Project Title:

Standard Operating Procedure (SOP) for biological sample shipment

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SOP for biological sample shipment-
Project Background

Rationale

- We select this project as our laboratories previously do not have any written specific SOPs on the shipping of biological samples.

- This SOP ensures consistency in practice and in compliance with regulations and standards.

- This SOPs ensure quality and safety in the process of shipping of biological samples.

SOP for biological sample shipment

Main goal

- To develop master Standard Operating Procedure (SOP) for biological sample shipment.

Objectives

- To develop SOP for the classification of biological samples for shipment.
- To develop SOP for packaging of biological samples for shipment.
- To develop SOP for documentation of biological samples for shipment.

Methodology and Resources

- Assigned tasks to team members-
  - literature review
  - template selection (Sandia National Lab).
  - draft SOP for classification of biological samples, packaging & documentation.
- Collecting the partial draft documents from team members, editing & compiling.
- Circulate the draft SOP to all team member for comments.
- Collecting the comments from team members & editing SOP.
- Circulate the email to mentor & Collecting, compiling the comments
- Finalize the SOP & Presentation.

Result: SOP for biological sample shipment

1. Purpose
2. Scope
3. Responsibilities
4. Preparation
5. Procedure
   - 5.1 Classify biological material.
   - 5.2 Identification: Proper Shipping Names & UN Numbers
   - 5.3 Packaging Requirements: A Basic Triple Packaging System
     Packing Instruction for Category A, B & Exempt
   - 5.4 Marking and labeling outer packaging
   - 5.5 Documentation
   - 5.6 Make arrangements for transport

Annex

Standard Operating Procedure (SOP) for biological sample shipment

1. Purpose: The purpose of this SOP is

- To ensure the safe & secure shipment of the biological samples as per international regulations.
- To use this SOP as a reference documents for member countries of RPHL Network in the Asia and Pacific Region.

2. Scope

- This SOP is applicable to all laboratory personnel who are involve in the shipment of infectious materials.
- This SOP provide guidance to prepare shipments.
- This SOP is implemented once it is completed and approved by Respective National Laboratory.

3. Responsibilities

- Laboratory Manager have to manage the packaging materials & training to laboratory personal.

- Laboratory personnel have to follow this SOP.

- Shipper makes arrangements with the recipient of specimens.
  - ➢Classification, Identification, Packaging.
  - ➢Marking & labeling, Documentation and Arrangement.

- Carrier completes & files appropriate facility required & other documentation as needed. (cold-chain, certificate and training).

4. Preparation

a. Materials

- Disinfectant (5 % sodium hypochlorite solution)
- Leak proof primary and secondary container, outer box, Sufficient absorbent, Bubble wrap etc.

b. Equipment: Biological Safety Cabinet (BSC)

c. PPE: Gloves, Gowns, shoe covers, head covers, masks, respirators, eye protection, face shields, and goggles.

D. Records and Forms

- Shipper's declaration (if needed), Waybill, Itemized list of contents
- Package manufacturers use/assembly instructions

5. Procedure

5.1 Classify biological material; As per the IATA the materials should be classified and take proper precautions before shipment. There are nine classes of Dangerous Goods

Class 1	Explosives
Class 2	Gases
Class 3	Flammable Liquids
Class 4	Flammable Solids
Class 5	Oxidizing Substances and Organic Peroxides
Class 6	Toxic and Infectious Substances 6.1 Toxic Substances **6.2 Infectious Substances**
Class 7	Radioactive Material
Class 8	Corrosives
Class 9	Miscellaneous Dangerous Substances and Articles

5.1 Classify biological material

All infectious substances are classified on Class 6 , Division 6.2. & further sub-classified as Category A, B & Exempt / Not Regulated.

i. Category A

- the highest risk infectious substances which have severe consequences eg. Bacillus anthracis, Nipah virus, Rabies virus culture etc.
- There are two different UN numbers and proper shipping names associated with Category A infectious substances:

(1) **UN 2814**, **INFECTIOUS SUBSTANCE, AFFECTING HUMANS.**
(2) **UN 2900**, **INFECTIOUS SUBSTANCE, AFFECTING ANIMALS** only

ii. Category B

- Infectious substances which don't have severe consequences eg Salmonellosis.
- The UN number and proper shipping name for most shipments of Category B infectious substances is UN 3373, BIOLOGICAL SUBSTANCE, CATEGORY B.

iii. Exempt Patient Specimens / Not Regulated:

Many substances which have minimal risk & no consequences are entirely exempt/not regulated eg. Human or animal cell line or cell culture, most environmental samples (food, soil, etc.),

5.2 Identification: Proper Shipping Names & UN Numbers

- Every dangerous good must be assigned a Proper Shipping Name (PSN) with corresponding four digit UN numbers which are listed & published internationally by IATA for global recognition.

➢UN2814, Infectious substances, affecting humans

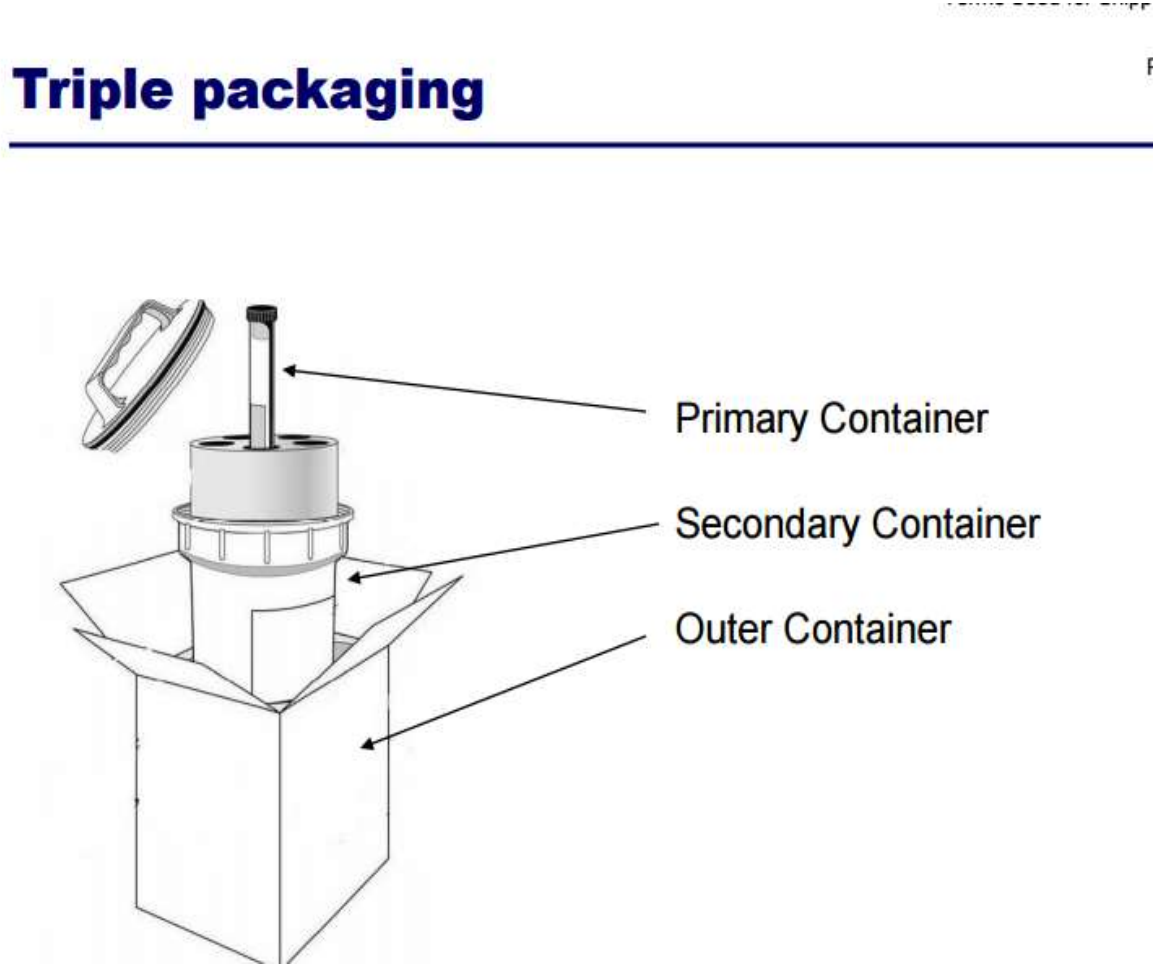
➢UN2900, Infectious substances, affecting animals

➢UN3373, Biological substances, Category B

5.3 Preparing Packaging Requirements

5.3.1 A Basic Triple Packaging System

- **All biological agents (Category A, B and Exempt) must be triple packed** with primary, secondary & Outer container as below.



5.3.1 A Basic Triple Packaging System

5.3.1a Prepare primary container.

- must be watertight & leak proof.
- must not become punctured, broken, affected by sample.
- most often done inside of a Biosafety Cabinet in laboratory with proper PPE.
- Ensure a leak proof seal by using parafilm on primaries.

5.3.1b Prepare secondary container

- must be watertight, leak proof & used to enclose the primary.
- Performed inside a Biosafety Cabinet in laboratory than disinfect the outer surface and bring out of lab.
- Place enough absorbent to absorb all contents of the primaries if leak.
- Do not place dry ice inside the secondary container.

5.3.1c Prepare outer container

- made of appropriate strength, weight, size & composition.
- Outer packaging should be done outside of laboratory.
- Place an itemized list of contents between the secondary & outer package.

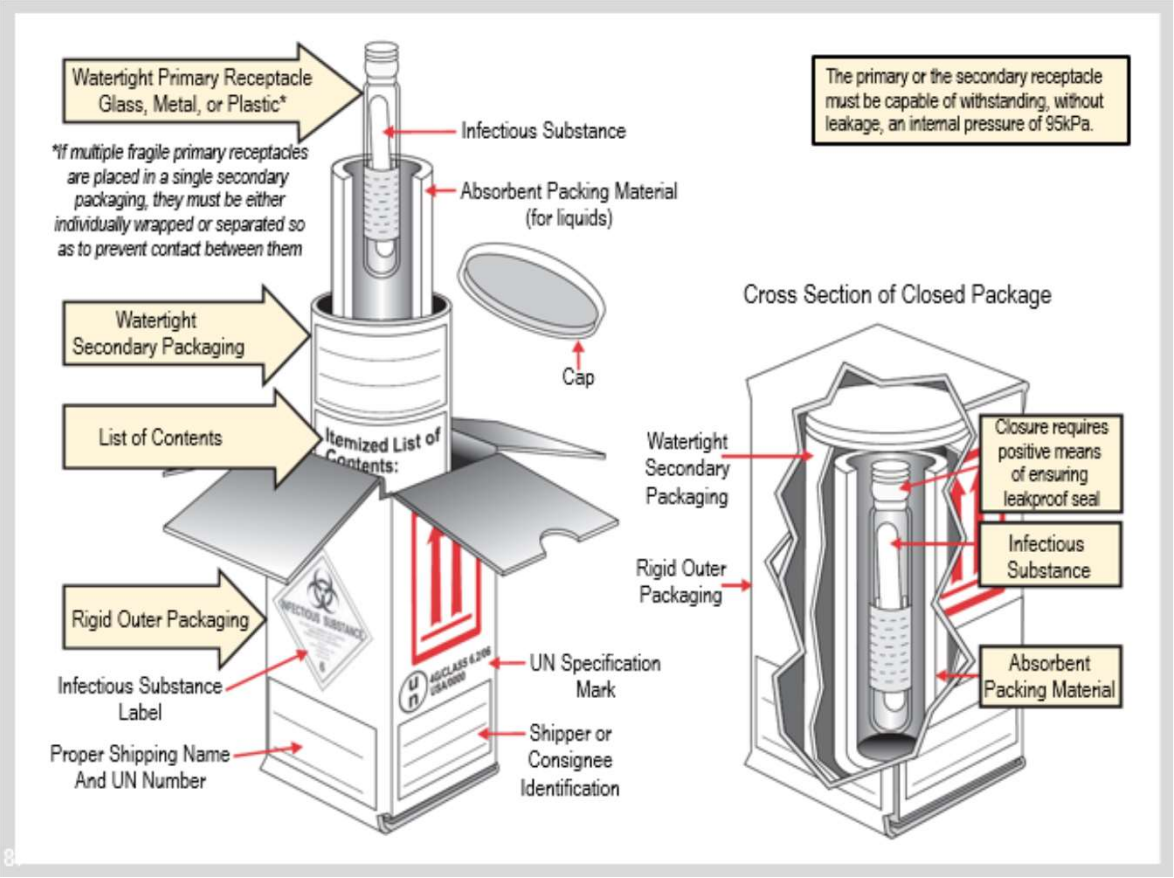
5.3.2 Packing Instruction for Category A (P620)

Basic triple packaging system

1. Primary Container. 2. Secondary Container. 3. Outer Container

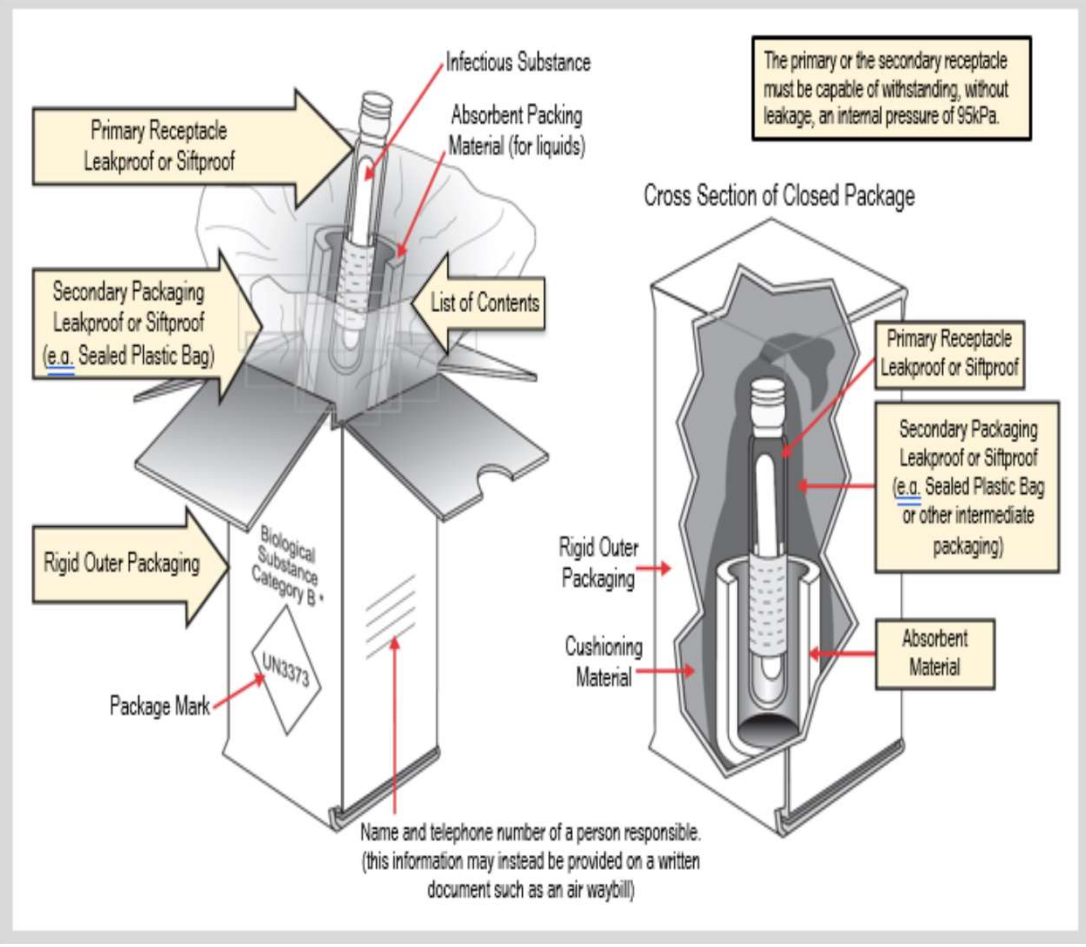
❖Category A package:

- **Pressure holding 95kPA & Drop tested from 9m,**
- must be **marked with UN Specification.**
- The quantity limit **50ml or 50gm for passenger aircraft. & 4 lit or 4 kg for cargo only aircraft**.



5.3.3 Packing Instruction for Category B (P650)

- Basic triple packaging system.
- The primary & secondary packaging **pressure holding of 95kPa.**
- Triple package **must pass 1.2m 'drop test'.**
- only Package mark or UN Number (UN3373).
- Quantity Limits for Category B shipments less than 4L or 4Kg.



5.3.4 Packing Instruction for Exempt.

Exempt Packaging requirements.

- Must use triple packaging system.
- Leak-proof Primary container & Secondary container.
- Package marked “Exempt Human Specimen” or “Exempt Animal Specimen”.

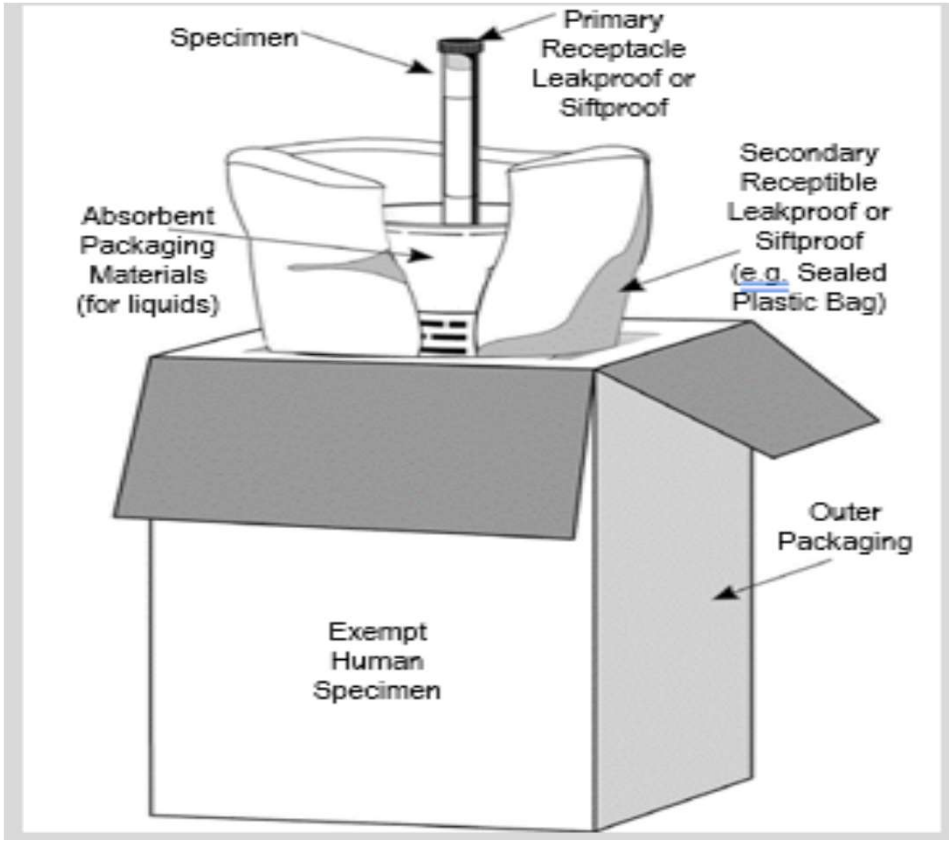


Fig: Triple packaging for Exempt Specimen.

5.4 Marking and labeling outer packaging

After complete packaging, they must be properly marked and labelled to provide information about the contents of the package, the nature of the hazard, and the packaging standards.

5.4.1 Marking

The following 'Marks' must be provided on the outer package of all infectious substances:

- Address of the shipper
- Address of the consignee
- Contact information for the shipper and consignee
- Name and telephone number of a responsible person.
- Appropriate hazard label(s)
- The UN number of the infectious substance, followed by the proper shipping name of the substance.
- When a coolant is used (e.g. dry ice), the UN number, the proper shipping name and quantity of the coolant.

5.4.1 Marking

For Category A infectious substances:	For Category B infectious substances:
The following additional 'Marks' must be provided on the outer package of all infectious substances of Category A. ➢ The UN Specification marks must be displayed. ➢ A 24-hour emergency contact person must be marked.	The following additional 'Marks' must be provided on the outer package of all infectious substances of Category B. ➢The Packaging Mark or UN Number (UN3373). ➢The Proper Shipping Name (BIOLOGICAL SUBSTANCE, CATEGORY B)
	

5.4.2 Labeling

- There are two types of labels
- Hazard labels required for most dangerous goods; diamond shaped.
- Handling labels required for some dangerous goods.

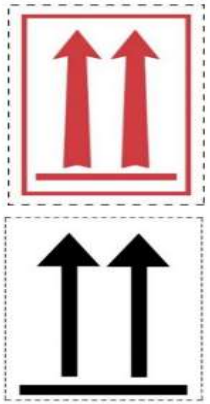
5.4.2a Hazard labels

- Hazard labels are always presented in the form of diamond- shaped.

	
Label: Infectious substances hazard label. Required for: Compulsory for all packages containing Category A infectious substances.	Label: Miscellaneous Dangerous Good hazard label. Required for: infectious substance packages containing Class 9 substances, namely dry ice, as coolant.

5.4.2b Handling Labels

- Handling labels may be found in various shapes, either alone or in addition to hazard labels, depending upon the nature and quantity of dangerous goods.

	
Label: Orientation Arrows Required for: Indicating the presence of a liquid in the package, requiring the packages only be handled in the upright position to prevent leakage. Colour: Black or Red arrows on a white.	Label: Cargo Aircraft Only (CAO) Label Required for: indicating a package of infectious substances contains more than the quantity limits for passenger aircraft and are eligible for cargo aircraft only. Colour: Orange background, Black writing

5.5 Documentation / Complete paperwork

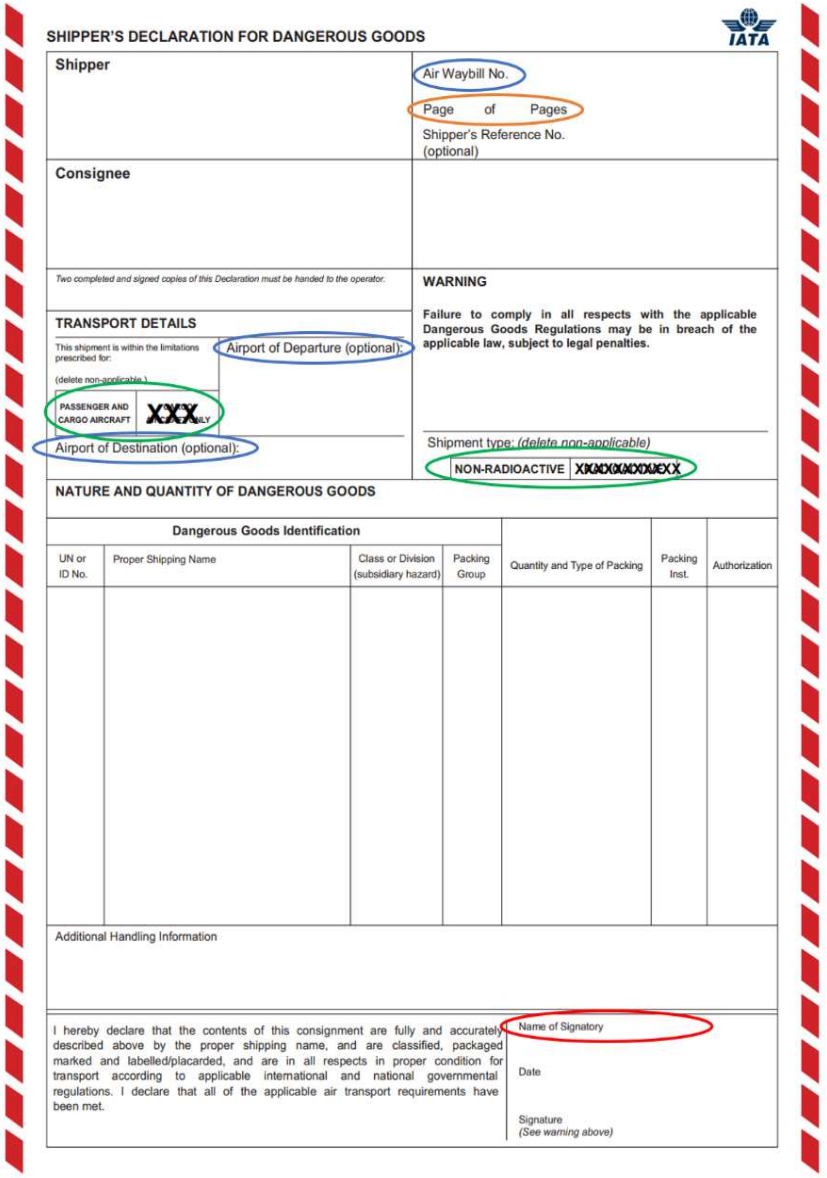
1. Shipper's Declaration for dangerous goods: required For Category A but optional for Category B shipments. It should have

- The Sender & Receiver information.
- "Air Waybill No.",
- Mark 1 of 1 pages in the top righthand corner
- "Airport of Departure" & "Airport of Destination".
- Cross out the non-applicable aircraft type & the word "RADIOACTIVE" .
- The Date, UN Number (e.g. UN2814, UN2900).
- Proper Shipping Name.
- The primary hazard Class eg. 6.2
- Net quantity & Type of packing.
- Packing instruction eg 620, 650
- Emergency Response Information:

2. Air Waybill (provided by the carrier).

3. Packing list / Proforma invoice.

4. An itemized list of contents (eg. Packing list)



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

IATA

Shipper

Air Waybill No.

Page of Pages

Shipper's Reference No. (optional)

Consignee

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

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for:

(delete non-applicable)

PASSENGER AND CARGO AIRCRAFT

CARGO AIRCRAFT ONLY XXX

Airport of Departure (optional):

Airport of Destination (optional):

Shipment type: *(delete non-applicable)*

NON-RADIOACTIVE XXXXXXXXXX

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (subsidiary hazard)	Packing Group	Quantity and Type of Packing	Packing Inst.	Authorization

Additional Handling Information

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. I declare that all of the applicable air transport requirements have been met.

Name of Signatory

Date

Signature *(See warning above)*

5.6 Make arrangements for transport

- Keep package secure prior to pick up. Follow appropriate security procedures.
- Transportation operations carried out by World courier or equivalent authentic services.
- If biological substances are shipped with dry ice, it is classified by UN 1845 as a Class 9 miscellaneous hazard. Following precautions should be taken when using dry ice:
  - Do not place dry ice in primary or secondary containers.
  - Only use dry ice in a well-ventilated area.
  - Dry ice is extremely cold, always handle with care and wear protective gloves and eyewear.

Annex:

- Annex 1. Classification of Dangerous Goods as per IATA Dangerous Good Regulations.
- Annex 2: List of biological agents sub classified as category A.
- Annex 3: Proper shipping names UN numbers.
- Annex 4: Shipper's Declaration filled Form for dangerous goods

Conclusions

- This master SOP for biological sample shipment has been developed. This SOP can be taken as a reference for any countries and can be used once it is approved by Respective National Laboratory. This SOP is applicable to all laboratory personnels involved in sample shipment & provide guidance to prepare shipments.

- The best quality of samples sent to any WOAH/FAO/WHO reference laboratories in compliance with international regulations from any countries using this SOP may indicate the effective implementation of this SOP

- This SOPs can be amended as per requirements of any countries in compliance with international rules and regulations for safe & secure shipment of biological materials.

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Thank You