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GUIDELINES FOR THE SAFE TRANSPORT OF CLINICAL SPECIMENS AND INFECTIOUS SUBSTANCES IN MALAYSIA 2023

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Guidelines for the Safe Transport of Clinical Specimens and Infectious Substances in Malaysia
Ministry of Health,
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The document outlines optimal achievable standards in accordance with best practices and guidelines

Foreword by the

Director-General of Health Malaysia

The launch of the Guidelines for the Safe Transport of Clinical Specimens and Infectious Substances in Malaysia is very timely, offering a reference for all the medical laboratories regarding biological specimen by air transportation, land or water. Medical laboratories are responsible for safety of specimen transportation and collection. It is important to ensure biological specimens are properly packed, handled, stored and transported to safeguard the health, safety and welfare of handlers.

Biological specimens may contain infectious materials and can be a potential source of disease outbreaks. It is crucial to collect and handle specimens during transportation with utmost care, ensuring the minimum risk of infection to staff. The responsibility for the safe collection and packaging of biological specimens shall not rest entirely upon the sender. All areas of pathological specimen generation must also comply with up-to-date guidelines, and safety code of practice.

I would like to extend my heartiest congratulations to the editorial committee and members from multiple disciplines under the Pathology Services and the Medical Development Division for their contributions to this guideline. I hope that this guideline will serve as an important and comprehensive reference for all the stakeholders involved in specimen transportation.

Datuk Muhammad Radzi bin Abu Hassan
Director-General of Health
Ministry of Health Malaysia

Foreword by the

Head of Specialty for Pathology

The development of this guideline is a revision of previous Ministry of Health Malaysia Standard Operating Procedure for Transport of Biological Specimens in Malaysia 2012. Current guideline is aimed to aid all stakeholders on the safe transport of clinical specimens and infectious substances in Malaysia which involves transport activities of pathological specimens through different modes of transportation.

This guideline provides guidance on the proper methods of packaging, labelling, marking and actual transportation of various types of pathological specimens according to local and international standards. The guideline also emphasizes on awareness and training on safe transportation of specimens. The compliance to this guideline will reduce the risk of injuries in any untoward incident during transportation. The success of implementing this guideline rests on support, commitment and dedication of all related parties. This cooperation will overcome challenges of the transport of clinical specimens and infectious substances.

Finally, I would like to extend my acknowledgement to the editorial committee and reviewers for their full commitment and diligence in producing this guideline. This guideline will be continuously revised in accordance to the latest policies and requirements to remain relevant.

Dr Tengku Norita binti Tengku Yazid
Head of Specialty for Pathology
Ministry of Health Malaysia

EDITORIAL COMMITTEE & CONTRIBUTORS

Advisors

Datuk Dr. Muhammad Radzi bin Abu Hassan
Director-General of Health
Ministry of Health Malaysia

Dato' Dr. Asmayani binti Khalib
Deputy Director-General of Health (Medical)
Ministry of Health Malaysia

Dato' Dr. Mohd Azman bin Yacob
Director
Medical Development Division
Ministry of Health Malaysia

Dr Tengku Norita binti Tengku Yazid
Head of Specialty for Pathology
Ministry of Health Malaysia

Chairperson

Dr. Zanariah binti Alias
Consultant Pathologist (Anatomic Pathology)
Hospital Kuala Lumpur

Members:

Dr. Rohaidah binti Hashim
Consultant Pathologist (Medical Microbiology)
Institute for Medical Research

Dr. Mimi Azura binti Abdul Aziz
Consultant Pathologist (Haematology)
Hospital Tunku Azizah

Dr. Norhayati binti Omar
Consultant Pathologist (Anatomic Pathology)
Hospital Kuala Lumpur

Dr. Noorasmaliza binti Md Paiman
Pathologist (Anatomic Pathology)
Hospital Putrajaya

Dr. Noor Hafizah binti Hassan
Pathologist (Chemical Pathology)
Institute for Medical Research

Dr. Shenaz Banu binti Said Khan
Pathologist (Haematology)
Hospital Tunku Azizah

Dr. Ana Daliela binti Masiman
Pathologist (Chemical Pathology)
Hospital Melaka

Dr. Munirah binti Abdul Razak
Pathologist (Haematology)
Hospital Tunku Azizah

Dr. Donal Huda binti Nasril
Pathologist (Medical Microbiology)
National Public Health Laboratory

Dr. Sahlawati binti Mustakim
Pathologist (Medical Microbiology)
Hospital Sungai Buloh

Dr. Marniza binti Aziz
Pathologist (Medical Microbiologist)
Hospital Sultan Idris Shah

Dr. Subasri Armon
Pathologist (Anatomic Pathology)
Hospital Kuala Lumpur

Dr. Hafizah binti Abdullah
Pathologist (Chemical Pathology)
Hospital Tunku Azizah

Dr Olivia Tan Yen Ping
Senior Principal Assistant Director
Medical Development Division
Ministry of Health Malaysia

Dr. R N Dineshinee A/P Nadaraja
Pathologist (Chemical Pathology)
Hospital Queen Elizabeth

Dr. Khamisah binti Mohd Gaus
Pathologist (Haematology)
Hospital Umum Sarawak

Dr. Ahmad Fazlin bin Nasaruddin
Pathologist (Anatomic Pathology)
Hospital Sultan Haji Ahmad Shah

Pn. Norafaedah binti Mohd Nor
Scientific Officer (Biochemistry)
Hospital Sultan Idris Shah

Dr Suriana Aishah binti Zainal
Senior Principal Assistant Director
Medical Development Division
Ministry of Health Malaysia

EXTERNAL REVIEWERS:

1. **Dr. Jacqueline Wong Oy Leng**
   Consultant Pathologist

2. **Dr. Nor Zahrin binti Hasran**
   Public Health Physician (Epidemiology)
   National Public Health Laboratory

3. **Dr. Rozainanee binti Mohd Zain**
   Consultant Pathologist (Medical Microbiology)
   Institute for Medical Research

4. **En. Amrish Shah bin Osman**
   Scientific Officer (Microbiology)
   National Public Health Laboratory

TABLE OF CONTENT

1 INTRODUCTION

- In laboratory testing, clinical specimens and infectious substances are being transported internally within the facility or externally either within the country or abroad. Specimen integrity and timely processing of specimens are highly dependent on the handling of the specimen during transportation. Apart from that, ensuring the security and safety of specimens are very important especially if it involves infectious or hazardous substances. The possibility of becoming infectious from a leakage or an unexpected incident propel the need for specimen transportation guidelines.

- The Standard Operating Procedure (SOP) for Transport of Biological Specimens were jointly prepared by Pathology Service and Institute Medical Research in 2012. This SOP provides reference in ensuring proper and safe transport of all biological materials. The current guidelines are developed to provide more comprehensive requirements for the packaging and transportation of clinical specimens and infectious substances from collection site to medical laboratory by all modes of transportation.

- The sender, carrier and receiver involved in the transportation of clinical specimens and infectious substances shall conform to the guidelines in order to ensure safe, secure and efficient specimen transportation.

- The transportation of blood and blood products, stem cells and stem cell products are beyond the scope of this guideline and shall be referred to the respective guideline and standards.

- Transport of specimens shall comply with local and international regulations, e.g., Akta Pencegahan dan Pengawalan Penyakit Berjangkit 1988 and IATA Dangerous Goods Regulations.

2 AIM AND PURPOSE

- This guideline provides practical guidance to facilitate compliance on safe and secure packaging and transportation of clinical specimens and infectious

substances by all modes of transport, both within the country and abroad. This guideline is applicable to all parties which are involved in specimen packaging to transportation including the roles and responsibility of the sender, carrier and receiver.

3 SCOPE

This guideline will be used to ensure safe and secure packaging and transportation of clinical specimens and infectious substances within the country and abroad.

This guideline, however, does not describe the packaging and transportation of blood products, stem cell products, clinical waste and chemical waste.

4 DEFINITION / TERMINOLOGY

4.1 Specimen

In this guideline, it refers to clinical specimens or infectious substances.

4.2 Clinical specimens

Products or materials that are collected directly from humans for the purpose of diagnostic investigations / research / investigational activities / disease treatment and prevention. This includes, but is not limited to body fluids (excreta, secreta, blood, bone marrow aspirate), tissues (including fresh tissue) or body parts collected in containers, on swabs, submerged in preservative media, on glass slide, or paraffin blocks.

4.3 Infectious substances

Any materials or products that contain, or are reasonably expected to contain, biological agents(pathogens) that cause disease in humans. Pathogens include microorganisms such as bacteria, viruses, parasites, fungi and other agents such as prions. Materials such as also medical devices or equipment's contaminated by biological agents, or sampling from environment (e.g. operating theatre) are also included in this category.

Infectious substances shall be classified as in table 7.2

4.4 Cultures

The result of a process by which living organisms are intentionally propagated under controlled laboratory conditions, inside a designated medium or in animals. This results in a concentrated collection of cultivated biological agents known as cultures.

4.5 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 (Table 7.1 and Table 7.2).

4.6 Overpack

A large box that is used to transport multiple packages.

4.7 Primary container

A container or receptacle in contact with the clinical specimen.

4.8 Secondary packaging

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

4.9 Referring laboratory

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

4.10 Referral laboratory

Laboratory which receives specimens from other facilities for investigation.

4.11 Sender

A person or company that is involved in any activity involving specimen transportation by sea, land, or air.

4.12 Carrier

Assigned hospital staff or agency / company that has been authorised or licensed to transport specimens.

4.13 Dry ice

A solid/ frozen form of carbon dioxide that is used primarily as a cooling agent. It is available in block or pellet form and has a surface temperature of - 78.5℃. It is commonly used as it does not have a liquid state and sublimates directly from the solid state to the gas state.

4.14 Dry shippers

A dry shipper also known as vapour shipper is a specialized dry nitrogen insulated container that contains refrigerated liquid nitrogen (at or below -150℃) that is fully absorbed into a porous material. The careful design ensures that liquid nitrogen is kept well contained inside the walls of the outer layer, however over time depending on the size of the shipper, the vapour will dissolve. It is considered a non-dangerous product, hence not subjected to IATA regulations as a dangerous good if properly filled (i.e., no free residual liquid phase of the nitrogen remains). Pressure is prevented from building up inside even when its orientation is changed.

4.15 Biobanking

A facility that receives, stores, processes, and / or distributes specimens, as needed for future use. It encompasses the physical location as well as the full range of activities associated with its operation.

4.16 Cryopreservation

Preservation of structurally intact living cells and tissues by freezing to ultra-low temperatures (to a minimum of -196℃) using liquid nitrogen.

4.17 Dewar

A specialised non-pressurized, vacuum jacketed container that holds liquid form of gases. The dewar is also referred to as dewar flask or dewar vessel, or a liquid nitrogen tank depending on the size of the container. Dewars are used for storage or transfer of small amounts (2-50L) of liquid nitrogen. Dewar flasks are small (<5L) open-mouthed vacuum jacketed steel or glass storage devices.

4.18 Liquid nitrogen

Coolant used to cool and store samples. Nitrogen becomes liquid at −196 °C. Samples stored in the vapour phase of liquid nitrogen are −190 °C and warmer, depending on the distance from the liquid phase.

4.19 Snap-freezing

The process by which the temperature of samples is lowered very rapidly to below −70 °C using dry ice or liquid nitrogen.

4.20 Waybill

A document prepared by the carrier of a shipment of goods that contains details of the shipment, route, and charges.

5 TRANSPORT STAKEHOLDERS

The efficient transfer of infectious substances requires good coordination and harmonization between all parties involved in the shipment. This includes the person or institution sending the substance, the commercial entities involved in carrying the package, and the person or institution receiving the substance. The primary stakeholders involved are listed as the following:

5.1 Sender

5.1.1 May also be known as the consignor or shipper.

5.1.2 Ensures the correct identification, classification, packaging, marking, labelling, and documentation of the infectious substances destined for transport.

5.1.3 Ensures that the packaging selected is suitable, and compliant, for the specimens being shipped.

5.1.4 Confirms with the national authorities that the material may be legally exported.

5.1.5 Makes aware of all regulations applicable to their shipment, based upon the place or origin, transit, destination and / or mode of transport.

5.1.6 Explore whether additional approvals are required, such as export permits.

5.1.7 Makes primary contact with the receiver of the package to ensure they are able and prepared to receive the shipment.

5.1.8 Ensures that the package is prepared in accordance with the transport instructions and regulation.

5.1.9 Makes advance arrangements with the carrier to ensure:

i. There are no additional operator variations applicable to the shipment.
ii. The shipment will be accepted for appropriate transport.
iii. The shipment is undertaken by the most direct routing (direct transport if possible) avoiding arrival on weekends.

5.1.10 Prepares necessary documentation, including permits, despatch and shipping documents according to requirements, retaining a copy of each.

5.1.11 Notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time.

5.2 Packaging supplier

5.2.1 Ensures packaging materials supplied comply with national and / or regulation.

5.2.2 Makes available documents on packaging qualities to users of their packages, and / or national competent authorities.

5.2.3 Provides instructions to users regarding the procedures to be followed, and additional components needed, to ensure their packaging materials are capable of meeting performance requirements.

5.3 Carrier

5.3.1 May include logisticians, courier companies, airline freight forwarders and other transport operators, including department / hospital transport.

5.3.2 Shall ensure and monitor required holding conditions or suitable environment temperature of the shipment during transportation and in transit. Proof of temperature monitoring should be made available when requested.

5.3.3 May provide advice to the sender regarding the correct packaging, necessary shipping documents and instructions for their completion.

5.3.4 Assists the sender in arranging the most direct routing and then confirms the routing.

5.3.5 Shall have a tracking system.

5.3.6 Maintains and archives copies of the documentation for shipment and transport.

5.3.7 Notified the sender of any anticipated (or actual) delays in transit.

5.3.8 Apply for CAAM approval / permits for carriage of infectious substances.

5.4 Receiver

5.4.1 May also be known as the consignee. It is referred to the referral laboratory.

5.4.2 Confirms with the national authorities that the substance may be legally imported.

5.4.3 Obtains the necessary authorization(s) from national authorities for the receipt of the substance, for example importation permits. These may need to be provided to the sender, as applicable.

5.4.4 Arranges for the most timely and efficient collection on arrival.

5.4.5 Acknowledges receipt to the sender and to complete relevant documentation.

5.4.6 Temperature check upon arrival.

6 PACKAGING

When a specimen is transferred between the collection point of origin and to its destination, it can be subjected to challenges, including movement, vibrations, changes of temperature, humidity, and pressure. It is therefore essential that the packaging used during transport is of good quality and strong enough to withstand the shocks and loadings normally encountered during transportation.

To determine appropriate packaging for transport, specimens need to be classified according to the guide as in Appendix 1.

Basic triple packaging can be used to transport clinical specimens by all modes of transportation.

Additional requirement is required for transporting infectious specimens / substances (Classified under Category A, Category B). This is to ensure safe containment in various modes of transport.

The UN model regulations, as well as other modal agreements, provide information sheets that outline the detailed packaging requirements for various classifications and subclassifications of dangerous goods. These instruction sheets are generally referred to as “packing instructions”, and three of these may be applicable to the shipment of infectious substances:

i. P620 for Category A infectious substances.
ii. P650 for Category B infectious substances assigned to UN 3373; and if dry ice is used as coolant, additional requirements are also needed as in PI954.

The inner package:

i. Must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.
ii. The sender shall make arrangements with the carrier for each shipment, to ensure safety procedures are followed.

6.1 Basic Triple Packaging

This system consists of three layers:

i. Primary receptacle.
ii. Secondary receptacle to enclose and protect the primary receptacle.
iii. Third outer layer of packaging.

This system is illustrated in **Figure 1**.

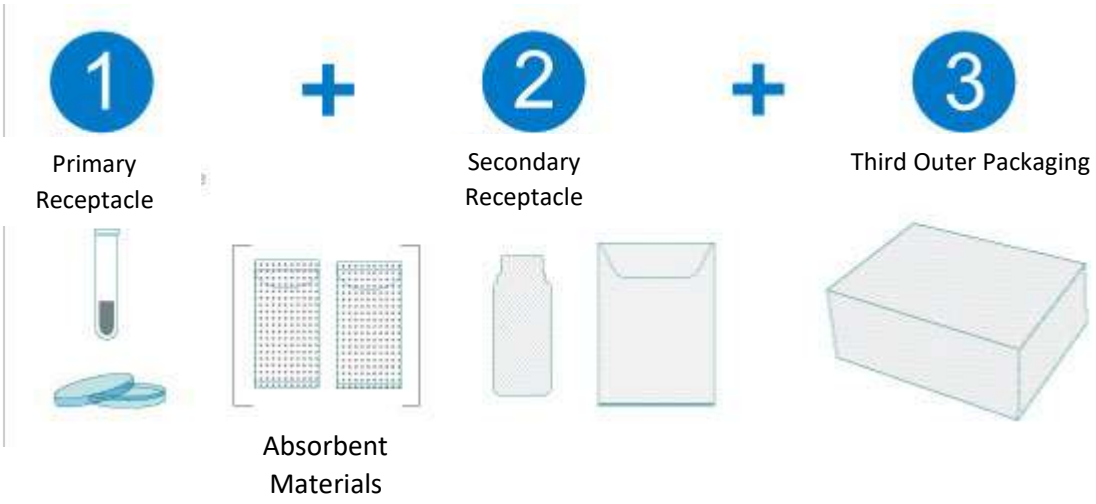


Figure 1: Examples of basic triple packaging.
Source: Safety Way Website

6.1.1 Primary Receptacle

6.1.1.1 Primary receptacle is the container (e.g., tube, vial, and bottle) that holds the specimen (Refer Figure 1).

6.1.1.2 It must be watertight and leak proof. The cap should be correctly and securely closed.

6.1.1.3 As far as practicable, the primary receptacles should be kept at an upright position during transportation.

6.1.1.4 It should be appropriately labelled as to its contents.

6.1.1.5 If the specimen is in a liquid or semi-liquid form, the primary receptacle must be wrapped by sufficient absorbent material to absorb all the liquid in the event of a breakage or leakage. Examples of absorbent materials are gauze, cotton, and super-absorbent packets.

6.1.1.6 The primary receptacle must be packed in the secondary receptacle in such a way that it will not break.

6.1.2 Secondary Receptacle

6.1.2.1 Secondary receptacle is the container into which the primary receptacle and the surrounding absorbent materials are placed. It is used to protect the primary receptacle.

6.1.2.2 It must be watertight and leak proof. Examples of secondary receptacles are:

i. Disposable, zip-lock biohazard plastic bags (preferably with outside pocket).
ii. Screw-cap plastic containers or canisters.

6.1.2.3 Multiple primary receptacles may be placed in a single secondary receptacle. They shall be secured together, individually wrapped or separated to prevent contact between them.

6.1.2.4 Place the accompanying laboratory request form, in protective cover e.g., envelope or plastic, on the outside of the secondary receptacle. This is to prevent soiled forms in case the ice packs thaw.

6.1.2.5 All secondary receptacles shall be put into a third outer packaging.

6.1.3 Third Packaging

6.1.3.1 A third packaging is the outer packaging where the secondary receptacle is placed.

6.1.3.2 It is used to protect the secondary packaging from physical damage during transportation.

6.1.3.3 This packaging must be of an appropriate strength, weight and size to contain the composition of the inner packages.

6.1.3.4 It must be rigid and able to withstand the shocks and loadings that will be encountered during transportation.

6.1.3.5 Specimen laboratory request forms, despatch lists, letters, supplementary documentation, and other types of information that identify or describe the specimens should be placed between the secondary packaging and outer layers of packaging. If necessary, these documents may be taped to the secondary packaging.

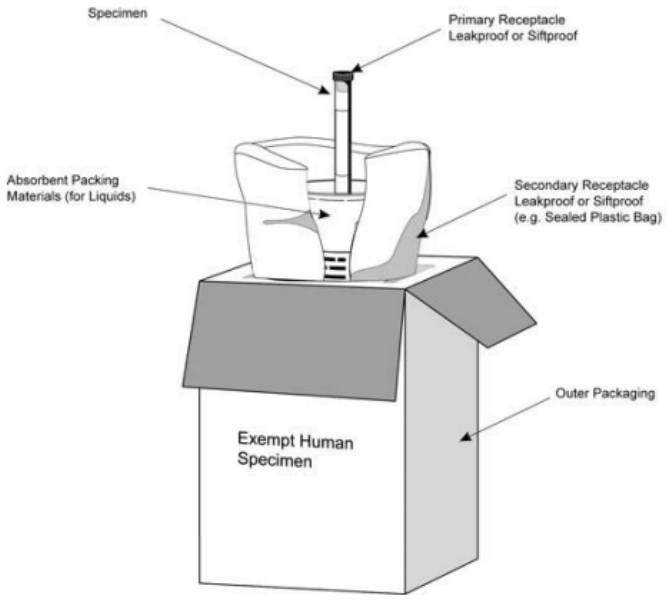


Figure 2: Diagrammatic presentation of the Basic Triple Packaging
Source: International Air Transport Association (IATA)

6.2 Specific Packaging

6.2.1 Packaging for Clinical Specimens

All clinical specimens are potentially infectious therefore should be handled as Category B.

Packaging for clinical specimens shall follow the basic triple packaging as described above.

Primary receptacles may contain up to 500mL each, with the total volume inclusive of the outer triple package not exceeding 4L.

Additional requirements shall be practiced for:

6.2.1.1 Histopathological / cytology specimens:

Formalin-fixed tissues are not generally considered infectious specimens because they have been biologically inactivated. Thus, the possibility for these materials to pose an infectious disease risk is extremely low. Even so, these materials should be packaged in a manner that will prevent any possibility for the release of liquids while in transit. This can be achieved through the following actions:

i. Limit the amount of 10% formalin to not more than one litre per shipping container.

ii. sent by sea, land or air transportation. In the event more than 1 litre 10% formalin is required, the formalin fixed specimens shall be transported by land. Precautionary measures shall be made to prevent formalin spillage. Label the container with a four-inch diamond UN3334 content logo.

iii. Do not use biohazard plastic bags as primary receptacles for tissues that contain liquid preservatives.

iv. Microscopic slides shall be packaged together labelled with identification number. The slides should be sufficiently wrapped and cushioned inside their shipping container to prevent breakage.

v. Paraffin blocks shall be packaged together by surgical number and shipped in an appropriately labelled box or plastic bag. Do not wrap in

gauze. Paraffin blocks may melt in hot climate so appropriate packaging is recommended prior to shipment.

vi. Use non-breakable primary containers with a leak-proof seal and reinforce the seal with parafilm or sealing tape.

vii. Package primary containers and enough absorbent material to absorb all liquids (in the event of a leak) in a secondary container (e.g., larger plastic container or sturdy sealed plastic bags, etc.).

viii. Use a sturdy outside container such as a heavy-duty cardboard box as the final structure holding the specimens.

6.2.2 Packaging for Infectious Substances

An infectious substance can be classified into 2 categories:

6.2.2.1 Category A

The substance belongs to Category A if it is transported in a form that, when exposure to it occurs, could cause permanent disability, or life-threatening or fatal illness in otherwise healthy humans or animals.

Indicative lists of the biological agents that may meet the criteria for a Category A infectious substance are provided in many transport regulations and modal agreements. A copy of the indicative list from the UN model regulations is provided; however, many of the biological agents in that list will only meet the definition for a Category A infectious substance when being transported as cultures.

Two UN numbers and proper shipping names are associated with Category A infectious substances:

i. Infectious substances capable of causing disease in humans, or both humans and animals, are assigned to UN 2814, and given the proper shipping name of Infectious substance affecting humans.

ii. Infectious substances capable of causing disease only in animals are assigned to UN 2900, and given the proper shipping name of Infectious substance affecting animals only.

For materials that fall into the category UN 2814, if the technical name of the hazardous biological agent present contained within the infectious substance is known, it may be provided in brackets after the proper shipping name; for example:

UN 2814, Infectious substance affecting humans (Mycobacterium tuberculosis cultures).

If the biological agent is unknown but is thought to meet the definition for Category A infectious substance, “Suspected Category A infectious substance” must be provided in brackets after the proper shipping name.

PACKING INSTRUCTION P620 (CATEGORY A PACKAGING REQUIREMENT)

Packing instruction P620 outlines the requirements and special packaging provisions that must be met for “approval” for use with Category A infectious substances.
In addition to the components of a basic triple packaging system, packaging for Category A infectious substances must include the three layers outlined below.

PRIMARY RECEPTACLE

Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging must be capable of withstanding a pressure differential of not less than 95 kPa, as well as temperatures in the range of –40 °C to +55 °C.

When the shipment is being carried at ambient temperature (or above), the primary receptacle must be glass, metal or plastic. A positive means of ensuring a leakproof seal should be provided (e.g., a heat seal, skirted stopper or metal crimp seal). If screw caps are used, they should be secured by positive means (e.g., paraffin sealing tape, tape or manufactured locking closure).

Lyophilized substances may also be transported in primary receptacles that are flame-sealed ampoules or rubber-stoppered glass vials fitted with metal seals.

SECONDARY PACKAGING

Shall be able to withstand a pressure differential of not less than 95 kPa, and temperatures in the range of –40 °C to +55 °C.

THIRD, OUTER PACKAGING

The outer packaging must be rigid.

The smallest dimension of the package shall not be less than 100 mm.

An itemized list of contents shall be enclosed on the outer packaging, including the proper shipping name and technical name in brackets (“Suspected Category A infectious substance” if the technical name is unknown) of the biological agent present in the infectious substance.

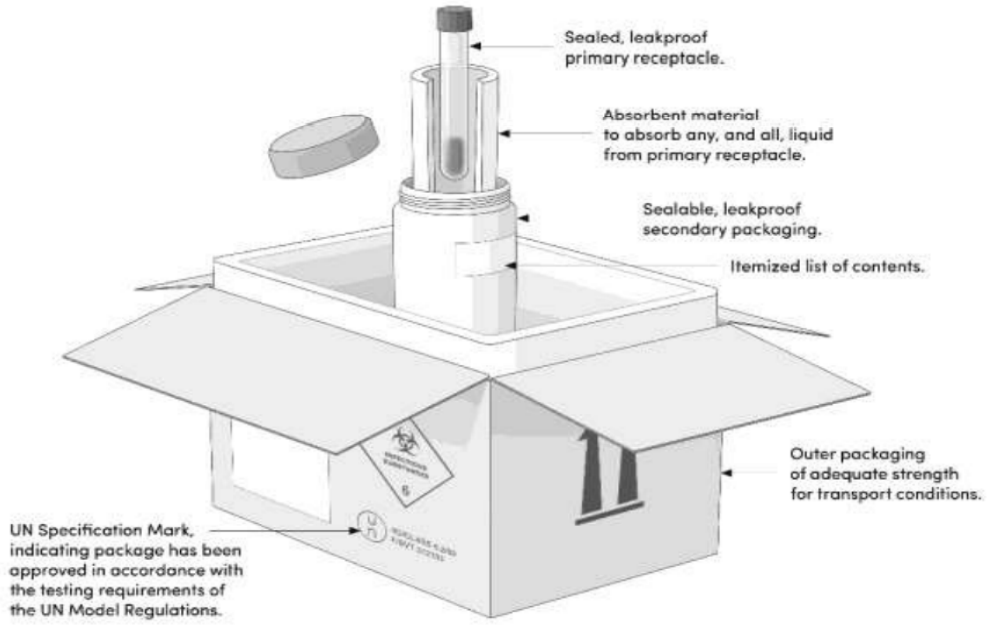


Figure 3: Example of triple packaging materials that may be used for Category A infectious substances

Source: Illustration created for the 4th edition of the WHO Laboratory Biosafety Manual.
*Note * - itemised list of contents enclosed on outer packaging*

QUANTITY LIMITS FOR CATEGORY A

For shipments being carried in the cargo hold of passenger aircraft, no more than 50mL or 50g of Category A infectious substance per package is allowed.

For shipments being carried on a cargo only aircraft, no more than 4L or 4kg of Category A infectious substance per package is allowed.

6.2.2.2 Category B

Infectious substances are subclassified as Category B when they contain biological agents capable of causing infection in humans or animals, but NOT meeting the criteria for Category A; that is, the consequences of an infection are not considered severely disabling or life-threatening.

With the exception of substances containing high-risk biological agents, in the forms listed in Annex 3 (in chapter 8), most shipments of infectious substances can be compliantly transported under Category B:

i. The UN number and proper shipping name for most shipments of Category B infectious substances is UN 3373, Biological substance, Category B.

ii. If the infectious substances are defined as clinical or medical wastes, and contain an infectious biological agent (or there is even a minimal likelihood that they do so) that does not fit the criteria for Category A, they must be assigned to UN 3291 and given a proper shipping name that reflects their contents or origin (or both). According to the UN model regulations, proper shipping names may include:

   a. Clinical waste, unspecified, NOS (not otherwise specified)
   b. Biomedical waste, NOS
   c. Regulated medical waste, NOS

PACKING INSTRUCTION P650 FOR CATEGORY B INFECTIOUS SUBSTANCES REQUIREMENT

Packing instruction P650 provides a slightly more detailed set of triple packaging requirements than is the case for the basic triple packaging system. Infectious substances

subclassified as Category B (UN 3373) and packaged in accordance with P650 may be considered safe and compliant for all modes of transportation.

Additional requirements are:

For shipments being carried by air (passenger or cargo aircraft), the primary container must not contain more than 1L of material, and no more than 4L in the outer package.

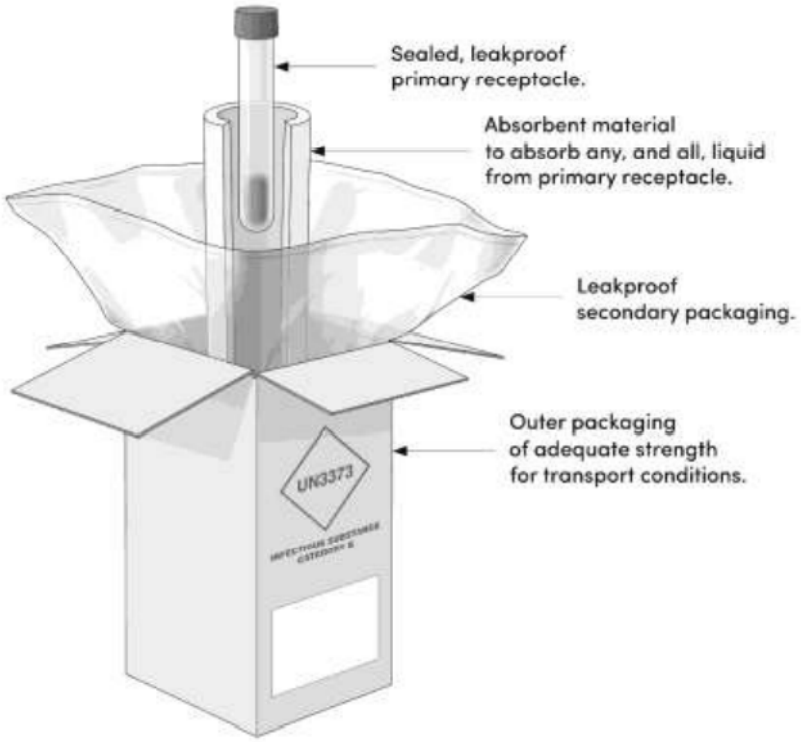


Figure 4: Example of triple packaging materials that may be used to comply with P650 for Category B infectious substances

Source: Illustration created for the 4th edition of the WHO Laboratory Biosafety Manual.

6.2.3 Packaging for Cryopreserved Material

Types of Specimens:

i. Cryopreserved biobanking specimen

ii. Cryopreserved Hematopoietic Stem Cell Product - to refer to National Standards for Stem Cell Transplantation: Collection, Processing, Storage and Infusion of Haemopoietic Stem Cells and Therapeutic Cells, 2nd Edition 2018.

Cryopreservation is the recommended standard for preservation of human biological samples for a wide range of research applications. At low temperatures, most biological activity is effectively stopped, including the biochemical reactions that would lead to cell autolysis.

Hence, cryopreserved biobanking specimens are stored in specialised cryogenic containers that are used to hold or transport specimens i.e., cryotube, cryo straw, cryobags, cryosette, cryomold, etc. The containers are designed for temperatures at or below ultra-low temperatures (-190℃).

(a) (b)

Figure 5: Example of cryo containers a) cryotube, and b) cryo straw.

Source: Origen Biomedical, Nalgene and Cryo Bio System

The cryogenic containers (Figure 5) are stored in a dry shipper where it is frozen in liquid nitrogen (LN2) vapor phase or in cases where immediate snap-freezing of the collected material is required, interim storage of the samples in portable dewars filled with LN2 (Figure 7) is a widely used method. However, cross-contamination has been reported for samples immersed directly in LN2, so the right cryovial type, secondary containment options, and use of vapor-phase storage when considering flash-freezing methods should be considered. These containers are hermetically sealed and specifically designed for the safe storage of specimens in the liquid phase of nitrogen.

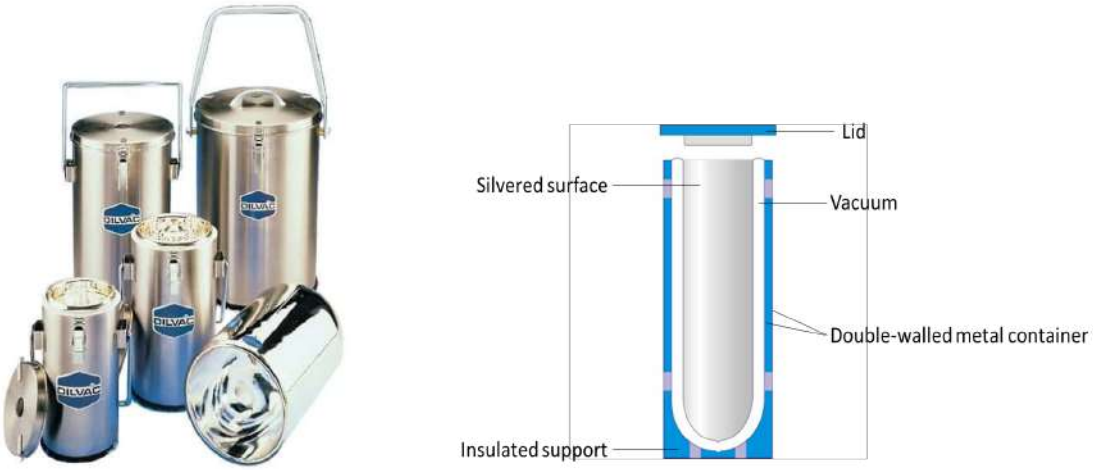
Pre-labelled cryogenic containers should be organized before the storage of the specimen. Each cryogenic specimen container should be labelled with a barcode label, either printed or hand-written. Ensure the ink and label quality is resistant to all common laboratory solvents and cryo-resistant.

Information on the label should include the minimum requirement of at least two identifications with or without barcodes, while maintaining the anonymity of the donor. Radio-frequency identification (RFID) is another option.

(a) (b) (c)

Figure 6: Pre-labelled cryogenic specimen storage container. (a) Printed linear barcode, (b) Printed two-dimensional barcode, and (c) pre-labelled tube with two-dimensional barcode.

Source: IARC Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research.



(a) (b)

Figure 7: Example of (a) Universal-Style Stainless Steel and Glass Dewar Flask with Handle and Lid (b) Characteristics of a Dewar

Source: Cole-Parmer Dilvac.

In the case of greater distance of travel, for maintenance at a regulated temperature during transportation and shipping at or below -150° C, a liquid nitrogen dry shipper should be used.

Liquid nitrogen contained in a properly manufactured dry shipper is not subject to any other dangerous goods requirements. This means that the package would not be subject to the detailed requirements of free liquid nitrogen whilst still maintaining the extremely low temperatures liquid nitrogen can afford. Further information regarding liquid nitrogen as in Appendix 2.

The vessel must be appropriately marked and labelled to indicate the presence of infectious substances inside. For more information, please refer to Section 7 on marking and labelling. The use of a dry shipper also needs to be indicated appropriately in shipment documentation.

Figure 8: Example of Dry Shipper container and its characteristics (change after description)

Source: MVE Cryoshipper Product description.

Figure 9: Examples of different types of cryo shippers used for transportation of biological samples and cryopreserved stem cells.

Source: Taylor-Wharton Cryoshipper, MVE Cryoshipper

Figure 10: Dry Shipper with Shipping case and labelling

Source: MiTeGen, LLC, NY

7 MARKING AND LABELLING

7.1 Introduction

7.1.1 Specimens should be marked and labelled adequately to provide essential information to convey to all parties involved in transportation and handling of specimens.

7.1.2 Information should include content of package, nature of the hazard and the packaging standards applied.

7.1.3 Markings and labelling should be:

a. Legible and easily understood
b. On the outer packaging preferably vertical sides
c. Visible and not obscured or overlapped by other label or markings
d. Durable to weather exposure (freezing or humid condition)

7.2 Marks

7.2.1 Marks provided on the outer package of infectious substance should have all the information below:

a. The Sender's and Consignee's name and address.
b. Name and telephone number of emergency contact sender which is available for 24 hours.
c. The UN number for infectious substances. All infectious substances are assigned to Dangerous Good Division 6.2. Refer Table 7.1 for Dangerous Goods Class.
d. The UN number of the infectious substance, followed by the proper shipping name of the substance. Refer Table 7.2 and Table 7.3 for detailed information.
e. 'NET quantity' refers to the weight or volume of the dangerous goods contained in a package, excluding the weight or volume of any packaging material.
    - The net quantity of dry ice may be particularly important for handling of the shipment as, along with the thermal capabilities of the packaging, it will determine how long a cool temperature can be maintained for preserving or stabilizing the infectious substance in transit. In some cases, the net quantity of dry ice may need to be

replenished whilst in transit to maintain the cold chain through a long journey.

- The net quantity of the infectious substance is also important for biosecurity and chain of custody purposes, as well as providing information for assessing biosafety risks if a spillage or leakage were to occur.

f. When a coolant is used (e.g., dry ice), the UN number and the proper shipping name of the coolant must be provided, followed by the words 'AS COOLANT'. In addition, the net quantity of coolant present should be provided.

g. Whenever an overpack is used, the required marks and labels shown on the packages of infectious substance inside must be repeated on the outermost layer of the overpack (unless already clearly visible, for example through a clear plastic wrapping). Overpacks must be marked with the word "OVERPACK" in lettering at least 12mm high.

h. Temperature storage requirements (optional).

i. Any documents required by the carrier shall be accessible without opening the package.

7.2.2 Overview of Dangerous Goods Class shown below in **Table 7.1**:

DANGEROUS GOODS CLASS		
Class 1	Explosives	
Class 2	Gases	
Class 3	Flammable Liquids	

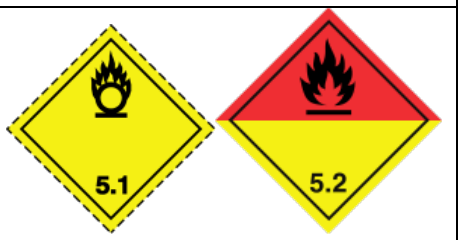
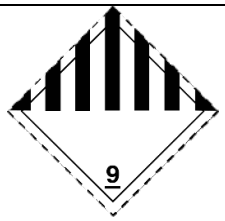
Class 4	Flammable Solids; Substances Liable to Spontaneous Combustion; Substances which, in Contact with Water, Emit Flammable Gases	
Class 5	Oxidising Substances and Organic Peroxides	
Class 6 Division 6.1 Division 6.2	Toxic and Infectious Substances 6.1 Toxic Substances 6.2 Infectious Substances	 
Class 7	Radioactive Material	
Class 8	Corrosive Substances	
Class 9	Miscellaneous Dangerous Substances and Articles, Including Environmentally Hazardous Substances.	

Table 7.1: Dangerous Goods Classes

Source pictograms :: https://unece.org/transportdangerous-goods/ghs-pictograms

7.2.3 Once classified as a dangerous good under Guidance of Regulation for The Transport of Infectious Substances 2021 to 2022 Division 6.2, the material shall then be further sub-classified based on infectious substance categories as shown below in **Table 7.2:**

CATEGORY	UN NUMBER	PROPER SHIPPING NAME	INFECTIOUS SUBSTANCE
A	**UN 2814**	**INFECTIOUS SUBSTANCE, AFFECTING HUMAN**	Infectious substances capable of causing permanent disability, or life-threatening or fatal disease in otherwise healthy humans or animals, or both humans and animals.
	UN 2900	**INFECTIOUS SUBSTANCE, AFFECTING ANIMALS**	Infectious substances capable of causing disease only in animals.
B	**UN 3373**	**UN 3373, BIOLOGICAL SUBSTANCE, CATEGORY B**	Infectious substances containing biological agents capable of causing infection in humans or animals, but NOT meeting the criteria for Category A, that is, the consequences of an infection is not considered severely disabling or life-threatening.

- The proper shipping name is shown in bold (dark) type or in capital letters
- The descriptive text is shown in light type or lowercase letters within the respective dangerous goods regulations
- The technical name of the hazardous biological agent present contained within the infectious substance must be provided in (parentheses) after the proper shipping name. **For example: UN 2814, Infectious substance affecting humans (Mycobacterium tuberculosis cultures).**

Examples of infectious substances included in CATEGORY A in any form are listed in ***TABLE 7.3***.

Table 7.2: Infectious Substances Categories Guidance of Regulation for The Transport of Infectious Substances 2021 to 2022

7.2.4 Example of infectious substances in Category A shown below in **Table 7.3**:

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED	
UN Number and Proper Shipping Name	**Microorganism**
UN 2814 Infectious substance, affecting humans	*Brucella abortus* (cultures only) *Brucella melitensis* (cultures only) *Brucella suis* (cultures only) *Burkholderia mallei – Pseudomonas mallei* – Glanders (cultures only) *Burkholderia pseudomallei – Pseudomonas pseudomallei* (cultures only) *Chlamydia psittaci* – avian strains (cultures only) *Clostridium botulinum* (cultures only) *Coccidioides immitis* (cultures only) *Coxiella burnetii* (cultures only) Crimean-Congo haemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) *Escherichia coli*, verotoxigenic (cultures only) Ebola virus Flexal virus *Francisella tularensis* (cultures only) Guanarito virus Hantaan virus Hantaviruses causing haemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis* (cultures only) Nipah virus Omsk haemorrhagic fever virus Poliovirus (cultures only)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED	
UN Number and Proper Shipping Name	**Microorganism**
	Rabies virus (cultures only) *Rickettsia prowazekii* (cultures only) *Rickettsia rickettsii* (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus *Shigella dysenteriae type 1* (cultures only)1 Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) *Yersinia pestis* (cultures only)
UN 2900 Infectious substance, affecting animals only	African swine fever virus (cultures only) Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Goatpox virus (cultures only) Lumpy skin disease virus (cultures only) *Mycoplasma mycoides* – Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

Table 7.3: Indicative List of Biological Agents Sub- Classified as Category A

7.2.5 FOR CATEGORY A INFECTIOUS SUBSTANCE: The outer shipping package must bear the UN Packaging Specification Marking as illustrated in Figure 3 (SECTION 6.2.2.1) *and* as shown below in Figure 7.1 and **Table 7.4**:

 1	4G/Class 6.2/21/GB/2470 2 3 4 5 6
1. The United Nations packaging symbol 2. An indication of the type of packaging as detailed in *TABLE 7.4* (in this example a fibreboard box (4G)) 3. An indication that the packaging has been specially tested to ensure that it meets the requirements for Category A infectious substances (Class 6.2) 4. The last two digits of the year of manufacture (in this example 2021) 5. The competent state authority that has authorized the allocation of the mark (in this example GB, signifying Great Britain) 6. The manufacturer's code specified by the competent authority (in this example 2470)	

Figure 7.1: Features of UN Specification Mark for Category A Infectious Substances Packaging (For UN 2814 and UN 2900)

TYPE OF PACKAGING	MATERIAL	CATEGORY
1 - Drums 2 - (Reserved) 3 - Jerricans 4 - Boxes 5 - Bags 6 - Composite Packaging	A - Steel B - Aluminium C - Natural Wood D - Plywood F - Reconstituted Wood G - Fibreboard H - Plastic L - Textile M - Paper N - Metal other than Steel or Aluminium P - Glass, Porcelain or Stoneware	For Drums: 1 - Non-Removable Head 2 - Removable Head For Bags: 5M1 - Multiwall 5M2 - Multiwall, Water-Resistant

Table 7.4: Type of Packaging and Identification Codes for Category A

Source: https://unece.org/DAM/trans/danger/publi/unrec/rev17/English/08ERev17_Part6.pdf

7.2.6 UN specification marking for Category B infectious substances can be referred to in Figure 7.2

	• **Specifications**: the width of the line forming the square must be at least 2 mm, and the letters / numbers must be at least 6 mm high. For air transport, each side of the square shall have a minimum dimension of 50 mm x 50 mm. • **Colour**: No colour is specified; however, the mark must be displayed on the outer packaging, on a background of contrasting colour, and be clearly visible and legible. • The Proper Shipping Name (**BIOLOGICAL SUBSTANCE, CATEGORY B**) in letters at least 6 mm high must be displayed adjacent to the mark.

Figure 7.2: Mark for Category B Infectious Substances

7.2.7 Examples of marks associated with infectious substances shipment is shown below in **Table 7.5**

MARKS	DESCRIPTION
SENDER ALIF HAZRI JABATAN PATOLOGI HOSPITAL KUALA LUMPUR **RECEIVER** ROZI RASHID UNIT BAKTERIOLOGI INSTITUTE MEDICAL RESEARCH	'To' and 'From' marks required for all packages, showing the name and address of the sender and receiver.

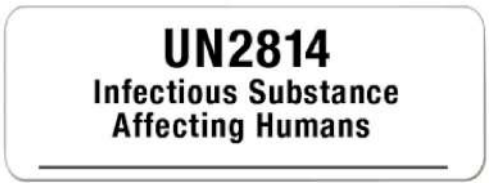
	The UN number and Proper Shipping Name marks. (For Category B packages sub-classified as UN3373.)
 4G/Class 6.2/21/GB/2470	Marking of UN specification packaging, indicating outer packaging has been tested according to UN standard is required for all Category A infectious substance packages.
	The UN number and Proper Shipping Name marks (for Category A packages)
EMERGENCY **CONTACT 24H/24H** **Dr HALIM AHMAD:** **+60 034267855**	A 24-hour emergency contact person must be marked on all Category A and Category B infectious substance packages.
UN1845 **CARBON DIOXIDE, SOLID** **AS COOLANT** **Net 3 kg**	The UN Number, proper shipping name followed by the words “AS COOLANT”. The net quantity of coolant present should also be provided.

Table 7.5: Marks Associated with Infectious Substance Shipments

7.3 Labels

In general, there are two types of labels that may need to be used for packages of infectious substances which are hazard labels and handling labels.

7.3.1 Template for hazard label shown below in Figure 7.3:

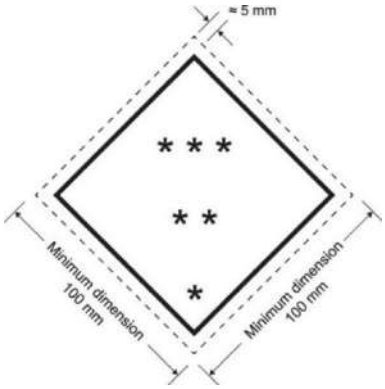
	• Presented in a form of a square set at an angle of 45° (diamond shaped). • Minimum dimensions: 100 × 100 mm (If the package is very small, the label size may be reduced proportionately, provided all elements of the label are easily visible) • **ONE** hazard label(s) **for each dangerous good** in the package (unless specifically exempted) must be affixed. This means there may be more than one hazard label required if the infectious substance is being shipped with a coolant (e.g.dry ice).

Figure 7.3: Template For Hazards Labels

7.3.2 Example of hazard labels that may be applicable to infectious substances shipments shown below in **Table 7.6**:

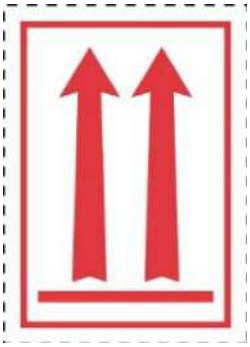
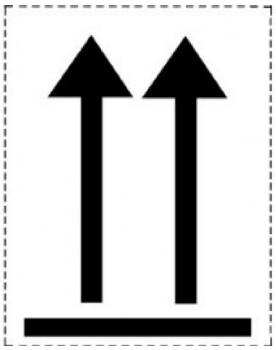
MARKS	DESCRIPTION
	**Label:** Infectious substances hazard label. **Required for:** Compulsory for all packages containing Category A infectious substances. **Specifications:** The upper half of the diamond must display three crescents superimposed on a black circle. The lower half of the diamond should bear the inscriptions: “INFECTIOUS SUBSTANCE” and “In case of damage or leakage immediately notify the Public Health Authority” in black colour. A number ‘6’ must be displayed in the bottom corner. **Colour:** White background, Black writing

MARKS	DESCRIPTION
	**Label:** Miscellaneous Dangerous Good hazard label. **Required for:** infectious substance packages containing Class 9 substances, namely dry ice, as coolant. **Specifications:** The upper portion must contain 7 vertical stripes, and an underlined number '9' must appear in the bottom corner. **Colour:** White background, Black writing.
	**Label:** Non-flammable, non-toxic gas hazard label. **Required for:** Infectious substances packages containing a Class 2, Division 2.2 compressed gas as a coolant, namely liquid nitrogen. Specifications: Must show a symbol of a gas cylinder, with the number '2' in the bottom corner. **Colour:** Green, with writing in black or white.

Table 7.6: Hazard Labels That May Be Applicable to Infectious Substances Shipments

7.3.3 Handlings Labels

Handling labels have various shapes, and can be affixed either alone or in addition to hazard labels, depending on the nature and quantity of dangerous goods present. Example of handling labels that may be applicable to infectious substances shipments is shown below in **Table 7.7**:

LABELS	DESCRIPTION
 	**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. For infectious substances, orientation arrows are required when in primary receptacles exceeding 50mL. Not required for UN3373 packages. **Specifications:** The label must show two arrows pointing in the correct upright direction. They shall be rectangular and of a size that is clearly visible, commensurate with the size of the package. The label must appear on two opposite vertical sides of the package (minimum dimensions 74mm x 105mm). A rectangular border around the arrows is optional. **Colour:** Black OR Red arrows on a white, or suitably contrasting, background.
	**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 therefore eligible for transport by cargo aircraft only. **Specifications:** Minimum dimensions of the label are 120mm on the horizontal axis and 110mm on the vertical axis. For small packages, these dimensions may be reduced by half. **Colour:** Orange background, Black writing.

LABELS	DESCRIPTION
	**Label:** Cryogenic liquid warning label. **Required for:** Infectious substances packages, being transported by air, containing cryogenic liquids (deeply refrigerated liquefied gases) as a coolant (e.g., liquid nitrogen). This label must be used in addition to the hazard label for non-flammable, non-toxic gases. This label is NOT required for specialized insulated packagings for liquid nitrogen, known as dry shippers, which are discussed in more detail in Section 4.3.5 on coolants. **Specifications:** Minimum dimensions of 74mm on the horizontal axis and 105mm on the vertical axis. The words "*Caution – may cause cold burn injuries if spilled or leaked*" are optional and may be included. **Colour:** Green background, with white writing.

Table 7.7: Handling Labels That May Be Applicable to Infectious Substances Shipment

8 TRANSPORTATION

The principle of safe transport is the same for air, international or local surface transport as in the material should not have any possibility of escaping from the package under normal conditions of transport.

8.1 General Requirement

a. Specimen containers should be watertight and leak-proof.
b. If the specimen container is a tube, it must be tightly capped and placed in a rack to maintain it in an upright position.
c. Specimen containers and racks should be placed in robust, leak-proof plastic, transport boxes with secure, tight-fitting covers.
d. The transport box (outer packaging) should be secured in the transport vehicle.
e. Each transport box should be labelled appropriately consistent with its contents.
f. Specimen transport documents should accompany each transport box (refer 8.7).
g. A spill kit containing absorbent material, a chlorine disinfectant, neutralizing buffer, a leak-proof waste disposal container and heavy-duty reusable gloves should be kept in the transport vehicle.

Recommended Good Management Practice for shipping materials are as below

a. Place coolant packs in zip-locked bags in case of coolant leakage or rupture
b. Avoid overfilling of transport box
c. Avoid exceeding 1/3 of transport box capacity
d. Put paperwork / document / delivery log in waterproof bag / file

8.2 Specific Recommendation

8.2.1 Formalin-fixed Tissues

Formalin-fixed tissues are not considered ‘infectious specimens’ as they have been biologically inactivated. These materials should be packaged in a manner that will prevent any risk of leakage of fixatives during transportation (refer Packaging Instruction for Histopathological / Cytology specimen).

In the event of an accident or spillage, to refer **Appendix 6** for Spillage protocol.

8.2.2 Cryopreserved Specimen

The cryopreserved specimens should be transported to the recipient in cry shipper. Temperature should be monitored using temperature monitoring devices. Usage of dewar should only be within institutional facilities.

Further details on transportation and appropriate storage temperature conditions can be referred to in relevant Biobanking Guidelines & Best Practices as referenced in this document.

8.3 Storage prior to transportation (receipt –prior packaging & post packaging)

Specimens that are meant to be transported to examination laboratory shall be kept in laboratory or centralised collection centre. Specimens are maintained at the correct temperature and under recommended conditions for examinations as per instruction by referral laboratory in order to prevent deterioration of specimens.

8.4 Document and Records on Specimen Transportation

Each laboratory shall have its documented procedure and records on handling and managing specimens for examination at referral laboratory. The procedure shall also include management of laboratory reports as well as retrieving the reports. The relevant record shall be retained.

8.5 Maintaining Cold Chain

The cold chain is the temperature-controlled supply chain (below ambient), which must remain unbroken over a series of collection, storage, and distribution events (from field, to repository, to other research institutions). Cold chain shall be maintained according to required temperature. Refrigerants e.g., ice packs, dry ice or liquid nitrogen may be used to stabilize specimens during transportation by placing them outside the secondary receptacle.

The following are typical temperature conditions required for transport of specimens and the insulation / refrigerant helpful to maintain that temperature:

TEMPERATURE CONDITIONS	TEMPERATURE MAINTENANCE INSULATION	POINTS TO NOTE
Ambient (20 – 30°C)	Appropriate packaging to protect from extreme heat or cold ambient conditions.	
Refrigerated (2 to 8°C)	Wet ice or gel packs designed to keep conditions at –15°C.	Wet ice shall be placed in a leak-proof container, the outer packaging or overpack shall also be leak-proof.
Frozen (-20°C)	Gel packs designed to keep conditions at or below -20°C.	
Frozen (-70°C)	Dry ice pellets, blocks, or sheets (solid carbon dioxide).	Used to transport frozen specimens or if transportation time exceeds 72 hours. A specially designed insulated packaging may be used to contain dry ice, typically a polystyrene or waxed-treated cardboard box to prevent leakage and maintain temperature. The packaging must permit the release of carbon dioxide gas if dry ice is used.
Frozen (at or below –150°C)	Liquid nitrogen dry shipper, also referred to as a vapor shipper.	Dry nitrogen shippers are insulated containers that contain refrigerated liquid nitrogen that is fully absorbed in a porous material and is therefore considered a non-dangerous product and is not subject to IATA regulations as a dangerous good if properly filled (i.e., no free residual liquid nitrogen remains).

The secondary receptacle shall be secured within the outer package to maintain the original orientation of the inner packages after the refrigerant has melted or dissipated.

8.6 Transport Planning

It is the responsibility of the sender to ensure the correct designation, packaging, labelling and documentation of all clinical specimens and infectious substances. The efficient transport and transfer of infectious materials requires good coordination between the sender, the carrier and the receiver (receiving laboratory), to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon well-established communication and a partner relationship between the three parties. All have specific roles and responsibilities to carry out in the transport effort (refer 5.0 Transport Stakeholders).

8.7 Documenting shipment

Document prepared for any shipment of clinical specimens and infectious substances is important as it is the only measure to inform the carrier / courier / logistic party about the contents of the consignment and how it is prepared. The person preparing the consignment shall ensure all documents indicated for shipment are complete.

Any information provided in the document should be readable and resilient. If the document is more than one page, pages should be consecutively numbered.

A minimum set of information shall be recorded for any clinical specimens and infectious substances. That information is as outlined below:

a. The sender and receiver information
b. Date despatch
c. Description of consignment
d. The type and net quantity of specimens for each package
e. Handling requirement
f. Emergency response information
g. Shipper's declaration

8.7.1 Sender and receiver information

The name and address of the sender (consigner) and the receiver (consignee) of the clinical specimens or infectious substances shall be

included. For infectious substances packages, the name and contact number for a responsible person knowledgeable about the infectious substance, must be provided. This person may be the same or different to the sender or receiver, and should be contactable at all times throughout the shipment process.

8.7.2 Date despatched

The label should display the date on which the transport document is prepared and despatched to the carrier.

8.7.3 Description of the consignment

The details of the consignment description as in Chapter 7: Marking and Labelling.

8.7.4 Type and net quantity of clinical specimens / infectious substances for each package

The number of packages, the type or material of outer packaging used (e.g., fibreboard, plastic drum) and the quantity of the specimens in each package must be provided. Quantity should be given by volume (e.g., mL, L) or mass (e.g., g, kg) as appropriate
If more than one dangerous good is present, (e.g., dry ice) then this information must be provided for each item

8.7.5 Handling requirements

Handling requirements are actions that are required to be taken by the carrier in the treatment and handling of the package / consignment. Those requirements may be specified by carrier or national authorities and should at least include:

i. Any supplementary requires for handling (loading, storing, unloading etc)
ii. Restrictions applied on the mode of transportation that can be used
iii. Any routing instructions - transport must be made by quickest possible route
iv. Emergency arrangement applicable to the package

8.7.6 Emergency response information

All shipments must have the name, address and telephone number of a person responsible for the shipment on the packages (description on label) and on the sender's declaration.

Additional information such as contact information for public health authorities, medical or first aid should be available for carriers to be used in emergency incidents during transport. This may include requirements (e.g., prophylaxis for exposed persons) or procedures for spill clean-up.

8.7.7 Certification / Sender's declaration

A statement should be given on the form from the shipper, acknowledging that the package has been prepared according to the applicable requirements. This statement must be signed and dated.

Example of sender's / shipper's declaration

Example of a shipper's declaration

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.

8.8 Mode of Transportation of Clinical Specimens and Infectious Substances

8.8.1 Air transportation

Transport of clinical specimens and infectious substances by air must comply with the International Air Transport Association (IATA) Restricted Articles Regulations, and Civil Aviation Authority of Malaysia (CAAM) regulation as in its Technical Requirement which follows International Civil Aviation Organization (ICAO) regulations.

The sender who offers clinical specimens and infectious substances for carriage by air shall provide the carrier 2 copies of completed and signed transport document that:

a. Accurately describes the infectious substances in the following order:
    i. Proper shipping name
    ii. Class or, when assigned, division including for Class 6 or compatibility group
    iii. UN number, if any, preceded by the letters UN
    iv. Where assigned, the appropriate packing group
b. Bears the declaration signed by the person who offer the infectious substances for carriage by air (shippers' declaration).
c. Provides name, date and signed by the sender.
d. Full name of departing and destination airport.

The carrier shall apply for CAAM approval / issue permit for carriage of infectious substances.

8.8.2 Water transportation

Transportation of clinical specimens and infectious substances by water transport shall follow the principle of safe transport to prevent any possibility of specimen leakage from packages under normal conditions of transportation. If the consignment / package is not transported by commercial carrier, it shall be handled by hospital staff.

The sender must write and send a formal notification letter to the State Maritime Department involved. The details that to be included in the letter are:

a. Name, designation and identification of the person in-charge
b. Name of health care centre involved (sender's and receiver's address)
c. Nature of specimen, any fixative used and its estimated volume
d. Frequency of transportation (e.g., twice a week)

The notification letter should be submitted to the State Maritime Department at least every 2 years or where there are any changes.

The sender who offers clinical specimens and infectious substances for carriage by water transportation shall provide the carrier 2 copies of completed and signed transport document that:

a. Accurately describes the infectious substances in the following order:

i. Proper shipping name
ii. Class or, when assigned, division including for Class 6 or compatibility group
iii. UN number, if any, preceded by the letters UN
iv. Where assigned, the appropriate packing group

b. Bears the declaration signed by the person who offer the infectious substances for carriage by water (senders' / shippers' declaration)
c. Have name, dated and signed by the sender
d. Full name of departing and destination port

8.8.3 Land transportation

This mode of transportation includes sending specimens from wards / clinics to laboratory, from a hospital to a diagnostic laboratory or from one laboratory to another. The package / consignment may be transported by using hospital transport, commercial carrier or public transport including e-hailing services by bike or car. The principle of safe transport shall be applied to prevent any possibility of specimens' leakage from the package under normal conditions of transport.

When transporting clinical specimens and infectious substances to other diagnostic laboratory, shipper shall provide transport documents that clearly described below information:

a. Name and address of sender
b. Name and address of receiver
c. Nature and quantity of clinical specimens
d. Proper shipping name – supplemented with technical name on shipping document
e. Additional handling information for emergency contact person

Example of send out document as in **Appendix 4**.

8.8.3.1 Specimen transportation by Hospital / Institution vehicles.

It is the common method of specimen transportation. Staff from the sending laboratory shall accompany the package / consignment with documents required according to local procedures.

8.8.3.2 Specimen transportation by commercial carrier

In the event where the package / consignment is transported by a commercial carrier, the documents shall be completed as required by the carrier company.

8.8.3.3 Specimen transportation by e-hailing

This guideline is also applicable for transportation of specimens using e-hailing services. The specimen shall be packaged in appropriate transport containers as outlined (Chapter 6). Specimens transported by-e-hailing shall be accompanied by trained hospital staff / trained carriers.

In the event the specimen is sent through e-Hailing, the following shall be complied with:

i. The drivers (carriers) shall be trained on handling and transportation of clinical specimens and infectious substances.
ii. Drivers must not remove or tamper with the consignment or its contents
iii. Ensure that delivery is taken directly to the correct location as identified in the transport box.
iv. If there is a breakdown or delays, the sender shall be informed.
v. Sender shall be informed of any loss or damage to the consignment as soon as possible.
vi. Drivers must ensure compliance with all road traffic and transport laws and any request by the local authorities
vii. Drivers must have appropriate motor licence and insurance

Taxi or e-hailing services shall not be used to transport infectious substances Category A.

8.9 Waybill

A waybill shall accompany all shipments of clinical specimens and infectious substances transported via any mode of transportation. It is a common practice for the carrier to be the one to fill up the waybill, however, the sender may be asked to provide information.

The format of waybill shall contain information about the shipment, such as the shipper's and receiver's name and address, carrier information and quantities and types of packages. Examples of waybills as **Appendix 3**.

8.10 Spill & clean up procedure

An emergency response information should be available for reference shall there be any breach of packaging occurs. The appropriate response shall be as follow:

8.10.1 Biological spillage

In the event of any biological spillage from the packaging, the following clean-up procedures are to be taken:

i. Wear gloves and protective clothing, including face and eye protection if indicated.
ii. Cover the spill with a cloth or paper towel to contain it.
iii. Pour an appropriate disinfectant (e.g., 5% bleach solutions) over cloth or paper towel and the immediate surrounding area. For spills on aircraft, quaternary ammonium disinfectants should be used.
iv. Apply the disinfectant concentrically, beginning at the outer margin of the spill area, working towards the centre.
v. After about 30 minutes, clear away the materials. If there is broken glass or other sharp materials involved, use a dustpan or piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.
vi. Clean and disinfect the area of spillage. If necessary, repeat step ii – v.
vii. Dispose of contaminated materials including gloves and protective clothing into a leakproof, puncture-resistant waste disposal container.
viii. After a successful disinfection, report the incident to the competent authority and inform them that the site has been decontaminated.

8.10.2 Formalin spillages

In the event of a formalin spillage, salvaging the tissue specimen should be the highest priority as the specimen may not be replaceable. Only trained carriers shall be allowed to handle any spillage using the Formaldehyde Spillage Kit. The classification of formalin spillage as per Appendix 5. The response to the spillage and its actions as **Appendix 6**.

8.10.3 Liquid nitrogen Leakage / Spillage

In the event of liquid leakage or spillage, adequate ventilation and immediate evacuation of personnel from the spillage site is required until

the liquid has been fully evaporated, in view of the potential danger for asphyxiation.

Specimen transportation in liquid phase of liquid nitrogen (e.g., in Dewars):

i. The use of face shield / goggles, long-sleeved buttoned lab coat or non-absorbent cryogenic apron, heavy gloves, fully covered sturdy non-absorbent shoes / boots and a portable oxygen monitoring device shall be mandatory when handling cryogenics.
ii. Heavy gloves (appropriate for LN2 use) shall be worn to avoid thermal burns from cold.
iii. The use of cryo-appropriate protective equipment is recommended to be used for face, eye and body protection to protect from splashes and explosions.
iv. Specimen cryo-containers selected for storage in LN2 shall be impenetrable by liquid nitrogen to avoid explosion hazard.

Specimen transportation in vapour phase of liquid nitrogen (e.g., in dry shipper):

i. Nitrogen vapour leakage poses a very low hazard risk.
ii. A portable oxygen monitoring device and adequate ventilation is sufficient for handling gas leakage in large quantities.
iii. Non-absorbent and insulated cryogenic gloves (specifically made for vapor phase LN2 handling) shall be used when handling cryogenics stored in the vapour phase.

Appropriate training in the safe handling of cryogenics shall be provided and included in local procedure to all personnel working with LN2, describing the potential health hazards and required safety precautions.

9 SPECIMEN TRANSPORTATION WITHIN FACILITY

This includes transport of specimens from clinics, wards and operation theatres to the laboratory either by hospital porters or any other hospital staff or pneumatic tube system.

The delivery of clinical specimens to the laboratory by the patient, or relative shall be discouraged unless required.

The following practices shall be observed:

i. All specimens shall be sent to the laboratory as quickly as possible after collection
ii. Specimen containers shall be watertight and leak-proof.
iii. If the specimen container is a tube, it must be tightly capped and if possible, in an upright position to prevent leaking.
iv. Specimen containers shall be placed in a sealed plastic biohazard bag.
v. An itemized list of contents is required (examples laboratory request form and specimen dispatched list). DO NOT place documents inside the secondary container
vi. The transport box shall be secured.
vii. Never leave the specimen unattended in a public area.

9.1 Specimen transportation by pneumatic tube system.

Pneumatic Tube System (PTS) is computer-controlled and automated to provide efficient, rapid, and secure interdepartmental transport of specimens.

The following practices shall be observed:

i. Specimen containers shall be placed in a sealed plastic biohazard bag.
ii. All specimen caps / lids are securely tightened, and specimen bags are completely contained inside the carrier.
iii. Latches at both ends of the carrier are securely fastened before sending the carrier.

The following items/specimens shall not be transported using PTS:

i. Specimens containing needle and syringe
ii. Blood gas samples (Arterial / Venous Blood Gas – ABG / VBG)
iii. Body fluids (CSF, synovial, pleural, peritoneal, pericardial, gastric and ascitic fluids, aspirates, bronchoalveolar lavage, washes, drainage, etc.)
iv. Urine & stool specimens
v. Blood culture bottle
vi. Blood specimens from a difficult venepuncture

vii. Any specimens on ice
viii. Any specimens requiring special handling, e.g., kept at 37°C.
ix. Any tissue specimen

10 TRAINING

Each stakeholder must ensure all relevant persons involved in the transport process and its preparation shall receive training to enable them to carry out their responsibilities in an efficient manner. Personnel shall be trained in a manner that corresponds to their contractual responsibilities.

The training objectives are to provide employees with the knowledge and skills necessary to perform their job functions safely. Training may be provided directly by the employer or by other public or private sources. Until training is completed, employees must be directly supervised by a person who has been trained. Refresher training shall be provided at least once every two years or when necessary.

10.1 Stakeholders requiring training

A wide range of stakeholders shall be trained appropriately for the safe and compliant shipment of infectious substances. These stakeholders include:

i. The people or organizations undertaking the responsibilities of the sender / shipper
ii. Personnel of transport operators (e.g., drivers, pilots and captains)
iii. Ground handling agencies that act on behalf of the operators / carriers to accept, handle, load and unload dangerous goods packages
iv. Individuals involved in the transferring, processing or screening of cargo or mail
v. Receiver

10.2 Types of required training

10.2.1 General Awareness and Familiarization Training

A training that provides familiarity with the general provisions of dangerous goods transport requirements, including:

i. Description of the classes of dangerous goods
ii. Labelling, marking and placarding

iii. Packaging
iv. Segregation
v. Compatibility of dangerous goods
vi. Purpose and content of dangerous goods documentation and
vii. Descriptions of available emergency response documents

10.2.2 Function-Specific Training

A training that provides a detailed understanding of the requirements applicable to the functions performed by the individual employee.

10.2.3 Safety Training

A training that covers:

i. Methods and procedures for avoiding accidents (e.g., proper handling, including equipment use, and methods of stowage);
ii. Emergency response information and how to use it;
iii. General dangers and hazards of the various dangerous goods classes;
iv. Prevention of exposure to hazards, including the use of personal protective equipment; and
v. Procedures to be followed in the event of release or exposure to any dangerous goods.

Areas of training to be covered for sender / shipper, carrier and receiver are as follows:

i. General awareness of infectious substances and transport requirements
ii. Classification of infectious substances
iii. List of dangerous goods
iv. Triple packaging and packing requirements for infectious substances
v. Labelling and marking
vi. Method of transportation
vii. Transport declaration and documentation
viii. Storage and loading / unloading procedures
ix. Spillage and clean up procedure
x. Emergency procedure and incident reporting

10.3 Training Records

Employer is responsible for maintaining training records for each employee. These records shall be kept and made available by the employer for the needs of audit and review by regulatory authorities upon request.

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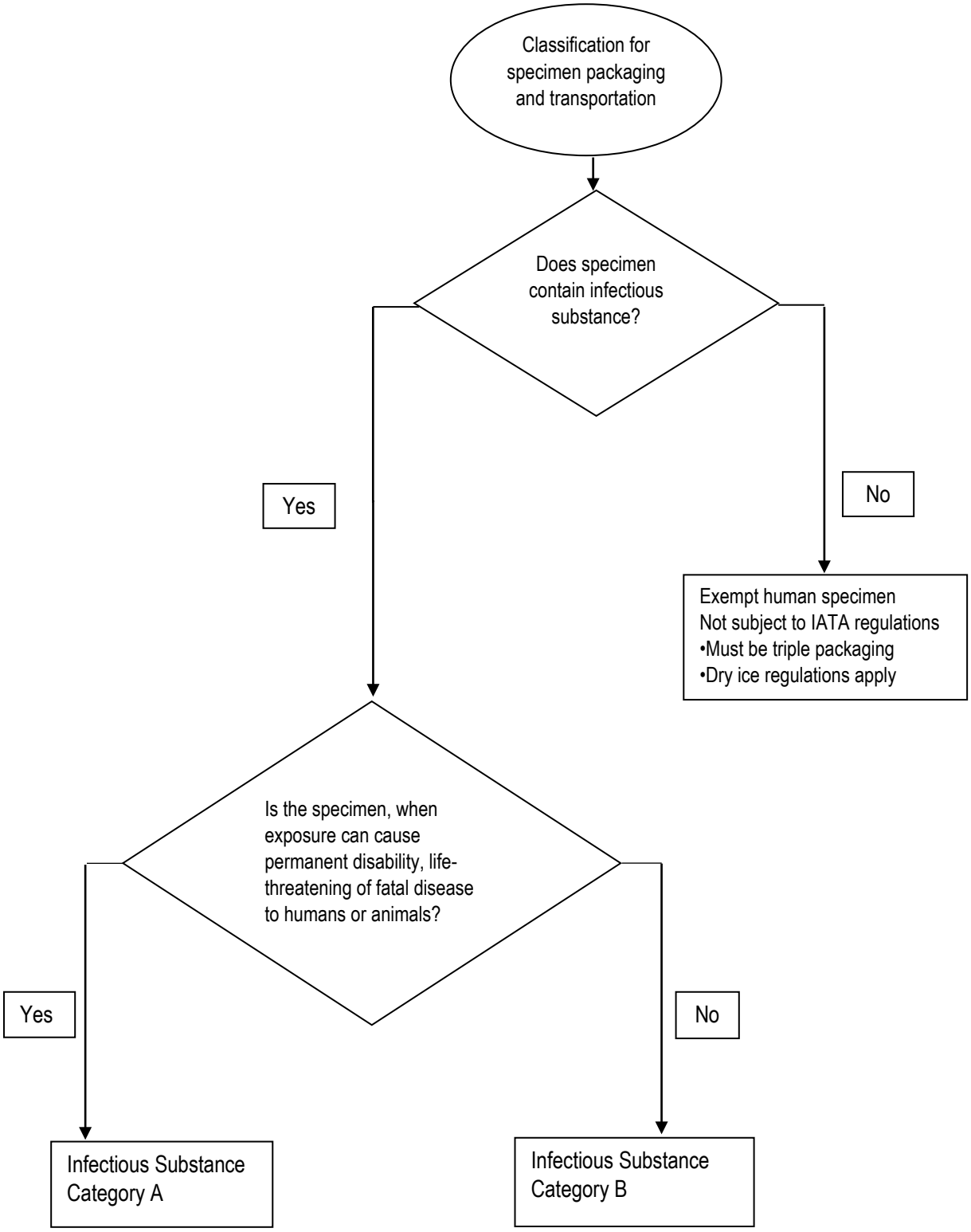
ABBREVIATIONS

IATA	-	International Air Transport Association
UN	-	United Nation
MS	-	Malaysian Standard
ID	-	Identification
DGR	-	Dangerous Goods Regulations
SDDG	-	Shipper's Declaration for Dangerous Goods
PCR	-	Polymerase Chain Reaction
MSDS	-	Material Safety Data Sheet
HPE	-	Histopathology Examinations
ICAO	-	International Civil Aviation Organization
CAAM	-	Civil Aviation Authority Malaysia
PPE	-	Personal Protective Equipment
LN2	-	Liquid nitrogen

APPENDIX 1

CLASSIFICATION GUIDE FOR SPECIMEN PACKAGING AND TRANSPORTATION



APPENDIX 2

LIQUID NITROGEN

Liquid nitrogen is used when extremely low temperatures are required to maintain the integrity of the shipment. Hence, both the primary and secondary packaging must be able to withstand ultra low temperatures without damage.

It belongs to Dangerous Goods Class 2: Gases, and is assigned the proper shipping name "Nitrogen refrigerated liquid cryogenic liquid" and the UN number UN 1977.

Figure 11: Custom label example for dewar body

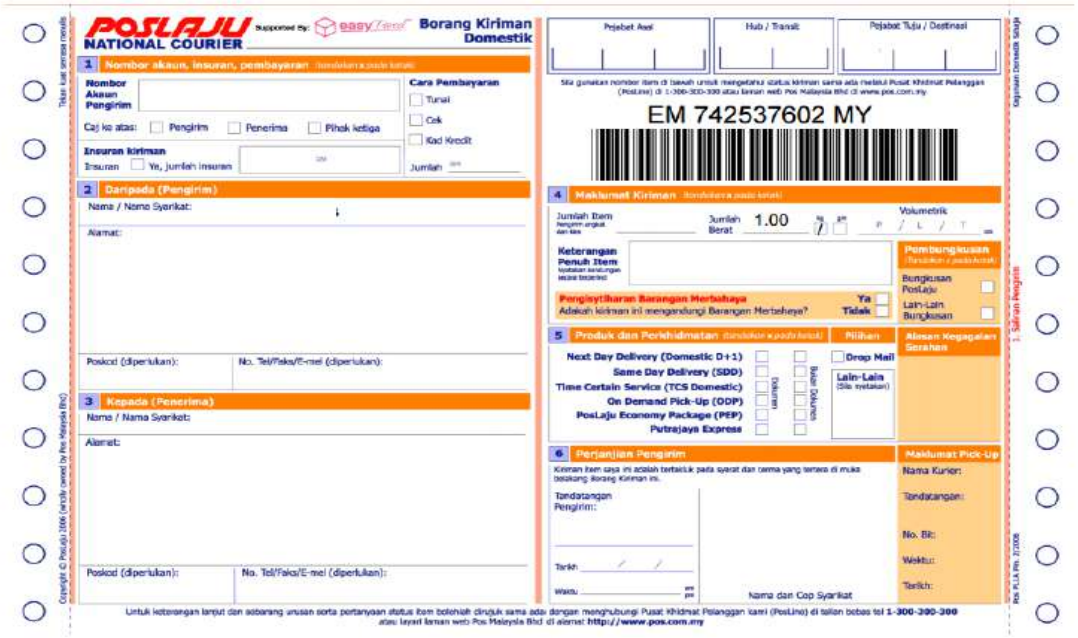
Source: Ratermann Cryogenic and Compressed Gas Equipment and Supplies

When considering storing in LN2 vapor phase (≤ -150°C) or submersion in liquid phase (≤ -190°C), vapor phase storage is preferred because it provides sufficiently low temperatures to maintain specimens below the Tg (Glass Transition Temperature; -132°C) while avoiding contamination issues and safety hazards inherent in liquid phase storage.

Because of the detail and complexity of the regulations, this document does not provide further guidance on the regulations applicable to shipments of liquid nitrogen (except for the use of liquid nitrogen as part of dry shippers and dewar flasks).

APPENDIX 3

EXAMPLES OF WAYBILLS



APPENDIX 4

EXAMPLES OF SEND OUT SAMPLES LIST

HM/QS. JP/QP-006/1
Keluaran: 01 Pindaan: 00
Lampiran 1

REKOD PENGHANTARAN SPESIMEN KE MAKMAL RUJUKAN
JABATAN PATOLOGI, HOSPITAL MELAKA
(TEL: 06 – 2892851, FAX: 06 – 2812148)

Bahagian:..... **Tarikh:**..... **JTMP bertanggungjawab:**..... **Ext:**.....

Pegawai yang mengesahkan: .....

Bil	Rujukan Makmal	RN / KP Pesakit	Nama Pesakit	Jenis Spesimen	Ujian dipohon	Makmal Rujukan	Catatan	Perakuan penerimaan spesimen (Nama Pegawai / TT / Tarikh / Masa)

APPENDIX 5

Classification of Formalin Spillage

Minor Spills	Major Spills
A single leaking specimen container containing 10% formalin or formaldehyde	Multiple broken specimen containers that contained 10% formalin
A broken specimen container that contained up to 100 ml of 10% formalin or formaldehyde.	A partial or full container containing more than 100 mL of 35% formaldehyde onto vehicles
A partial or full container (greater than 100 mL) of 35% formaldehyde in a chemical fume hood	
A splash of concentrated formaldehyde or paraformaldehyde onto a surface	

APPENDIX 6

Formalin Spillage Protocol

A. Minor Spill Protocol

i. Wear the required PPE - disposable plastic apron, gloves, face mask, safety goggles
ii. Pour neutralizing buffer over surface of spillage
iii. Clean surfaces with cold water at least two times using absorbent material
iv. Place used absorbent material into plastic bag and seal the plastic bag
v. Tag the waste (e.g., plastic bag containing contaminated absorbent material)
vi. Disposed as hazardous waste
vii. If there is leaking of specimen container that holding a specimen:
    - Transfer the specimen into another specimen container
    - Pour the formalin solution from the leaking container into a waste container for disposal as hazardous waste
    - Clean the contaminated surface as above

B. Major Spill Protocol

i. Involve more than 5 litres of formalin
ii. It should be handled by Jabatan Bomba dan Penyelamat Malaysia

Ministry of Health Malaysia

MEDICAL DEVELOPMENT DIVISION
Ministry of Health, Block E1, Parcel E,
Federal Government Administrative
Centre,
62590 Putrajaya, Malaysia.
Tel : 603-8883 3888
Fax : 603-8883 1155
http://www.moh.gov.my

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