90 days after the change if packing and shipping samples are to be part of the employee's new responsibilities.

- Employees employed after November 15, 1992, or have changed job functions may perform sample packing and shipping functions prior to the completion of training provided they are supervised by properly trained and knowledgeable employees.

3.9.2 Recurrent Training Requirements

- Employees shall receive training in packing and shipping samples as required by 49 CFR Parts 171 through 177 at least once every three years.
- Employees must keep their training up to date to be in compliance. Failure on the part of any employee to comply with the requirements of these procedures may be cause for disciplinary action, including discharge.

4.0 RESPONSIBILITIES

4.1 Field Personnel

Field personnel are responsible for packaging and shipping samples in accordance with this SOP and the IATA Dangerous Goods Regulations. Field personnel must attend initial and recurrent training as described above and are responsible for notifying the Carrier in advance of a sample shipment containing Infectious Substances.

4.2 Task Leaders

Task Leaders are responsible for ensuring samples are packaged and shipped accordance with this SOP and the IATA Dangerous Goods Regulations, for obtaining packaging and shipping information, when required, from the SERAS shipping/receiving department and assuring that all field personnel have the required training.

4.3 Shipping/Receiving Department

The SERAS shipping/receiving department is responsible for providing appropriate packaging and shipping information when requested by Task Leaders or field personnel. The SERAS shipping/receiving department in conjunction with Health and Safety are responsible for providing initial and recurrent training as described above.

4.4 Section Leaders and the QA Officer

The Section Leaders and QA Officer are responsible for ensuring that this SOP is implemented.

5.0 APPENDICES

A Tables
B Figures

6.0 REFERENCES

International Air Transport Association. 2003. Dangerous Goods Regulations, Montreal, Quebec, Canada

Code of Federal Regulations, Title 49, Parts 171 through 177 - Revised as of October 1, 2002.

World Health Organization. 1997. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens.

World Health Organization. 1993. Laboratory Biosafety Manual, 2nd ed.

APPENDIX A
Tables
SOP #2075
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SAMPLE PACKAGING AND SHIPPING OF INFECTIOUS SUBSTANCE SAMPLES

TABLE 1. IATA List of Dangerous Goods

UN/ID No.	Proper Shipping Name/Description	Class or Div.	Sub Risk	Hazard Label(s)	PG	Pkg Inst	Max Net Qty/Pkg	Pkg Inst	Max Net Qty/Pkg	Pkg Inst	Max Net Qty/Pkg	S.P.	ERG Code
2814	Infectious substance, affecting humans[%] (liquid)	6.2		Infectious Subst.		-	-	602	50 mL	602	4 L	A81	6L
2814	Infectious substance, affecting humans[%] (solid)	6.2		Infectious Subst.		-	-	602	50 g	602	4 kg	A81	6L
2900	Infectious substance, affecting animals[%] (liquid)	6.2		Infectious Subst.		-	-	602	50 mL	602	4 L	A81	6L
2900	Infectious substance, affecting animals[%] (solid)	6.2		Infectious Subst.		-	-	602	50 g	602	4 kg	A81	6L

APPENDIX B
Figures
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August

FIGURE 1. Miscellaneous Label - Dry Ice

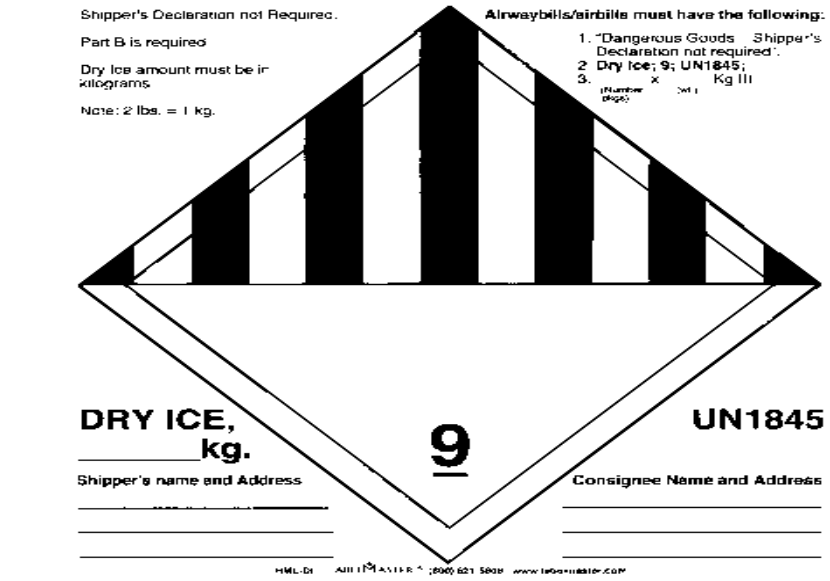

FIGURE 2. Inner Packages Compliance

FIGURE 3. Arrow Labels

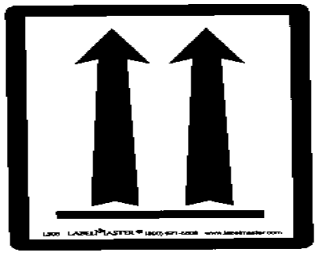

FIGURE 4. Infectious Substance Label

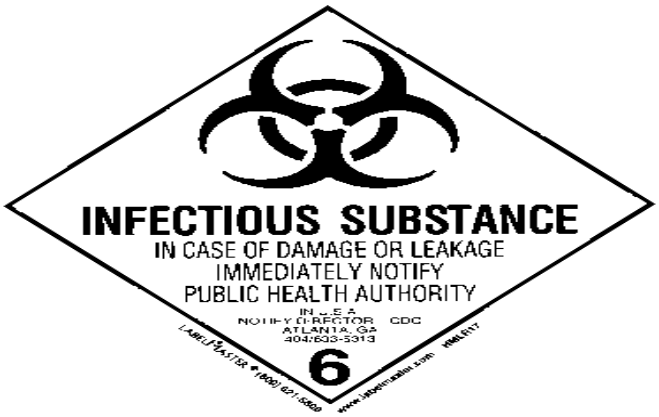

FIGURE 5. Air Eligible Label

FIGURE 6. Cargo Aircraft Only Label

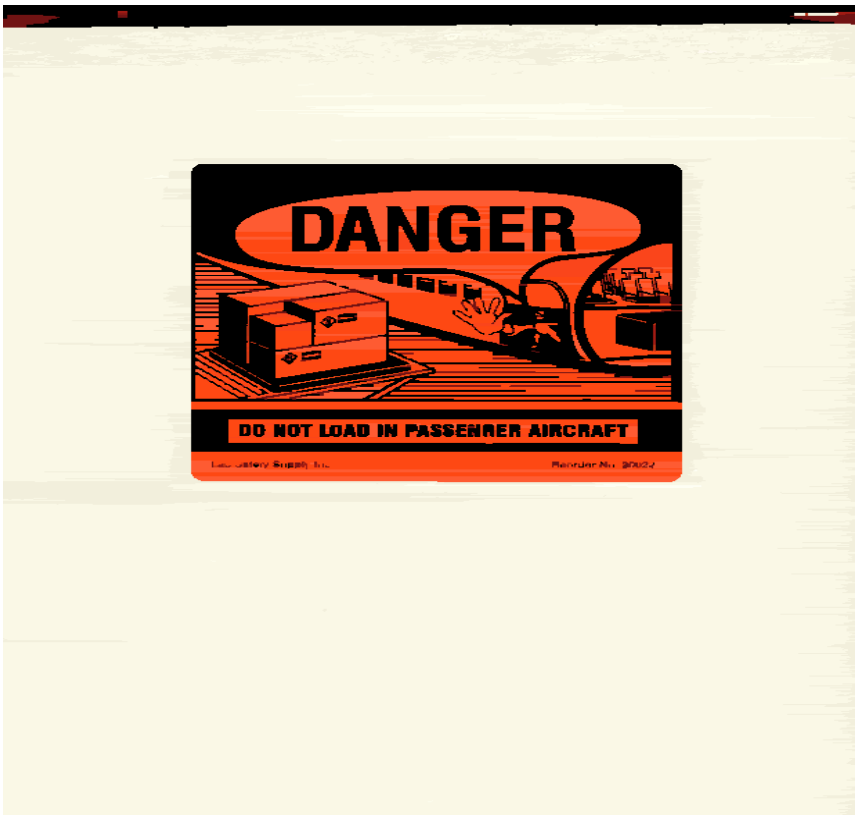

FIGURE 7. Example Shipper's Declaration For Dangerous Goods

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least two copies to the airline.)

Shipper

Air Waybill No.

Page of Pages

Shipper's Reference Number (optional)

Consignee

FedEx Express

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non applicable)*

PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure

Airport of Destination:

Shipment type: *(delete non applicable)*

NON-RADIOACTIVE | RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Proper Shipping name, Class or Division, UN Number or Identification Number, Packing Group (if required), and all other required information

Additional Handling Information

Emergency Telephone Number

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations.

Name/Title of Signatory

Place and Date

Signature *(see warning above)*

Emergency Telephone Number (Required for US Origin or Destination Shipments)

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

FIGURE 8. Example Shipper's Airbill