

# PACKAGING AND TRANSPORTING OF INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS



NATIONAL PUBLIC HEALTH LABORATORY (NPHL) DIVISION OF MICROBIOLOGY

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#### INTRODUCTION

These guidelines are applicable to the transport of infectious substances and diagnostic specimens both nationally and internationally. The guidelines stress the importance of developing a working relationship between the groups involved – the sender, the carrier and the receiver – in order to provide for the safety.

Postal, airline and other transport industry personnel hold concerns about the possibility of their becoming infected as the result of exposure to infectious microorganisms that may escape from broken, leaking or improperly packaged material. The packaging of infectious materials for transport must therefore address these concerns and be designed to minimize the potential for damage During transport. In addition, the packaging will serve to ensure the integrity of the materials and timely processing of specimens.

## **DEFINITIONS**

#### Infectious substances

An infectious substance is defined as a substance containing a viable microorganism, such as a bacterium, virus, rickettsia, parasite or fungus that is known or reasonably believed to cause disease in humans or animals.

## Infectious substances include:

- 1. All cultures containing or suspected of containing an agent which may cause infection:
- 2. Human or animal samples that contain such an agent in quantities sufficient to cause infection, should an exposure to them occur due to a transport mishap;
- 3. Sample from a patient with a serious disease of unknown cause.
- 4. Other specimens not included above and designated as infectious by a qualified person, e.g. a physician, scientist, nurse, etc.

## Diagnostic specimens

A diagnostic specimen is defined as any human or animal material including, but not limited to, excreta, blood and its components, tissue and tissue fluids collected for the purposes of diagnosis.

Diagnostic specimens collected during an investigation of an outbreak of a serious disease of unknown cause must be handled as infectious substances.

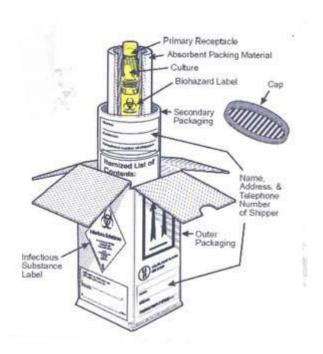
## PACKAGING, LABELLING AND DOCUMENTATION FOR TRANSPORT

## **Basic Triple Packaging System**

The system consists of three layers as follows.

- 1. Primary receptacle is the container (e.g. tube, vial, and bottle) that holds the specimen. (Figure 1)
  - The primary receptacle must be securely sealed and leak proof (Screw-top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit).
  - The primary receptacle must be surrounded by absorbent material capable of taking up the entire liquid contents.
  - The primary receptacle must be packed in the secondary receptacle in such a way that it will not break.
  - International Air Transport Association (IATA) regulations allow 1 liter in a primary receptacle for diagnostic specimens. The outer packaging must not contain more than 4 liters.

Figure 1: Primary packaging

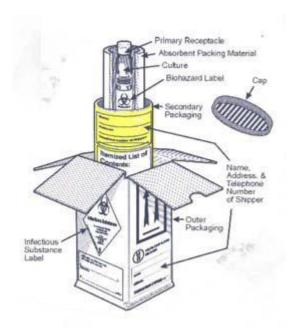


- 2. Secondary packaging is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed. (Figure 2)
  - The secondary packaging must be leak proof and securely sealed.
  - The secondary packaging must be placed in the outer packaging so that it does not move.
  - The biohazard marking should be on the secondary receptacle and may be on the primary receptacle.

## 3. Itemized List of Contents

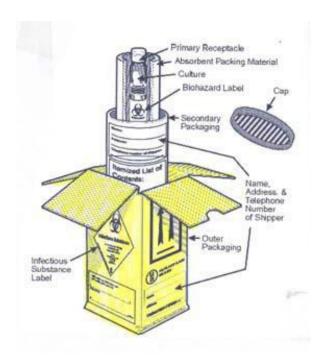
- An itemized list of contents is required. DO NOT place documents inside the secondary container.
- The itemized list is placed **OUTSIDE** the secondary container.
- The laboratory request form should be placed OUTSIDE the secondary container.

Figure 2: Secondary packaging



- 4. Outer packaging is the receptacle which the secondary packaging with cushioning materials is placed. (Figure 3)
  - The outer packaging must be rigid (effective 1-1-2005).
  - The outer packaging bears the addressing information along with all required markings and labels such as;\
    - The full name and address of the shipper and consignee must be on the outside packaging.
    - The outside packaging must have the name and telephone number of a person who is knowledgeable about the contents of the shipment.
    - This is important emergency information in the event an exposure occurs during shipping.

Figure 3: Outer packaging

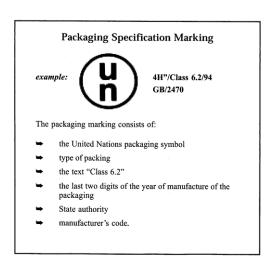


## Requirements for infectious substances

Infectious substances may only be transported in packaging which meets the UN class 6.2 specifications (Appendix 1) and packaging instruction (PI) 602 and (PI) 605 (Appendix 2)

- The outer shipping package must bear the UN Packaging Specification Marking (Figure 4).
- The maximum net quantity of infectious substances which can be contained in an outer shipping package is 50ml or 50g if transport is by passenger aircraft. Otherwise, the limit per package is 4L-4kg for transport by cargo aircraft.

Figure 4: Packaging Specification Marking



For all dangerous goods to be shipped by airfreight, specific hazard labels
 (s) must be affixed to the outside of each package (Figure 5).

Figure 5: Hazard labels for infectious substances, Category A, PI 602



- 4. Labelling of the outer package for shipment of infectious substances must include:
  - The International Infectious Substances Label
  - An address with the receiver's (consignee) and shipper's (consignor) name, address and telephone number.

- The UN Shipping name (Infectious Substances Affecting Humans OR Animals as the case may be) followed by the scientific name of the substance
- The UN Number (Human UN2814, Animals-UN2900)
- 5. Required shipping documents these are obtained from the carrier and are fixed to the outer package:
  - The shipper's Declaration of Dangerous Goods (eg.in Appendix 3).
  - A packing list / custom (proforma) invoice which includes the receiver's address, the number of packages, detail of contents, weight, value (note: state that there is "no commercial value" as the items are supplied free of charge).
  - An air waybill if shipping by air. (Appendix 4 is one example)
- 6. An import and / or export permit and /or declaration if required (Appendix 5)

## Requirements for diagnostic specimens

The basic triple packaging system is used with the following specifications and labeling requirements. Primary receptacles may contain up to 500mL each, the total volume in the outer package not to exceed 4L.

Figure 6: Hazard labels for Biological Substances, Category B, PI 605



Labeling of the outer package for the shipment of diagnostic specimens must include the following:

- 1. An address label with the following information:
  - The receiver's (consignee) name, address and telephone number
  - The shipper's (consignor) name, address and telephone number
  - The statement "Diagnostic Specimen, Not Restricted, Packed in Compliance with Packaging Instruction 650".
- 2. Required shipping documents these are obtained from the carrier and are fixed to the outer package:
  - A packing list / custom (proforma) invoice which includes the receiver's address, the number of packages, detail of contents, weight, value (note: state that there is "no commercial value" as the items are supplied free of charge).
  - An air waybill if shipping by air. (Appendix 4 is one example)
- 3. An import and/or export permit and/or declaration (if required).

**Note**: The infectious substance label and the shipper's declaration of dangerous goods are not required for diagnostic specimens.

## Refrigerants

Ice or dry ice must be placed outside the secondary receptacle. If wet ice is used it should be in a leak-proof container and the outer package must also be leak-proof.

The secondary receptacle must be secured within the outer package to prevent damage after the refrigerant has melted or dissipated.

## LOCAL SURFACE TRANSPORT

The principle of safe transport by this means is the same as for air or international transport – the material should not have any possibility of escaping from the package under normal conditions of transport.

The following practices should be observed:

- 1. Specimen containers should be watertight and leak-proof.
- 2. If the specimen container is a tube, it must be tightly capped and placed in an upright position.
- 3. Specimen containers should be placed in robust, leak-proof plastic with secure and screw cap container.
- 4. The transport box should be secured in the transport vehicle.
- Each transport box should be labeled appropriately consistent with its contents.
- Laboratory request forms and identification data should accompany for each sample

**Note**: The practices 1 – 6 described above are not intended to supersede local or national requirements.

#### TRANSPORT PLANNING

It is the responsibility of the sender to ensure the correct designation, packaging, labeling and documentation of all infectious substances and diagnostic specimens.

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 responsibilities to carry out in the transport effort.

#### The sender

- 1. Makes advance arrangements with the receiver of the specimens.
- 2. Makes advance arrangements with the carrier to ensure:
  - That the shipment will be accepted for appropriate transport
  - That the shipment (direct transport if possible) is undertaken by the most direct routing, avoiding arrival at weekends;
- Prepares necessary documentation including, dispatch and shipping documents;
- Notifies the receiver of transportation arrangements once these have been made, well in advance of expected arrival time.

## The carrier

- 1. provides the sender with the necessary shipping documents and instructions for their completion;
- provides advice to the sender about correct packaging;
- Assists the sender in arranging the most direct routing and then confirms the routing;
- 4. Maintains and archives the documentation for shipment and transport.

## SPILL CLEAN-UP PROCEDURE

In the event of a spill of infectious or potentially infectious material, the following spill clean-up procedure should be used.

- Wear gloves and protective clothing, including face and eye protection if indicated.
- 2. Cover the spill with cloth or paper towels to contain it.
- 3. Pour an appropriate disinfectant over the paper towels and the immediately surrounding area (generally, 5% bleach solutions are appropriate; but for spills on aircraft, quaternary ammonium disinfectants should be used).
- 4. Apply disinfectant concentrically beginning at the outer margin of the spill area, working toward the centre.
- 5. After the appropriate amount of time (e.g. 30 min), clear away the materials. If there is broken glass or other sharps involved, use a dustpan or a piece of stiff cardboard to collect the material and deposit it into a puncture-resistant container for disposal.

## REFERENCES

- Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997). World Health Organization.
- 2 Laboratory Biosafety Manual, Third edition **(2004).** Geneva: World Health Organization: (pp. 95).
- Infectious Substances Shipping Guidelines, 10<sup>th</sup> edition **(2009)**. Geneva: International Air Transport Association
- 4 Garispanduan Pengimportan atau Pengekspotan organisma atau mana-mana bahagiannya, Edisi Pertama **(2006).** Kementerian Kesihatan Malaysia

# APPENDIX 1: INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A

UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substance affecting humans	Bacillus anthracis (cultures only) 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 hemorrhagic 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 hemorrhagic 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 hemorrhagic fever virus Poliovirus (cultures only) 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) 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	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)

# APPENDIX 2: PACKAGING INSTRUCTION (PI) 602 AND (PI) 650

Feature	PI 650	PI 602 (follow for PI 913)
Primary container	Present	Present
Secondary container	Present	Present
Outer container	Present	Present
Absorbent material for entire contents	Present	Present
United Nations design type testing* (performance requirements)		
1.2 m drop test	Must pass	Must pass
9 m drop test	Not required	Must pass
Puncture test	Not required	Must pass
Water immersion test	Not required	Must pass
Test reports	Should be available	Must be available
UN specification mark	Not required	Required
Minimum dimensions	Not defined	Defined
Volume and weight restrictions	Not defined	Defined
Packaging size restrictions	Not defined	Defined

1.2m drop test.

Pressure testing of either primary or secondary containers for both PI 602 and PI 650 must pass requirements of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range of  $-40^{\circ}$ C to  $+55^{\circ}$ C (-40°F to 130°F).

# **APPENDIX 3: SHIPPER'S DECLARATION OF DANGEROUS GOODS**

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UN or ID No.	Proper Shippin	g Name	Class or Division (Subsidiary Risk)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorizatio
UN 2814	Infectious substan humans (HIV cultu		6.2		45 mL	602	
UN 1845	Dry ice		9	fll	6 kg All packed in one Fibreboard box	904	
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## **APPENDIX 4: AIR WAYBILL**

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# APPENDIX 5: IMPORT PERMIT (CONTOH PERMIT MEMBAWA MASUK / KELUAR MIKRORGANISMA)

JADUAL KELIMA
[Subperaturan 4(5) dan 5(4)]

## **BORANG**

## AKTA PENCEGAHAN DAN PENGAWALAN PENYAKIT BERJANGKIT 1988 PERATURAN-PERATURAN PENCEGAHAN DAN PENGAWALAN PENYAKIT BERJANGKIT

(PENGIMPORTAN DAN PENGEKSPORTAN MAYAT, TISU MANUSIA DAN ORGANISMA ATAU BAHAN PATOGENIK) 2005

## PERMIT UNTUK MENGIMPORT / MENGEKSPORT TISU MANUSIA ATAU MANA-MANA

## BAHAGIANNYA DAN ORGANISMA ATAU BAHAN PATOGENIK ATAU MANA-MANA BAHAGIANNYA

1. Nama pemohon:			
2. Alamat pemohon:			
4. Nama pengguna kedua:			
5. Nama pengguna ketiga:			
6. Nombor rujukan permoho	nan:		
Butir-Butir Konsainan	Kumpulan Risiko	No. Kelompok	Kuantiti
(Nama tempat masuk) untuk membenarkan konsainan tertakluk kepada terma-terma da	ın syarat-syarat yang dikena		rkan diimport/ eksport*
Permit ini sah sehingga:		_	
Satu konsaimen	Lebih daripada satu	konsaimen	
Tandatangan pegawai diberi kua	ısa:		_
Nama pegawai diberi kuasa:			
Tarikh dikeluarkan:			
		*Potong mana-ma	na yang tidak berkenaan
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# **APPENDIX 6: SUMMARY OF SHIPPING INFORMATION**

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	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	-	602	50 ml or 50 g	4 L or 4 kg
Category A infectious substance, affecting animals	Infectious substance, affecting animals (technical name)	UN 2900	6.2	-	602	50 ml or 50 g	4 L or 4 kg
Category B infectious substance	Biological / substance, category B	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	III	904	200 kg	200 kg
Non- infectious, transducing GMOs	Genetically Modified Micro- organisms	UN 3245	9	-	913	No limit	No limit
Non- infectious, non- transducing GMOs	None-not regulated	-	-	-		. <b>-</b>	
Infectious GMOs	Infectious substance, affecting humans ( ) OR Infectious substance,	UN 2814 Or UN 2900 Or UN 3373	6.2	-	602 650	50 mL or 50 g	4L or 4 kg
	affecting animals ( )						
Patient Specimens	"Exempt human specimens" or "Exempt animal specimens"	-	<del>-</del>	-	Triple packaging	Primary receptacle (500ml or 500g) Outer packaging (4L or 4kg)	Primary receptacle (500ml or 500g) Outer packaging (4L or 4kg)

# APPENDIX 7: Work Process For Specimen To Be Transported Out Of The Country

BIL	ACTIVITY
1.	Write letter informing requirement to export organisms or pathogenic substances (export permit).
	Fill-up request form ( as in appendix 5)
	Required documents  a) Letter request for export organisms or pathogenic substances b) Photocopy of I/C c) Photocopy of autoclave certificate (within expiry date)
	Contact person: KLIA Officer in charge Tel: 03-87768399 Fax: 03-87872054
2.	Request import permit from recipient country (consignee).
3.	Request for Air Waybill number from MAS Cargo
	Tel: 03-87771888
4.	Book flight for transportation of specimen.
	Get information regarding;
	a) Date b) Flight Number
	c) Departure time
	d) Arrival time
	Tel: 03-87771655
5.	Fill-up forms :     a) Shipper's Declaration For Dangerous Goods     b) Shipper's Instructions for dispatch
6.	Inform recipient / consignee information regarding specimen transportation (flight number, estimated arrival time, date etc (as in no.4), and Air Waybill Number.

7. Pack parcel accordingly. Bring parcel to MAS Cargo 5 hours before departure time.

Bring required documents;

- a) Shipper's Declaration for dangerous goods 2 copies
- b) Shipper's Instructions for dispatch 1 copy
- c) Export Permit (1 copy)
- d) Import Permit from recipient / consignee (1 copy)
- e) Custom Invoce 2 copies
- f) IATA certificate 1 copy

## 8. MAS Cargo Entry

Apply for entry pass to MAS Cargo Complex.

Required document;

- a) Application Letter
- b) ID Card

Free Commercial Zone (FCZ)

Tel: 03-87768286

## 9. MAS Cargo Complex

Send parcel to MAS Cargo Complex

Pay parcel accordingly (by LO or cash) according to location.

(Eg. Hong Kong - 1kg = RM 9.02)

# 10. Custom Complex

Bring in all necessary documents from Mas Cargo Complex to Custom Complex for custom clearance.

## Payment:

- a) Form = RM 5
- b) Declaration charge = RM 21.20

## 11. MAS Cargo Complex

Hand over all the custom clearance documents to MAS Cargo officer.

# APPENDIX 8: Work Process For Specimen To Be Transported Into The Country

BIL	ACTIVITY
1.	Write letter informing requirement to import organisms or pathogenic substances (import permit).
	Fill-up request form ( as in appendix 5)
	Required documents  a) Letter request for export organisms or pathogenic substances b) Photocopy of I/C c) Photocopy of autoclave certificate (within expiry date)
	KLIA Officer In Charge No. Tel: 03-87768399 No. Faxs: 03-87872054
2.	Email approved import permit to sender.
3.	Get the necessary information regarding imported parcel; a) Date b) Flight Number c) Departure time d) Arrival time
4.	COLLECTION OF PARCEL AT MAS CARGO COMPLEX:
	1) Entry point     Request for entry pass. Required documents;     c) Application Letter     d) ID Card
	2) MAS Cargo Complex Submit Airway bill No (from sender) and collect parcel.
	Note : Storage charge may applies according to weight and duration.
	3) Custom Complex Submit document from MAS Cargo for custom clearance. Do parcel inspection at Health Office.