



STANDARD OPERATING PROCEDURE FOR TRANSPORT OF BIOLOGICAL SPECIMENS IN MALAYSIA

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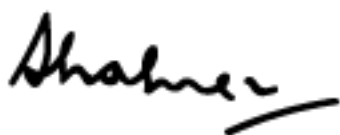
FOREWORD

The purpose of developing this Standard operating procedure is as a reference for Ministry of Health Malaysia hospital laboratories. It is timely that a standard operating procedure be made available as a reference for transportation of any biological specimens by air or surface. This is to ensure that the biological specimens are packaged and handled in a suitable manner to safeguard the health, safety and welfare of employees handling the pathological specimens and also to ensure that the specimens are packaged in suitable receptacles and maintained under suitable environmental conditions for transport.

Biological specimens may contain infectious materials and can be the potential source of an outbreak. It is important that care is taken when collecting and handling the specimens to ensure that the risk of infection to staff is kept to an absolute minimum. The packaged material should not have any possibility of escaping from the package under normal conditions of transport.

The responsibility for the safe collection and packaging of biological specimens shall not rest entirely upon the sender. It is imperative that all areas where pathological specimens are generated be it histopathology, chemical pathology, haematology and microbiology, remain conversant with the current rules, regulations and up to date safety code of practice. This includes the Biosafety act, the importation and exportation of organism guideline, Ministry of Health Malaysia, and the guidelines by International Air Transport Association.

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1. INTRODUCTION

International and national procedures have been established for the safe transport of biological materials by all modes of transportation (air, sea and land). Different packaging and transport arrangement apply depending on whether materials are infectious substances, biological products, cultures, genetically modified organism (GMO) or exempt substances. The requirements of various regulatory bodies are based on the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations which are adopted by International Air Transportation Association (IATA) and Malaysian Standards (MS 1513).

It is the responsibility of sender to ensure compliance with all packaging and transport regulations.

2. OBJECTIVE

This procedure is to ensure proper and safe transport of all biological materials including environmental samples such as patients' specimens, infectious substances, cultures, water samples, clinical wastes and genetically modified organisms for all modes of transportation (air, sea and land) to referral or other laboratories.

This procedure also ensures that the integrity of the specimens is preserved for accurate analysis by the receiving laboratory.

3. SCOPE

This procedure will be used for packing and transporting of patients' specimens, infectious substances, cultures, clinical wastes and genetically modified organisms to the designated Referral Laboratory in Malaysia and overseas.

4. DEFINITION

The following definitions align with the UN Model Regulations and are used in this Section:

4.1 Biological products

Products that are derived from living organisms, used either for prevention, treatment, or diagnosis of diseases in humans or animals, or for developmental, experimental or investigational purposes.

4.2 Patients' specimens:

Those collected directly from humans or animals, including, but not limited to, excreta (feces & urine), secretions (body fluids), blood and its components, tissue (including fresh tissue, preserved tissue, paraffin blocks and glass slides) and swabs, and body parts being transported for purposes such as diagnosis, research, investigational activities, disease treatment and prevention.

4.3 Cultures:

The result of a process by which living organisms are intentionally propagated. This definition does not include patient specimens.

4.4 Dangerous Goods:

Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are classified in the IATA Dangerous Goods Regulations. The Dangerous Goods should meet the criteria of one or more of the nine UN hazards classes (Appendix 1).

4.5 Genetically modified microorganisms:

Microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

4.6 Infectious substances:

Substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi and other agents such as prions) which can cause disease in humans or animals.

4.7 Medical/clinical wastes:

Wastes derived from the medical treatment of animals or humans or from bioresearch.

4.8 Outer container

A sturdy, leak-proof container, for example, a box, flask, styrofoam box, chiller box that is used to contain the secondary container.

4.9 Overpack

A large box that is used to transport multiple triple packages.

4.10 Primary container or receptacle:

A container or receptacle in contact with the biological or environmental material to be transported.

4.11 Referral Laboratory:

Laboratory which receives specimens from another facility for investigation.

4.12 Secondary packaging:

Provides additional protection for the primary container, is leak-proof and may include absorbent material.

4.13 Shipper:

Individual or agency that has the licence to transport specimen

4.12 Referring laboratory

A laboratory that sends biological substance or environmental sample to a referral laboratory for further investigations.

5.0 ABBREVIATIONS

5.1	IATA	–	International Air Transport Association
5.2	UN	–	United Nation
5.3	GMO	–	genetically modified organism
5.4	MS	–	Malaysian Standard
5.5	ID	–	Identification
5.6	DGR	–	Dangerous Goods Regulations
5.7	SDDG	–	Shipper's Declaration for Dangerous Goods
5.8	PCR	–	Polymerase Chain Reaction
5.9	MSDS	–	Material Safety Data Sheet
5.10	PI	–	Packaging Instructions
5.11	HPE	-	Histopathology Examinations

6.0 PROCEDURE FOR AIR TRANSPORT

6.1 General Requirements

- i. Determine the specimens to be transported.

- ii. Identify the UN class applicable to the specimen category. Refer to Appendix 1.
- iii. Categorize the patients' specimens according to Category A, Category B, Category C or Exempt Substances and specimens containing preservatives (Appendix 2, 3 and 4)
- iv. Pack all patients' specimens according to categories specified in IATA packaging instructions. Different categories have slightly different packaging needs specified in IATA packaging instructions, but all follow the basic **triple packaging** (Appendix 7 and 8) requirement. Ensure that packages will arrive at their destination in good condition and present no hazard to persons or animals during transport.
- v. Pack Category A biological materials for air transport following requirements in IATA Packaging instructions 620 (Appendix 11: Packaging Instruction/PI). Use the package which is marked with the appropriate UN numbers and proper shipping names (UN 2814 for infectious substance affecting human). Refer to Appendix 3.
- vi. Pack Category B biological materials for air transport following requirements in IATA Packaging instructions 650 (Appendix 11: PI). Use the package with the appropriate UN number and proper shipping name (UN 3373 for biological substance for Category B). Refer to Appendix 3.
- vii. Pack, mark and label all infectious substances using a **triple packaging system** (Appendix 7 and 8). The system comprises a primary receptacle, secondary packaging and an outer packaging.
- viii. A leak-proof primary receptacle (container):
 - Label the primary container with the name of patient, identification card or hospital registration number, specimen type (if necessary) and test request
 - Secure the primary receptacle with a water proof, leak-proof seal and secure the screw cap with a stretch wrapping eg. parafilm or masking tape.
 - For tissue specimen in preservative (for HPE) plastic bag should not be used as primary receptacle.
 - Specimens sent in liquid nitrogen should be placed in a dry shipper (a vacuum flask that are designed for the safe shipment of specimen at liquid nitrogen temperature without the risk of spilling liquid nitrogen).
 - Microscopic slides for HPE should be packaged together by surgical number. These often become broken in shipment unless carefully packaged. Commercially available plastic slide holders manufactured to withstand shipment should be used or the slides should be

- sufficiently wrapped and padded inside their shipping container to prevent breakage.
- Paraffin blocks should be packaged together by surgical number and shipped in an appropriately labeled box or plastic bag. Do not wrap in gauze. Paraffin blocks may melt in hot climate so appropriate packaging is recommended prior to shipment.
- ix. A leak-proof secondary packaging
- For liquids, place absorbent material e.g. gauze, cotton, paper towel or super absorbent pad between the primary container and the secondary packaging to absorb the entire contents so that, during transport any release or leak of liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.
 - Individually wrap the primary containers (Appendix 8) and place them in a single secondary packaging to prevent cross contamination.
- x. Use a rigid outer container of adequate strength for its capacity, mass and intended use and with at least one surface having a minimum dimension of 100 mm x 100 mm.
- For infectious substances belonging to Category A, the outer container must be certified with a UN specification mark UN2814 or UN2900 (Appendix 3).
 - Specimen data and/or request forms, letters and other types of information that identify or describe the specimens should be taped to the outside of the secondary container.
 - The maximum quantity of **Category A** infectious material that can be shipped in a single package via **passenger aircraft is 50 mL or 50g**.
 - For other categories the contents in the primary container must not exceed 500 mL or 500g.
 - The maximum quantity of patient's specimen material that can be shipped by **cargo aircraft in one package is 4L or 4kg**.
 - For infectious substances belonging to **Category B**, the maximum net quantity permitted in a single package is **4 L or 4 kg on both passenger or cargo aircraft** (Appendix 3).
 - There is no quantity limit specified for individual packages containing "Exempt: human specimens" or "Exempt: animal specimens" (Appendix 2).
- xi. Examine every component of the packaging if any secondary and/or/outer container is intended to be re-used. Do not re-use if packaging exhibit signs of interior or exterior damage. Decontaminate any soiled container with 10% sodium hypochlorite. Refer to Appendix 9 for Emergency Response Procedure.
- xii. If shipping using dry ice, use leak-proof container and an outer packaging that allow for the release of carbon dioxide gas when the solid evaporates

(refer Appendix 5). Place the dry ice outside the secondary packaging. Provide interior support to secure the secondary container as the refrigerant evaporates. Dry ice is considered a miscellaneous hazard (Class 9) by IATA. For labeling, refer to section 7.0.

- xiii. If wet ice is used, use leak proof outer packaging or over pack. Contain the ice within its own container, for example, a freezer brick or gel pack, or within the outer packaging or overpack. Provide interior support to secure the secondary packaging in the original position after the ice has melted.
- xiv. Use an overpack to combine several triple packages into one large package. Mark and label each triple package inside the overpack. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels, proper shipping names and net quantities. Mark the outer container of the overpack with the word "Overpack Used". The overpack marking is an indication that packages contained within comply with prescribed specification (Appendix 8).

6.2 MARKING AND LABELLING

Label the outer packaging in print or clear writing in capital letters:

- i. Shipper: Enter the full name, address and contact number of the person packing the shipment. THIS PERSON MUST BE TRAINED on packaging biological substances for transport.
- ii. Consignee: Enter the full name, address and contact number of recipient.
- iii. Transport Details: Enter the Category, Proper Shipping Name, UN Number and hazard Class (Appendix 3).
- iv. Quantity and Type of Packaging: Enter the quantity (Weight or Volume) of the specimen and type of packaging. If using an overpack, state **"OVERPACK USED"**.
- v. Packing Instructions: Enter appropriate packing instruction number (Refer to Appendix 3).
- vi. If refrigerants are used, indicate their presence. For example if dry ice is used, enter the UN number for dry ice and weight used. Example: UN 1845 DRY ICE NET WEIGHT 3.5 kg. Include the class 9 Miscellaneous label.

- vii. If the specimen contains chemical preservative for example: alcohol or formalin, include the label showing appropriate class number. Example for specimen inactivated with alcohol: Class 3.
- viii. If using an outer packaging other than the UN specified packaging, include a label with the phrase '**OVERPACK USED**' and a label phrased '**Inner packaging comply with prescribed specifications**'.
- ix. Enter emergency contact number of the referring laboratory (must be contactable 24 hours).
- x. All the information above must also be entered on the overpack container.

Refer to Appendix 5 for labels required.

6.3 DOCUMENTATION

- i. Complete a **Shipper's Declaration for Dangerous Goods (SDDG)** form in triplicates when infectious substance belonging to Category A or B is being transported. Retain one copy for your record for a minimum of 3 months or until the results are received .
- ii. Refer to Appendix 6 for an example of a SDDG form.
- iii. The shipper shall provide the carrier with 2 signed copies of the Shipper's Declaration.
- iv. The shipper shall complete an Airway bill (Appendix 10).
- v. For consignment containing dangerous goods: the column under "Handling Information" must be filled with the phrase 'Dangerous goods as per attached Shipper's Declaration' on the SDDG form. For a cargo aircraft shipment, include the word – 'Cargo Aircraft Only'.
- vi. The shipper shall prepare a Customs Invoice (International only) with regards to commercial value of shipment.

6.4 ARRANGEMENT WITH DESIGNATED INTERNATIONAL REFERRAL LABORATORIES AND TRANSPORTATION (**Not applicable to door-to-door courier services)

- i. The referral laboratory has to obtain an import permit from their own government and send a copy to the shipper. The referring laboratory must obtain export permit from Disease Control Division, Ministry of Health or KLIA health office.

- ii. Make prior arrangements with the receiving referral laboratory about time of sending and arrival of shipment by e-mail.
- iii. When the referral laboratory agrees to accept the shipment at the appointed time and date, make arrangements with cargo airlines and request for the following information:
 - Airway bill number
 - Flight number
 - Time and date of Departure
 - Time and date of Arrival

(Example: KARGO UDARA MAS contact number: For airway bill reservation: 03-87771888. For flight reservation: 03-87771655 / 1656 / 1652)
- iv. The following information is needed by the carrier airline during reservation:
 - Airport of destination
 - Type of specimen - DGR – e.g Infectious Substances
 - Class 6 or 6.2, UN number
 - Approximate weight of specimen
 - Information on any refrigerant used e.g Dry ice, Class 9, UN 1845 and the approximate weight.
- v. Inform the confirmed flight details with the receiving referral laboratory.
- vi. Make arrangements for transportation to the airport and preparation of payment by warrant.

6.5 CARGO ACCEPTANCE AT AIRPORT CARGO AREA

- i. Parcel must reach cargo acceptance counter at least 4 hours before the flight.
- ii. Weigh the package at MAS CARGO SERVICE DEPARTMENT, EXPORT SECTION (for KLIA - at Base CORE 1). Bring the weight slip to the acceptance counter. Submit the SDDG form together with a copy of the shipper's licence. The import permit and Customs invoice is only required for international shipment
- iii. Ensure all documents are in accordance with IATA regulations. An acceptance form will be issued. Proceed for parcel inspection.
- iv. Parcel inspection is carried out at the designated counter (for example at KLIA it is the SGS Petrotechnical Inspection Company Counter). A minimum

- of RM50 will be charged for an inspection. A letter of inspection confirmation for safe transport is issued.
- v. Return to the cargo acceptance counter to submit the letter of inspection and package. Proceed to E-Dagang Centre counter for payment of freight service charges. A Customs Declaration of Goods to be Exported is issued.
 - vi. Proceed to the Customs office for inspection. The Customs Declaration form is stamped for clearance.
 - vii. Submit the Customs Declaration form to the MAS Cargo acceptance counter. An acceptance receipt is issued.
 - viii. File all documents and receipts.

7. PROCEDURES FOR LAND AND WATER TRANSPORT

7.1 GENERAL REQUIREMENTS

- i. Follow IATA Packaging Instructions 620 for packaging Category A infectious substances for land transport or packaging 650 that is used for air transport as outlined in Section 6.
- ii. Pack, mark, document and transport Category B and Category C according to the requirements in MS 1042-3, outlined in the following sections
- iii. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport. This includes transshipment between transport units and laboratories as well as removal from an overpack for subsequent manual handling.
- iv. The packaging shall consist of three components:
 - a) A primary receptacle,
 - Examples of a primary receptacle are a urine container or a screw capped container or a blood tube. For tissues with preservative (for HPE) plastic bags should not be used.
 - The primary container must be labeled with the name of patient, identification card or hospital registration number, specimen type (if necessary) and test request.
 - Primary receptacles shall be packed in secondary packaging in such a way that under normal conditions of transport, they cannot break, be punctured or leak their contents. If multiple primary receptacles are

placed in a single secondary packaging, they shall be secured together, individually wrapped or separated to prevent contact between them.

- Specimens sent in liquid nitrogen should be placed in a dry shipper.
- Microscopic slides should be packaged together by surgical number. These often become broken in shipment unless carefully packaged. Commercially available plastic slide holders manufactured to withstand shipment should be used or the slides should be sufficiently wrapped and padded inside their shipping container to prevent breakage.
- Paraffin blocks should be packaged together by surgical number and shipped in an appropriately labeled box or plastic bag. Do not wrap in gauze. Paraffin blocks may melt in hot climate so appropriate packaging is recommended prior to shipment.

b) A leak-proof secondary packaging

- Examples of a secondary packaging are a snap lock plastic bag and an empty clean screw cap jar.
- Secondary packaging shall be secured in an outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
- For liquids, absorbent material e.g. gauze, cotton, paper towel or super absorbent pad, should be present in case of leakage and for cushioning.
- A liquid nitrogen dry shipper shall not be used as secondary packaging.

c) An outer packaging

- The outer packaging shall be a solid strong and durable container fitted with a secure closure to prevent loss of contents under normal transport conditions.
- v. Place primary receptacle into the secondary packaging. Each primary receptacle may be individually wrapped or separated with absorbent material or bubble wrap. If multiple primary receptacles are placed in a single secondary packaging, a rubber band may be used to secure all inner receptacles.

7.2 LABELLING, MARKING AND DOCUMENTATION

- i. Packaging of Category B and C biological materials for surface transport should be labeled clearly with the following information on the outer packaging.

- ii. Contact name and organization address of both referral and referring laboratories including 24 hours emergency contact number of the referring laboratory.
- iii. If refrigerants are used, their presence is indicated.
- iv. Documents identifying the contents of the primary receptacle or request forms should be outside the secondary package.
- v. Any documents required by a transporter shall be accessible without opening the package.

8. REFRIGERANTS

- i. Mark the outer packaging to indicate what refrigerant is being used. This is important because some of the refrigerants pose some hazards.
- ii. Use a leak-proof outer packaging or overpack if wet ice is used. Contain the ice within its own container, for example a freezer brick or gel pack or within the outer packaging or overpack. All the primary receptacles should not be in direct contact with the refrigerants
- iii. Design and construct the outer packaging so that the release of carbon dioxide gas is permitted to prevent a build-up of pressure that could rupture the packagings. Mark the outer packaging "Dry ice".
- iv. If liquid nitrogen is used as refrigerant, note the presence in the outer packaging. The outer packaging should have provision for the escape of the expanding refrigerant when a dry shipper is not used. Mark the outer packaging "Liquid nitrogen"
- v. Shipper shall ensure adequate and appropriate refrigerants being used in order to maintain required temperature (4-8°C) upon arrival at the referral laboratories. This is important to ensure good quality specimens.

9. PROCEDURES FOR BIOLOGICAL MATERIALS STORED IN HAZARDOUS CHEMICALS

Note: Biological materials that are stored in chemical preservatives may be non-infectious but are classified as Dangerous Goods, and assigned according to the Hazard class of the chemical. Four substances that are commonly used to inactivate or preserve biological substances are ethanol, isopropanol, formalin and glycerine. Glycerine or glycerol used for stained specimens are not regulated in any concentrations. (Refer Appendix 3)

- i. Most flammable liquids fall into Hazard Group 3. Within each Hazard Class, materials are classified into three Packaging Groups.
- ii. Materials in Packing Group 1: Considered the most dangerous; have a boiling point less than or equal to 35 °C.
- iii. Materials in Packing Group II: Considered moderately dangerous have a boiling point above 35 °C and a flash point less than 23 °C.
- iv. Materials in packing Group III: have a boiling point above 35 °C and a flashpoint between 23 °C and 60 °C.
- v. Ethanol or ethyl alcohol is most commonly used in concentrations of 70% and is assigned to UN 1170, Class 3. Concentrations between 10% to 80% fall into Packing Group III, while above 80%, for example specimens inactivated in 95% alcohol for PCR investigations fall into Packing Group II.
- vi. Isopropanol is most commonly used at concentrations of 50% and fall into Packing Group II. Concentrations at 10% to 30% fall into Packing Group III.
- vii. Preserved biological specimens such as fixed post mortem specimens are usually in 10% neutral buffered formalin solutions and contain 3.7% or 4% formaldehyde and are not regulated for transport, provided the volume is kept at the minimum requirement.
- viii. Formaldehyde more than 10% to less than 25% is classified as “UN 3334, Aviation regulated liquid, formaldehyde, Class 9”.
- ix. When shipping Formalin solutions refer to the MSDS to determine the percent of formaldehyde. Full strength Formalin is 37% formaldehyde. Formalin is a mixture of formaldehyde and methyl alcohol. IATA identifies formalin as Formaldehyde solution.
- x. Formalin with more than 25% formaldehyde and combined with a flammable substance such as methyl alcohol is classified as “Formaldehyde solution, flammable, UN 1198, Class 3 (Sub risk 8) Packing group III. (Note: Formaldehyde solutions in these concentrations are noxious and can cause extreme annoyance or discomfort to crew members in the event of a spill or leak on an aircraft.)
- xi. Formaldehyde, not less than 25% (> 25%) is assigned to UN 2209, Class 8, Formaldehyde solution, Packing Group III.

10. REFERENCES

This document uses the IATA Regulations and the UN Model Regulations to categorise the substances being transported. In addition the World Health Organization recommendations regarding appropriate packaging, labelling and handling of infectious substances have been followed.

The following resources and reference documents should be used in conjunction with this document:

1. World Health Organization (2011) Guidance on regulations for the Transport of Infectious Substances 2011–2012 WHO/HSE/IHR/2010.8
http://www.who.int/ihr/publications/who_hse_ihr_20100801_en.pdf.
2. IATA Dangerous Goods Regulations, 53rd Edition (2012); Infectious Substances Shipping guidelines. 12th edition. The complete reference guide for pharmaceutical and health professionals.
3. International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2011-2012 (Doc 9284 AN/905)
4. United Nations — *Recommendations on the Transport of Dangerous Goods, Model Regulations*, 17th edition.
5. World Health Organization (2004) *Laboratory biosafety manual*, 3rd ed., Geneva.
6. Department of Standards Malaysia. MS 1513 Manual of tests and criteria for transport of dangerous goods -Part 4: Classification procedures, test methods and criteria relating to Class 2, Class 3, Class 4, Division 5.1, Class 8 and Class 9.
7. Department of Standards Malaysia. MS 1042: Part 3 (Draft) Biocontainment and Biosafety in Microbiological Laboratories (Personal communication).
8. National Pathology Accreditation Advisory Council. 2007. Requirement for the packaging and transport of pathology specimens and associated materials.
9. A guide for shipping infectious substances. World Health Organization, June 2010.

Appendix 1: Classes of Dangerous Goods

Dangerous goods are articles or substances, which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the regulations or which are classified according to the regulations (*IATA DGR 1.0*).

Dangerous goods are defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of three UN packing groups according to the provisions of this section. The nine classes relate to the **type** of hazard, whereas the packing groups relate to the applicable **degree of danger** within the class. (*IATA DGR 3.0.1.1*). Some of the 9 nine classes are broken down into divisions.

A. The nine classes of dangerous goods

Class 1: Explosives



- 1.1 Mass explosion hazard
- 1.2 Projection hazard but not a mass explosion hazard
- 1.3 Fire hazard, minor blast hazard, and/ or a minor projection hazard but not a mass explosion hazard
- 1.4 No significant hazard
- 1.5 Very insensitive, mass explosion hazard
- 1.6 Extremely insensitive explosive, no mass explosion hazard

Class 2: Gases



- 2.1 Flammable gas
- 2.2 Non-flammable, non toxic gas

2.3 Toxic gas

Class 3: Flammable liquids (no divisions)



Class 4: Flammable solids



Flammable solid

1.1 Substances liable to spontaneous combustion

1.2 Substances which, in contact with water, emit flammable gas

Class 5: Oxidizing substances and organic peroxides



5.1 Oxidizer

5.2 Organic peroxide

Class 6: Toxic and infectious substances



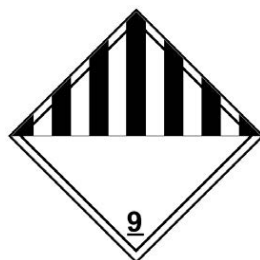
Class 7: Radioactive material (no divisions)



Class 8: Corrosives (no divisions)



Class 9: Miscellaneous dangerous goods – e.g dry ice



Appendix 2: Classification of biological materials for transport

The classification of biological materials are based on the level of the infectivity of the biological material and the mode(s) of the transportation used while acknowledging the regulatory requirements where applicable.

Infectious substances

Infectious substances shall be classified as Division 6.2 dangerous goods and assigned the appropriate UN number: UN 2814, UN 2900, UN 3291 or UN 3373 and classified either as Category A or Category B. There is no direct relationship between Risk Groups of microorganisms and categories A and B.

a) Category A, UN 2814

Category A biological materials comprise infectious substances which are 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.

NOTE: An exposure occurs when an infectious substance is released outside its protective packaging, resulting in physical contact with humans or animals.

Table 1 provides a list of indicative examples of substances that meet these criteria. This list is reproduced from the UN Recommendations on the Transport of Dangerous Goods, Model Regulations for Category A Infectious substances. This list is not exhaustive. Infectious substances including new or emerging pathogens which do not appear in the Appendix but which meet the same criteria need to be assigned to Category A. In addition if there is doubt as to whether or not an infectious substance meets the criteria for Category A it needs to be included in Category A.

Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814.

The proper shipping name for UN 2814 is "INFECTIOUS SUBSTANCE, AFFECTING HUMANS".

b) Category A, UN 2900

Infectious substances which cause disease only in animals shall be assigned to UN 2900.

The proper shipping name for UN 2900 is "INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY".

Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or

professional judgment concerning individual circumstances of the source human or animal.

c) Category B, UN 3373

An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373.

The proper shipping name of UN 3373 is BIOLOGICAL SUBSTANCE, CATEGORY B. (The shipping name DIAGNOSTIC SPECIMENS, CLINICAL SPECIMENS has been phased out.)

Packing instruction P650 (UN) or PI 650(IATA) apply to these substances.

Figure 1 shows examples of triple packaging systems for Category A and Category B infectious substances.

d) Category C

Category C applies to surface transport only. This covers human, animal or plant sample including excreta, secretions, blood and its components, tissues and tissue fluids, not belonging to Category A or B as listed in IATA Dangerous Goods Regulation. Category C biological materials comprises substances with a low probability of causing disease in humans, animals and plants that could cause community concerns if the specimen was to leak from its packaging.

If transported by air, IATA regulations for **Exempt Patient Specimens** shall be followed. If transported by land, Category C shall be packaged, marked, documented and transported according to the requirements in Malaysian Standard MS 1042-3. Where the transport is likely to be multi-modal, the packaging requirements of all modes shall be met. For example, if a package is to go by both air and road, the packaging requirements for air will satisfy both requirements.

d) Exempt substances

Substances which do not contain infectious substances, or substances which are unlikely to cause disease in humans or animals, are not subject to the IATA DGR unless they meet the criteria for inclusion in another class. Examples include:

- Non-infectious biological materials from human, animals or plants non-infectious cells (cell-lines), tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA or RNA or other genetic elements, antibodies and non-infectious plasmids.
- Substances which are unlikely to cause disease in human or animals
- Substances containing microorganism which are non-pathogenic to human or animals.

- Substances which have been neutralized or inactivated such that any pathogen present no longer pose a health risk.
- Environmental samples including food and water samples which are not considered to pose a significant risk of infection unless they meet the criteria for inclusion in another class.
- Dried blood spots
- Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation.
- Non-infectious biological products including an experimental or investigational products subject to approval permit or licensing by other regulatory agencies.

For a comprehensive list of *Exempt Substances*, the current edition of the IATA Dangerous Goods Regulations shall be consulted.

Table 1 Examples of microorganisms assigned as UN 2814 or UN 2900 included in category A (in any form unless otherwise indicated)

UN 2814 Infectious substance affecting humans	
<i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> , <i>Pseudomonas malei</i> , <i>Glanders</i> (cultures only) <i>Burkholderia pseudomallei</i> , <i>Pseudomonas pseudomallei</i> (cultures only) <i>Chlamydia psittaci</i> , avian strains (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Costello burnetti</i> (cultures only) Crimean-Congo haemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) Ebola virus <i>Escherichia coli</i> , verotoxigenic (cultures only) Flexal virus <i>Francisella tularensis</i> (cultures only) Guanarito virus Iceland virus Hantavirus causing haemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Highly pathogenic avian influenza virus (cultures only)	Human immunodeficiency virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus <i>Mycobacterium tuberculosis</i> (cultures only) Nipah virus Omsk haemorrhagic fever virus <i>Poliovirus</i> (cultures only) Rabies virus (cultures only) <i>Rickettsia prowazekii</i> (cultures only) <i>Rickettsia rickettsii</i> (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus <i>Shigella dysenteriae</i> type I (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only)
UN 2900 Infectious substance affecting animals	
African swine fever virus (cultures only) Avian paramyxovirus Type I, Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) <i>Mycoplasma mycoides</i> , Contagious bovine pleuropneumonia (cultures only)	Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goat-pox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

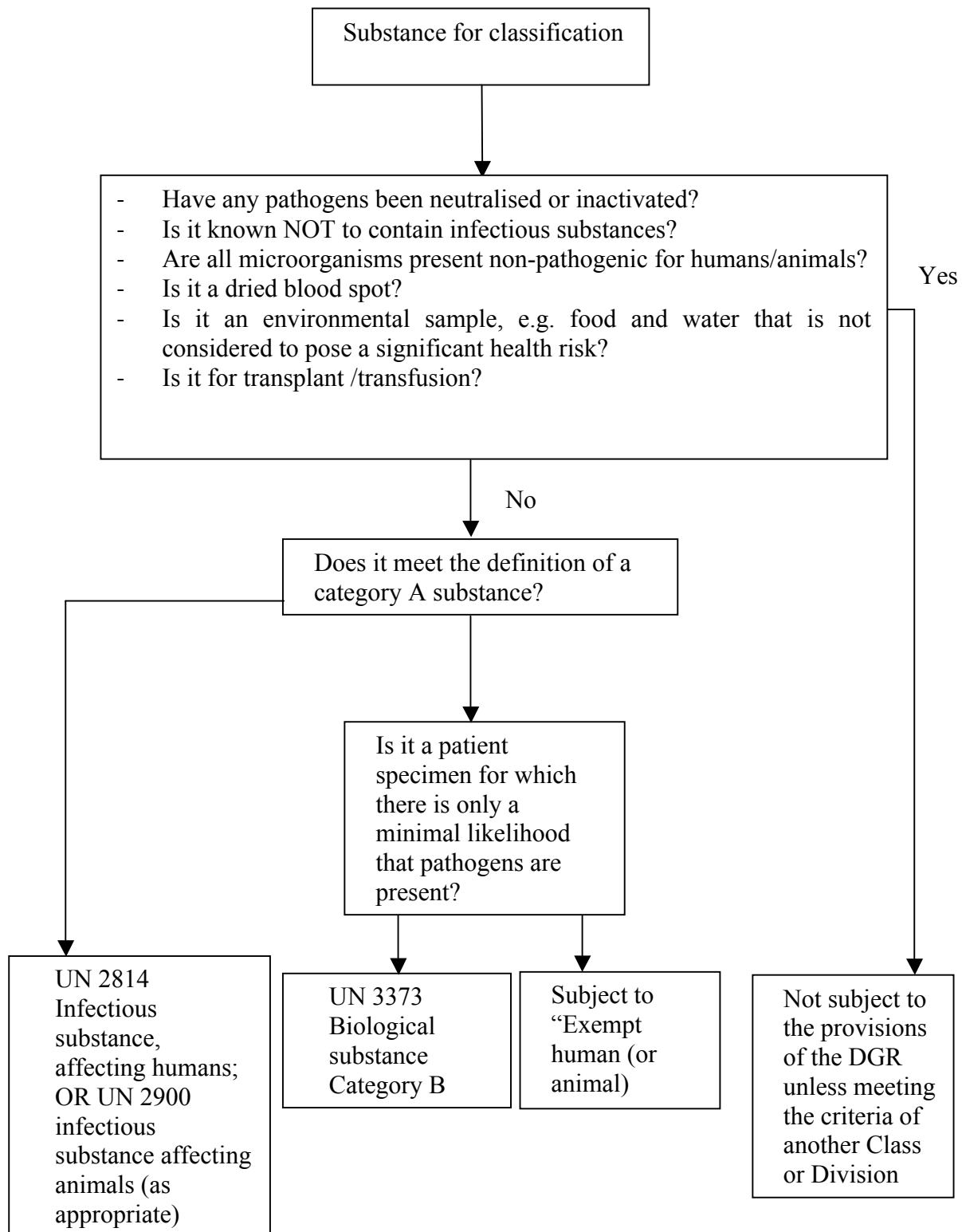
Appendix 3: Categories of specimen and preservatives

Description / Category	Proper Shipping name	UN number	Hazard Class	Packing Instruction (PI)	Max. Net Qty /Pkg for passenger aircraft	Max Net Qty /pkg for cargo aircraft
Category A Infectious substance, affecting humans	Infectious substance, affecting humans (Technical name)	UN 2814	6.2	620	50 ml or 50 g	4L or 4 kg
Category A Infectious substance, affecting animals	Infectious substance, affecting animals (Technical name)	UN2900	6.2	620	50 ml or 50 kg	4L or 4 kg
Category B Infectious substance	Biological substance	UN 3373	6.2	650	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon dioxide, solid	UN 1845	9	954	200 kg	200 kg
Non infectious GMOs	Genetically modified microorganisms		9	959	No limit	No limit
Infectious GMOs	Infectious substance affecting humans OR Infectious substance affecting animals	UN 2814 Or UN 2900 OR UN 3373	6.2	620 650	50 mL or 50 g	4L or 4 kg
Patient specimens	"Exempt human specimens" or "Exempt animal specimens"			Triple packaging	Primary receptacle (500 ml or 500g) Outer packaging (4L or 4kg)	Primary receptacle (500 ml or 500g) Outer packaging (4L or 4kg)
Category C	Any Biological substance For land transport			Triple packaging		
Preserved specimens In 10% Neutral buffered Formalin (containing 3.7% or 4% Formaldehyde)	"Exempt human specimens" or "Exempt animal specimens"					
Preserved specimens in Formalin solutions containing 10-24.9% Formaldehyde	"Exempt human specimens" or "Exempt animal specimens" REGULATED Formaldehyde solution with less than 25% formaldehyde	UN 3334	9 PG III	852	Primary receptacle (30 mL) Max Qty. Outer package 500 mL	
Formalin > 25%	Formaldehyde solution, flammable	UN 1198	3 (8)	Y342	1L	
	Formaldehyde solution	UN 2209	8 PG III	354 365	5L	

Description / Category	Proper Shipping name	UN number	Hazard Class	Packing Instruction (PI)	Max. Net Qty /Pkg for passenger aircraft	Max Net Qty /pkg for cargo aircraft
Inactivated specimens 70 % Ethanol	Ethanol	UN 1170	3 PG III	Y344	Primary receptacle (30 mL) Max Qty. Outer package 1L	
Inactivated specimens 90 % or 95% Ethanol (for DNA study)	Ethanol	UN 1170	3 PGII	Y344	Primary receptacle (30 mL) Max Qty. Outer package 1L	
Inactivated specimens in Isopropanol above 50%	Isopropyl alcohol (above 30%)	UN 1170	3 PGII	Y344	Primary receptacle (30 mL) Max Qty. Outer package 1L	

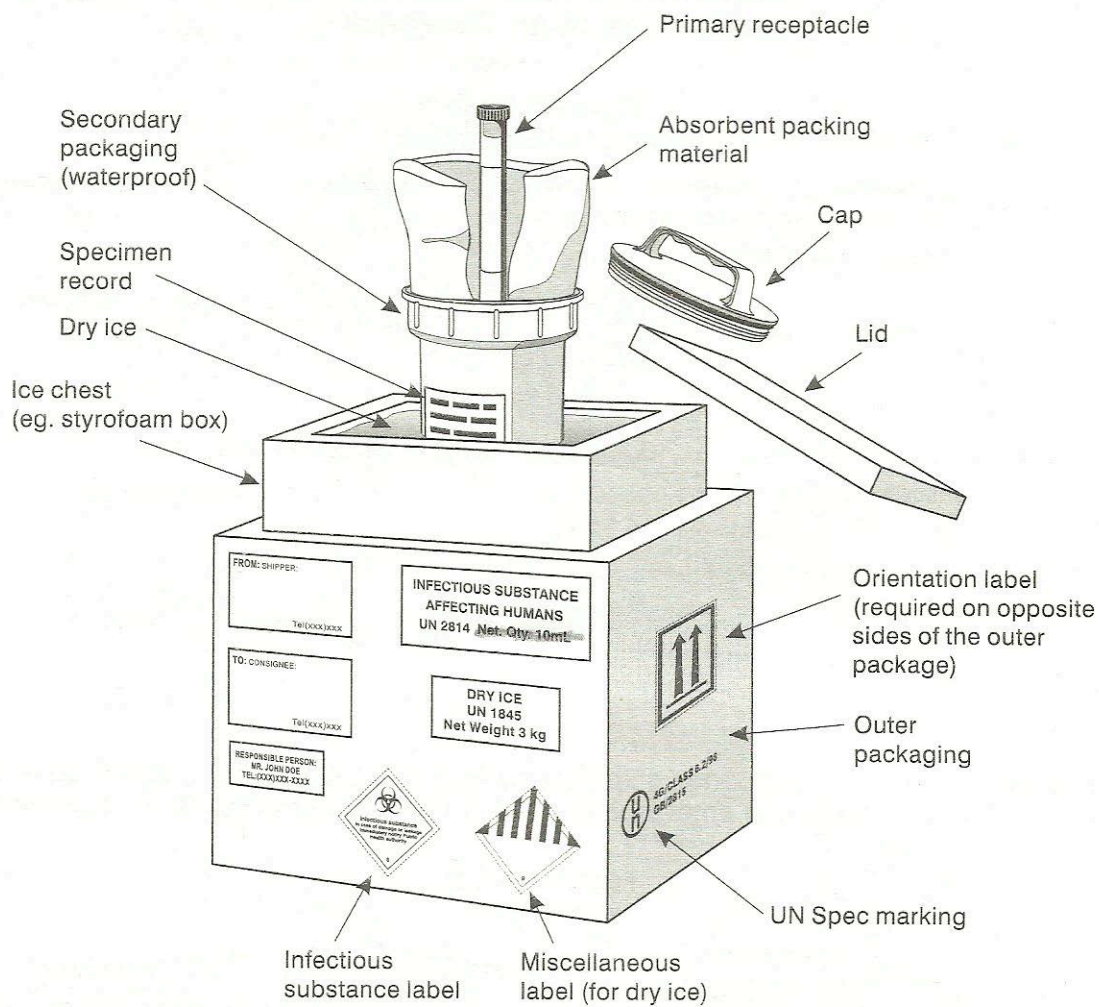
PG = Packaging group

Appendix 4: Flowchart for Specimen Classification




Appendix 5: UN specification mark and labels

An example of the outerbox for Category A infectious Substance with dry ice.



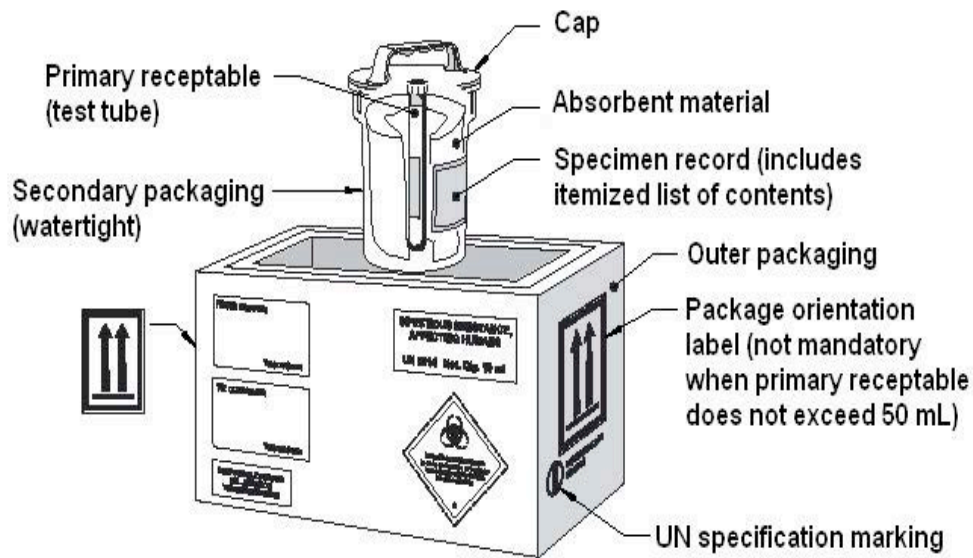
Appendix 6: Example of a Shipper's Declaration for Dangerous Goods (SDDG)

SHIPPER'S DECLARATION FOR DANGEROUS GOODS						
Shipper			Air Waybill No. Page of Pages Shipper's Reference Number (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) <input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT <input type="checkbox"/> CARGO AIRCRAFT ONLY			Airport of Departure			
Airport of Destination:			Shipment type: (delete non-applicable) <input type="checkbox"/> NON-RADIOACTIVE <input type="checkbox"/> RADIOACTIVE			
NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack- ing 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 government regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Place and Date Signature (see warning above)		

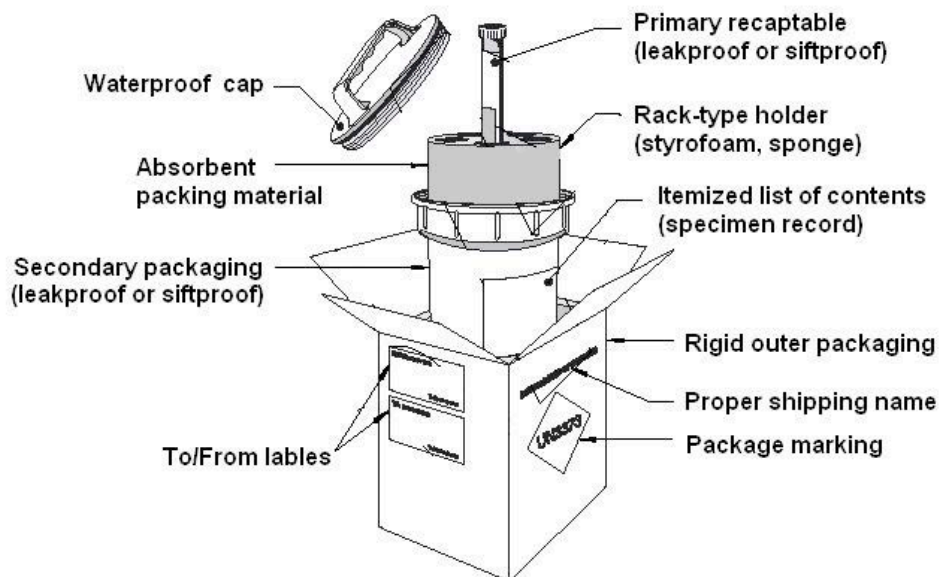
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Appendix 7 : Examples of triple layer packaging

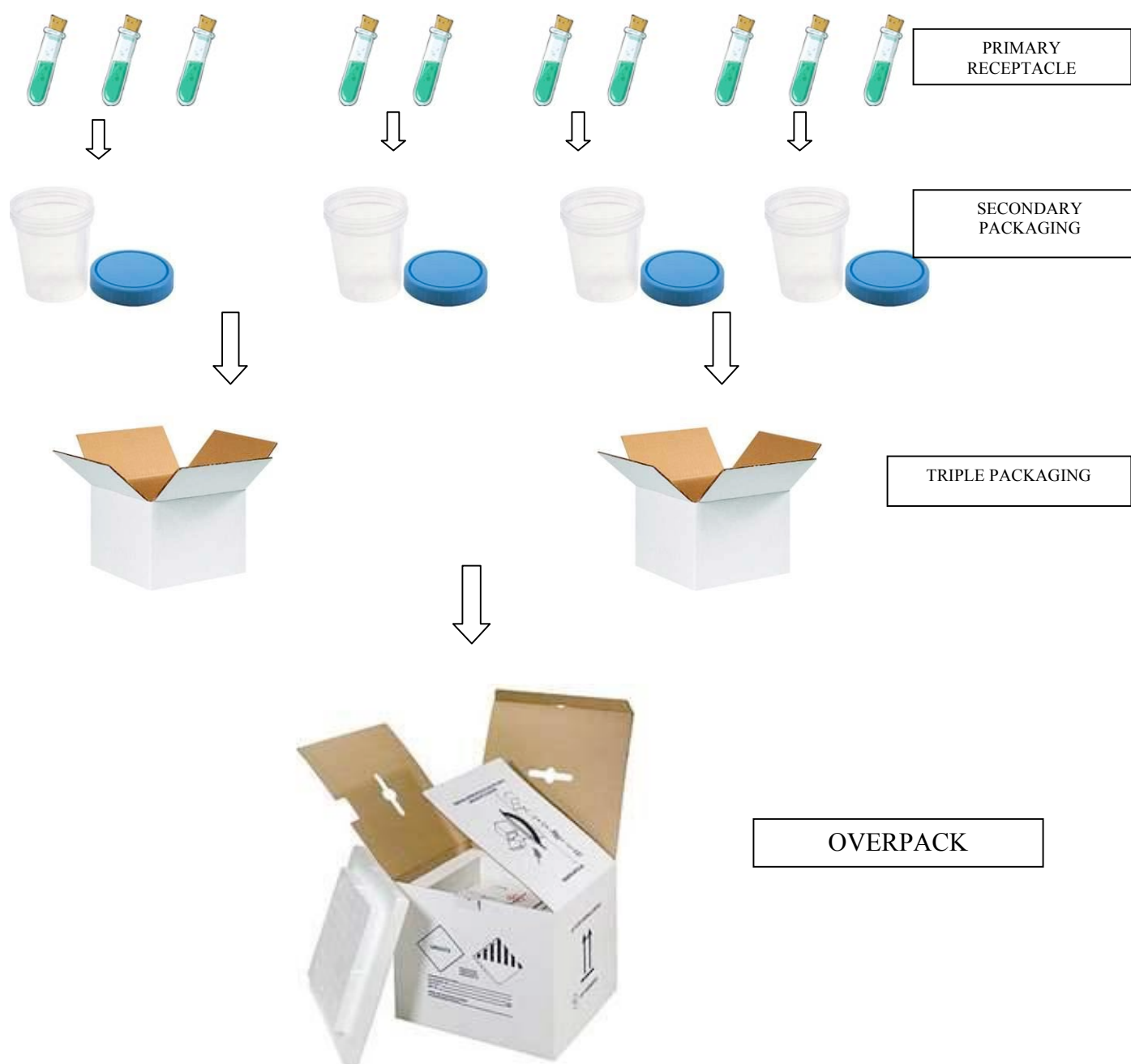


a) Packing and labeling of Category A infectious substances



b) Packing and labeling of Category B infectious substances

Appendix 8: Steps in triple layer packaging



Appendix 9: Emergency Response Procedure

The following information should be included in the packaging of all biological materials classified as UN 2814, 2900, 3373 and 3245. This enables carriers, operators and others to respond appropriately in the event of an emergency that includes spillage.

Emergency contact details

All shipment of infectious substances in Category A and Category B should have the name, address and emergency telephone number marked either on the package, or on the Air Waybill and Shipper's Declaration. The appropriate location for these emergency contact details is in the "Additional Handling Information" section of the Shipper's Declaration.

For land transport, the name, address and telephone number should be included either on the package or accompanying documentation

Responsibilities

Be sure, the person answering the emergency telephone number has the relevant information directly available or has direct access to a person with that information. This responsible individual should be knowledgeable of the hazardous material being shipped and has comprehensive emergency response and incident mitigation information for that material, or has immediate access to a biorisk officer who possesses such knowledge and information.

Reporting

Any spills, leaks, emissions or accidents involving biological substances should be notified to the Pathology Department of the Shipper and consignee. For infectious substances in Category A, classified as UN 2814, the incident should also be reported to the Disease Control Division, Ministry of Health, Malaysia.

Mitigation procedures

If any person responsible for the carriage or opening of packages containing infectious substances becomes aware of damage to or leakage from such a package, that person must:

- Avoid further handling of the package or keep handling to a minimum.
- Inspect adjacent package for contamination and put aside that may have been contaminated.
- Inform the appropriate public health authority or veterinary authority and provide information on any countries of transit where persons may have been exposed to danger.

- Notify shipper and the consignee.
- Proceed with further handling of the package only if authorized and trained. Use appropriate personal protective equipment (e.g. disposable gloves)
- Follow established spill clean up procedures if required.

Spill clean-up procedures

Clean-up or disposal should only be carried out by a competent person. **DO NOT CLEAN-UP OR DISPOSE OF INFECTIOUS SUBSTANCES UNLESS TRAINED OR UNDER SUPERVISION OF A COMPETENT PERSON.**

- Keep unauthorised personnel away.
- Do not touch or walk through spilled material.
- Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
- Be particularly careful to avoid contact with broken glass or sharp objects that may cause cuts or abrasions that could significantly increase the risk of exposure.
- Cover the spill with a cloth or paper towels to contain it.
- Pour an appropriate disinfectant over the cloth or paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).
- Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.
- After about 30 min, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.
- Clean and disinfect the area of the spillage.
- Dispose of contaminated materials into a leak-proof, puncture-resistant waste disposal container.
- Obtain identity of substance involved and report the incident and decontamination to the appropriate authorities.
- Detailed information on disinfectants and their recommended use can be found in *Laboratory biosafety manual*, 3rd ed., Geneva, World Health Organization, 2004.

- Damaged packages containing solid CO₂ as a refrigerant may produce water or frost from condensation of air. Do not touch this liquid as it could be contaminated by the contents of the package.
- Liquid nitrogen may be present and can cause severe burns.
- Cover damaged package with absorbent towels or rags and keep wet with liquid bleach or other disinfectant. Liquid bleach will generally effectively inactivate the released substance.

First Aid:

CAUTION: Exposed person(s) may be a source of contamination. Persons administering first aid should take precautions to avoid personal exposure or secondary contamination of others. Wear gloves and protecting clothing, including face and eye protection if indicated.

Medical advice should be obtained any time there is a suspected exposure to infectious substances resulting from a damaged package.

- In the event of exposure to any infectious substance, move exposed person(s) to a safe isolated area and remove and isolate contaminated clothing and shoes.
- Call emergency medical services.
- In case of contact with substance, wash or disinfect the affected area as soon as possible, regardless of the agent. Even if an infectious substance comes into contact with non-intact skin, washing of the affected area with soap and water or with an antiseptic solution can reduce the risk of infection. If exposure to eyes, immediately flush eyes with running water. Continue this until ambulance and emergency medical services arrives.
- Most effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.
- Ensure that medical personnel are aware of the substances involved, and take precautions to protect themselves.
- If appropriate, report the accident or incident to the Disease Control Division, Ministry of Health, Malaysia.

Appendix 10: Example of Airway Bill

NOTE : SHADED AREAS TO BE COMPLETED ONLY BY MAS OR MAS AGENT

AIRPORT OF DEPARTURE (ADDRESS OF FIRST CARRIER) AND REQUESTED ROUTING				AIRPORT OF DESTINATION				BOOKED		AIR WAY BILL NUMBER	
								FLIGHT/DAY		FLIGHT/DAY	
ROUTING AND DESTINATION											
TO		BY FIRST CARRIER		TO		BY		TO		BY	
SHIPPER'S INSTRUCTIONS FOR DESPATCH											
2/		CONSIGNEE'S ACCOUNT NUMBER				CONSIGNEE'S NAME AND ADDRESS					
↓											
3/		SHIPPER'S ACCOUNT NUMBER				SHIPPER'S NAME AND ADDRESS					
↓											
4/		ISSUING CARRIER'S AGENT ACCOUNT NO.				ISSUING CARRIER'S AGENT, NAME AND CITY					
↓											
5/		AGENT'S IATA CODE				SIGNATURE OF SHIPPER.....DATE.....					
5/		CURRENCY		DECLARED VALUE FOR CARRIAGE		DECLARED VALUE FOR CUSTOMS		AMOUNT OF INSURANCE		INSURANCE - If shipper requests insurance in accordance with condition on reverse hereof. Indicate amount to be insured in figures in box marked amount of insurance.	
6/		WEIGHT CHANGE AND VALUATION CHARGE PREPAID COLLECT		ALL OTHER CHARGES AT ORIGIN PREPAID COLLECT		ACCOUNTING INFORMATION					
6/		NO OF PACKAGES --- PCT		ACTUAL GROSS WEIGHT		Kg. IN		RATE CLASS		COMMODITY ITEM NO.	
6/		CHARGEABLE WEIGHT		RATE CHARGE		TOTAL		NATURE AND QUANTITY OF GOODS (INCL. DIMENSIONS OR VOLUME)			
7/		PREPAID WEIGHT CHARGE		PREPAID VALUATION CHARGE		TOTAL OTHER PREPAID CHARGES		TOTAL PREPAID		FLIGHT	
7/		DUE CARRIER		DUE AGENT		P		DATE STAMP		OTHER CHARGES (EXCEPT WEIGHT CHARGE AND VALUATION CHARGE)	
7/		CLEARANCE & HANDLING		CARTAGE		AWB FEE		RECEIVED BY:			
8/		COLLECT WEIGHT CHARGE		COLLECT VALUATION CHARGE		TOTAL OTHER COLLECT CHARGES		COD AMOUNT		RECEIVED BY:	
8/		DUE CARRIER		DUE AGENT		Z		HANDLING INFORMATION			
9/		HANDLING INFORMATION									

Maju Tulis Sdn. Bhd.

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5.6 Packing Instructions—Class 6—Toxic and Infectious Substances

PACKING INSTRUCTION 620

STATE VARIATIONS: AUG-03, BHG-02, CAG-05/10/11, DQG-03, GBG-05, VCG-04, VUG-02

OPERATOR VARIATIONS: AF-02, AM-06/10, AS-08, BR-14, BZ-07, CA-11, CI-01, FX-09, HA-03, IJ-06, JK-03, KC-08, LA-07, MS-06, OU-12/16, SV-12, TK-07, TY-03, UU-05

This instruction applies to UN 2814 and UN 2900.

Packagings must meet the requirements of 6.5 and must be marked as required by 6.5.3.1.

General Requirements

Shippers of infectious substances must comply with these Regulations and must ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.

The packagings must include:

(a) inner packagings, comprising of:

- leakproof primary receptacle(s);
- a leakproof secondary packaging;
- other than for solid infectious substances, absorbent material, such as cotton wool, in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them;

(b) an itemized list of contents, enclosed between the secondary packaging and the outer packaging; and

(c) a rigid outer packaging. The smallest external dimension must be not less than 100 mm (4 in).

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions in 5.0.6.7.

Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 13.8 lb/in²) and temperatures in the range of -40°C to 55°C (-40°F to 130°F).

Note:

The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:

- flexible receptacles and flexible packagings;
- receptacles and packagings filled and closed under a absolute atmospheric pressure lower than 95 kPa.

Additional Requirements

Inner packagings containing infectious substances must not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 5.0.1.5.

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. 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 these substances 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 need be met.

When the infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in Category A, the words "Suspected Category A Infectious Substance" must be shown in parentheses following the proper shipping name on the itemized list of contents inside the outer packaging.

PACKING INSTRUCTION 620 (continued)

- ✈ All packages containing infectious substances must be marked durably and legibly on the outside of the package with the NAME and TELEPHONE NUMBER OF A PERSON RESPONSIBLE.

Specific Requirements

Other than for exceptional consignments, for example, large body parts and whole organs which require special packaging, the following specific requirements apply:

Substances consigned at ambient or higher temperatures: Primary receptacles must be of glass, metal or plastic. Positive means of ensuring a leak-proof seal must be provided, such as heat seal, skirted stopper or metal crimp seal. If screw caps are used, these must be secured by positive means, e.g. tape, paraffin sealing tape or manufactured locking closure.

Substances consigned refrigerated or frozen (wet ice, prefrozen packs, Carbon dioxide, solid [dry ice]): Ice, Carbon dioxide, solid (dry ice) or other refrigerant must be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.5.3.1. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has dissipated. If ice is used, the outer packaging or overpack must be leak-proof. If Carbon dioxide, solid (dry ice) is used, the outer packaging or overpack must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

Substances consigned in liquid nitrogen: Plastic primary receptacles capable of withstanding very low temperatures must be used. The secondary packaging must be capable of withstanding very low temperatures and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen must also be fulfilled. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

Lyophilized substances: Primary receptacles must be either flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

Before an empty packaging is returned to the consignor, or sent elsewhere, it must be disinfected or sterilised to nullify any hazard and any label or marking indicating that it contained an infectious substance must be removed or obliterated.

PACKING INSTRUCTION 622

STATE VARIATIONS: AUG-03, BHG-02, CAG-05, DQG-03, GBG-05, USG-13, VCG-04, VUG-02

OPERATOR VARIATIONS: 7H-02, AA-02, AM-06, AS-07/08, AV-03, BA-04, BR-14, C8-02, CI-01, CV-02, DL-02, E8-04, FX-05/09, HA-03, LA-07, ME-06, UX-08

This instruction applies to UN 3291 on passenger and cargo aircraft and Cargo Aircraft Only.

The General Packing Requirements of 5.0.2 except 5.0.2.15 must be met.

Consignments must be packed in one of the outer packagings shown below, meeting Packing Group II performance Standards.

Consignments of clinical waste and medical waste must be prepared in such a manner that they arrive at their destination in good condition, and present no hazard to persons or animals during transport.

The packaging tests may be those appropriate for solids when there is sufficient absorbent material to absorb the entire amount of liquid present and the packaging is capable of retaining liquids. In all other circumstances the packaging tests must be those appropriate for liquids.

Packagings intended to contain sharp objects, such as broken glass and needles must be resistant to puncture and retain liquids under the performance test conditions for the packaging.

OUTER PACKAGINGS											
Type	Drums					Jerricans		Boxes			
Desc.	Steel	Aluminium	Plywood	Fibre	Plastic	Steel	Plastic	Wood	Plywood	Reconstituted wood	Fibreboard
Spec.	1A2	1B2	1D	1G	1H2	3A2	3H2	4C1 4C2	4D	4F	4G

PACKING INSTRUCTION 650

STATE VARIATIONS: BHG-02, CAG-05, DQG-03, FRG-05, GBG-05, VCG-04

△ OPERATOR VARIATIONS: AF-02, AM-06/10, AR-02, AS-08, BR-14, BZ-07, CI-01, CO-07, CS-07, FX-09, IJ-06/10, JJ-06, JK-03, KC-08, KE-06, LA-07, LH-05, MN-03, MS-06, MX-06/11, OO-01, OU-12/16, PX-08, SQ-10, SV-12, TN-05, TY-03, UA-14, UU-05

This instruction applies to UN 3373 on passenger and cargo aircraft and Cargo Aircraft Only.

General Requirements

The packagings must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

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 packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings must be secured in outer packagings with suitable cushioning material. Any leakage of the contents must not compromise the integrity of the cushioning material or of the outer packaging.

PACKING INSTRUCTION 650 *(continued)*

Packages must be prepared as follows:

(a) For liquid substances:

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;
- 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;
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent 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;
- 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).

Note:

The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:

- flexible receptacles and flexible packagings;
- receptacles and packagings filled and closed under a absolute atmospheric pressure lower than 95 kPa.
- The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(b) For solid substances:

- The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
- The secondary packaging must be siftproof;
- 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;
- Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

 An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm (4 in × 4 in).

The completed package must be capable of successfully passing the drop test described in 6.5.1.1 except that 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.

PACKING INSTRUCTION 650 *(continued)*

For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm (2 in), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high. The proper shipping name "Biological Substance, Category B" in letters at least 6 mm high must be marked on the outer packaging adjacent to the diamond-shaped mark.



Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- the overpack must be marked with the word "Overpack"; and
- the package markings must be reproduced on the outside of the overpack.

A Shipper's Declaration for Dangerous Goods is not required.

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions in 5.0.6.7.

Specific Requirements

Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If dry ice is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these Regulations except for the following:

- (a) the name and address of the shipper and of the consignee must be provided on each package;
- (b) the name and telephone number of a person responsible must be provided on the air waybill or on the package;
- (c) the classification must be in accordance to 3.6.2;
- (d) the incident reporting requirements in 9.6.1 must be met; and
- (e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

Note:

When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.

Passengers and crew members are prohibited from transporting infectious substances as or in carry-on baggage, checked baggage or on their person.

If an Air Waybill is used, the "Nature and Quantity of Goods" box must show "UN 3373", the text "BIOLOGICAL SUBSTANCE, CATEGORY B" and the number of packages.

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.



PACKING INSTRUCTION 650 *(continued)*

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. 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 these substances 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 need be met.

PACKING INSTRUCTION 852

This instruction applies to Class 8 liquids in Packing Group III on passenger aircraft.

The General Packing Requirements of 5.0.2 must be met.

Compatibility Requirements

- Substances must be compatible with their packagings as required by 5.0.2.6;
- Substances of Class 8 are permitted in glass inner packagings only if the substance is free from hydrofluoric acid.

Closure Requirements

- Closures must meet the requirements of 5.0.2.7;

Additional Packing Requirements

- Packagings must meet Packing Group II performance standards.

Single packagings are not permitted.

COMBINATION PACKAGINGS

Inner Packaging (see 6.1)	Net quantity per inner packaging	Total net quantity per package
Glass	2.5 L	5.0 L
Metal	5.0 L	
Plastic	2.5 L	

OUTER PACKAGINGS

Type	Drum						Jerricans			Box						
Desc	Steel	Alum- inium	Ply- wood	Fibre	Plastic	Other metal	Steel	Alum- inium	Plastic	Steel	Alum- inium	Wood	Ply- wood	Recon- stituted wood	Fibre- board	Plastic
Spec	1A2	1B2	1D	1G	1H2	1N2	3A2	3B2	3H2	4A	4B	4C1 4C2	4D	4F	4G	4H1 4H2



PACKING INSTRUCTION 954

OPERATOR VARIATIONS: AM-09, AS-11, CA-08, CO-09, CS-09, CZ-04, IC-08, KE-06, LC-09, TY-06, VN-11

This instruction applies to UN 1845, Carbon dioxide, solid (dry ice) on passenger and Cargo Aircraft Only.

The General Packaging Requirements of 5.0.2 must be met.

Additional Packing Requirements

Inner packages:

- (a) must be in packing designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging;
- (b) the shipper must make arrangements with the operator(s) for each shipment, to ensure ventilation safety procedures are followed;
- (c) the Shipper's Declaration requirements of Subsections 8.1 and 10.8.1 are only applicable when the Carbon dioxide, solid (dry ice) is used as a refrigerant for dangerous goods that require a Shipper's Declaration;
- (d) when a Shipper's Declaration is not required, the following information, as required by 8.2.3 for Carbon dioxide, solid (dry ice), must be contained in the "Nature and Quantity of Goods" box on the air waybill. Where an agreement exists with the operator, the shipper may provide the information by EDP or EDI techniques. The information should be shown in the following order:
 - UN 1845;
 - proper shipping name (**Dry ice** or **Carbon dioxide, solid**);
 - the number of packages; and
 - the net weight of dry ice in each package.
- (e) the net weight of the Carbon dioxide, solid (dry ice) must be marked on the outside of each package.

Dry ice used as a refrigerant for other than dangerous goods:

- (a) may be shipped in a unit load device or other type of pallet prepared by a single shipper provided that the shipper has made prior arrangements with the operator;
- (b) the unit load device, or other type of pallet must allow the venting of the carbon dioxide gas to prevent a dangerous build up of pressure (the marking and labeling requirements of Section 7 do not apply to the unit load device);
- (c) the shipper must provide the operator with written documentation or where agreed with the operator, information by EDP or EDI techniques, stating the total weight of the dry ice contained in the unit load device or other type of pallet.

Notes:

1. **Please contact EH&S at 492-6025 if shipping dangerous goods with dry ice.**
2. *Refer to the relevant airline's loading procedures for Carbon dioxide, solid (dry ice) limitations.*
3. *For Air Waybill requirements see 8.2.3. For loading instructions see 9.3.12.*
4. *For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of this packing instruction.*

UN number	Quantity per package Passage aircraft	Quantity per package Cargo Aircraft Only
UN 1845, Carbon dioxide, solid, or Dry Ice	200 kg	200 kg



PACKING INSTRUCTION 959

OPERATOR VARIATIONS: AM-09/12, MX-09/13, QA-09/13

This instruction applies to UN 3245 on passenger and cargo aircraft only.

General Requirements

The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

Packagings must meet the provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1, 5.0.2.8 and 5.0.6 and be so designed that they meet the construction requirements of IATA DGR 6.1 and 6.2. Outer packagings constructed of suitable material of adequate strength and designed in relation to the packaging capacity and its intended use must be used. Where this packing instruction is used for the transport of inner packagings of combination packagings, the packaging must be designed and constructed to prevent inadvertent discharge during normal conditions of transport.

Packagings which need not conform to the packaging test requirements of IATA DGR Chapter 6, but conforming to the following:

(a) an inner packaging compromising:

1. primary receptacle(s) and a secondary packaging, the primary receptacle(s) must be leakproof or liquids or siftproof for solids;
2. for liquids, absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material, must be in quantity sufficient 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;
3. if multiple fragile primary receptacles are placed in a single secondary packaging they must be individually wrapped or separated to prevent contact between them.

(b) a rigid outer packaging which must be strong enough for its capacity, weight and intended use, and with a smallest external dimension of at least 100mm (4 inches)

For transport the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting color and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm (2 inches); the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high.



When packages are placed in an overpack the package markings required by the Packing Instruction must either be clearly visible or the marking must be reproduced on the outside of the overpack and the overpack must be marked with the word "Overpack"

GMOs (or GMMOs) assigned to UN 3245 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations except for the following:

- a) the name and the address of the shipper and the consignee must be provided on each package;
- b) the classification must be in accordance with all applicable regulations
- c) the inspection for damage or leakage must be conducted to meet IATA DGR requirements 9.4.1 and 9.4.2;
- d) the incident reporting requirements of IATA DGR 9.6 must be met; and
- e) passengers and crew members are prohibited from transporting UN 3245 either as or in carry-on baggage or checked baggage or on their person

Additional Packing Requirements

Refrigerated or frozen specimens: ice, dry ice and liquid nitrogen

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated.
- If ice is used, the outside packaging or overpack must be leakproof.
- If carbon dioxide, solid (dry ice) is used, the requirements in Packing Instruction 954 must be met.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.