

ANNEX 3. GUIDELINES FOR THE SAFE TRANSPORT OF INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS¹

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INTRODUCTION

These guidelines are applicable to the transport of infectious substances and diagnostic specimens both nationally and internationally. They provide information for identifying and classifying the material to be transported and for its safe packaging and transport. 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 safe and expeditious transport of this material.

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 minimise the potential for damage during transport. In addition, the packaging will serve to ensure the integrity of the materials and timely processing of specimens.

There are no recorded cases of illness attributable to the release of specimens during transport, although there are reported incidents of damage to the outer packaging of properly packaged materials. The shipment of unmarked and unidentified infectious materials, improperly packaged, obviously increases the overall potential for exposure to all persons.

The international regulations for the transport of infectious materials by any mode of transport are based upon the Recommendations of the United Nations Committee of Experts on the Transport of Dangerous Goods (UN). The Universal Postal Union (UPU) reflects these recommendations in its regulations, particularly for packaging. The International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA) have also incorporated the UN Recommendations in their respective regulations, as have other international transport organizations. The World Health Organization serves in an advisory capacity to these bodies. This document provides practical guidance to facilitate compliance with current international regulations. If, at a future date, any modification is made in the section of the UN Recommendations on the Transport of Dangerous Goods dealing with infectious substances and diagnostic specimens, these guidelines will be updated accordingly.

DEFINITIONS

For the purpose of describing transport safety measures the terms “infectious substances” and “infectious materials” are considered synonymous. The term “infectious substances” will be used in this document.

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.*

With respect to packaging and transport situations, 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(s) 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.

* This definition is taken from the current UN Recommendations on the Transport of Dangerous Goods. Prions are not included in this definition, although they are considered to be infectious agents.

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, but excluding live infected animals.

Diagnostic specimens resulting from medical practice and research are considered a negligible threat to the public health.

Diagnostic specimens obtained from patients with suspected infectious diseases may contain limited quantities of an infectious agent. There are very few agents which may be the source of an infection as a result of a transport mishap. *If exposure to the specimen due to transport mishap could result in an infection, the diagnostic specimen must be packaged, labelled and transported as an infectious substance.* 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

Because of the distinction of risks between infectious substances and diagnostic specimens, there are variations to the packaging, labelling and documentation requirements. The packaging requirements are determined by the UN and are contained in ICAO and IATA regulations in the form of Packaging Instructions (PI) 602 and 650. The requirements are subject to change and upgrade by these organisations. The current packaging requirements are described below. UN-approved packaging systems are available commercially.

Basic triple packaging system

The system consists of three layers as follows (Figure A3.1).

1. Primary receptacle. A labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.
2. Secondary receptacle. A second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles.
3. Outer shipping package. The secondary receptacle is placed in an outer shipping package which protects it and its contents from outside influences such as physical damage and water while in transit.

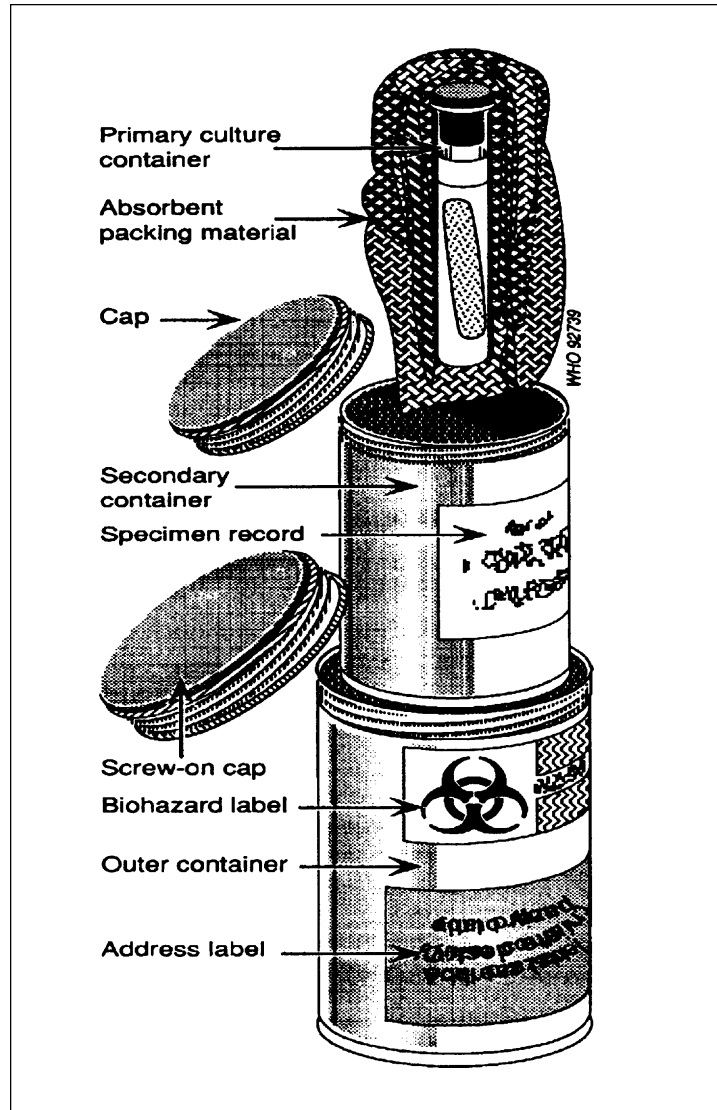
Specimen data forms, letters and other types of information that identify or describe the specimen and also identify the shipper and receiver should be taped to the outside of the secondary receptacle.

Requirements for infectious substances

The basic triple packaging system is used with the following additional specifications and labelling and documentation requirements.

Infectious substances may only be transported in packaging which meets the UN class 6.2 specifications and packaging instruction (PI)602. This ensures that strict performance tests which include a nine metre drop test and a puncture test have been met. The outer shipping package must bear the UN Packaging Specification Marking (Figure A3.2). UN-approved packaging supplier listings may be

FIGURE A3.1. Triple packaging system.

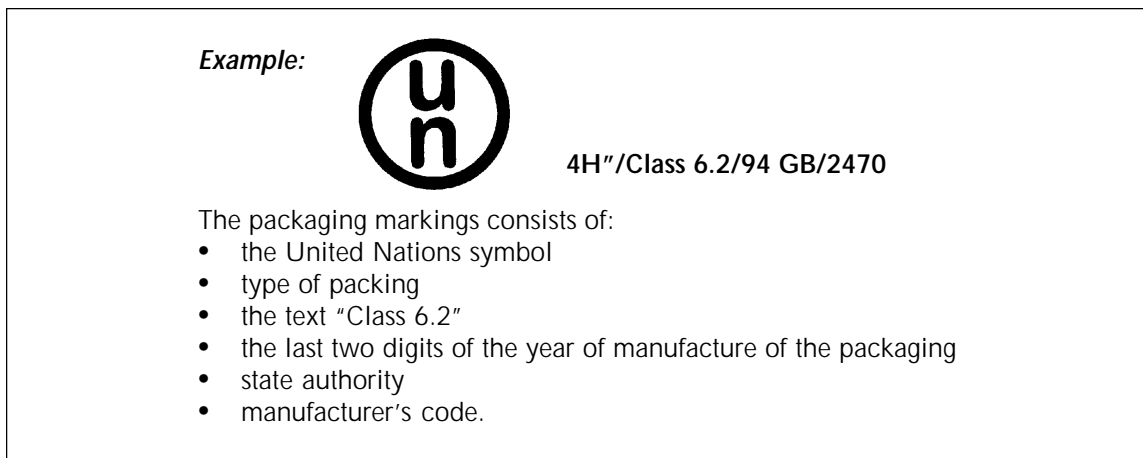


obtained from carriers or from the appropriate national ministry or department, e.g., the Ministry of Transport, etc.

Hand carriage of infectious substances is strictly prohibited by international air carriers, as is the use of diplomatic pouches for that purpose.

The maximum net quantity of infectious substances which can be contained in an outer shipping package is 50 mL or 50 g if transport is by passenger aircraft. Otherwise, the limit per package is 4 L–4 Kg for transport by cargo aircraft or other carriers. Primary receptacles exceeding 50 mL in combination packing must be oriented so the closures are upward, and labels (arrows) indicating the “UP” direction must be placed on two opposite sides of the package. The passenger aircraft quantity limits do not apply to blood or blood products for which there is no reason to believe they contain infectious substances, when in receptacles of not more than 500 mL each and with a total volume of not more than 4 L in the outer package.

FIGURE A3.2. Packaging specification marking.



In case shipments include only freeze-dried cultures the quantity should be given in g or mg, not in mL. The "PACKAGE ORIENTATION" labels should be affixed to avoid any delay.

Labelling of the outer package for shipment of infectious substances must include the elements listed hereafter.

1. The International Infectious Substance Label.
2. 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 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 (Humans—UN2814, Animals—UN2900)
 - temperature storage requirements (optional).

If the outer package is further packed in an overpack (with dry ice for instance) both outerpack and overpack must carry the above information, and the overpack must have a label stating "INNER PACKAGES COMPLY WITH PRESCRIBED SPECIFICATIONS."
3. Required shipping documents—these are obtained from the carrier and are fixed to the outer package:
 - the shipper's Declaration of Dangerous Goods (Figures A3.4 and A3.5 are examples)
 - a packing list/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 airwaybill if shipping by air.
4. An import and/or export permit and/or declaration if required.
5. If the outer package contains primary receptacles exceeding 50 mL in combination, at least two "Orientation Labels" (arrows) must be placed on opposite sides of the package showing correct orientation of the package.

Requirements for diagnostic specimens

The basic triple packaging system is used with the following specifications and labelling requirements. Diagnostic specimens may be transported in packaging which meets the packaging instruction (PI)650. The UN specification marking is not required.

Primary receptacles may contain up to 500 mL each, the total volume in the outer package not to exceed 4 L.

Labelling 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 Packing Instruction 650."
2. Required shipping documents—these are obtained from the carrier and are fixed to the outer package:
 - a packing list/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 airwaybill if shipping by air.
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.

Requirements for Air Mail

Infectious substances and diagnostic specimens may be shipped by registered air mail. The basic triple packaging system is used with the same requirements as for other means of conveyance.

The address label must display the word "LETTRE" and the green Customs Declaration Label for Postal Mail is required for international mailing. Diagnostic specimens are to be identified with the violet UPU "PERISHABLE BIOLOGICAL SUBSTANCES" label. Infectious substances are to be identified with the International Infectious Substance label (see Figure A3.3). Infectious substances must also be accompanied with a shipper's Declaration of Dangerous Goods form (see Figures A3.4 and A3.5 at the end of the document).

Because of local/international restrictions, prior contact should be made with the local post office to ascertain whether the packaged material will be accepted by the postal service.

Refrigerants

Ice or dry ice when used in a shipment 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. Dry ice must not be placed inside the primary or secondary receptacle because of the risk of explosions. An overpack (a specially designed insulated outer package) may be used to contain dry ice. The outer package must permit the release of carbon dioxide gas if dry ice is used. UN Packing Instruction 904 must be observed.

If dry ice is used for infectious substances, the details must appear on the shipper's Declaration for Dangerous Goods. In particular, the outermost packing must carry the "MISCELLANEOUS" hazard label for dry ice (see Figure A3.3).

If liquid nitrogen is used as a refrigerant, special arrangements must be made in advance with the carrier. Primary receptacles must be capable of withstanding extremely low temperatures and appropriate packaging requirement of the carrier must be observed. In particular, the outermost packing must carry the "NON-FLAMMABLE GAS" label for liquid nitrogen (see Figure A3.3).

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Examples include transport of specimens from a doctor's office/surgery to a laboratory, from a hospital to a diagnostic laboratory or from one laboratory to another. Such courier services

FIGURE A3.3. Hazard labels for dangerous goods.

For all dangerous goods to be shipped by airfreight, specific hazard label(s) must be affixed to the outside of each package. The following hazard labels are of importance for culture collections or other institutions shipping biological substances.

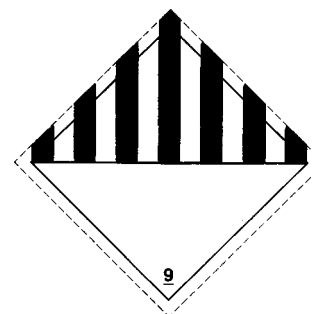
Hazard labels for infectious substances and for genetically modified microorganisms which meet the IATA definition of an infectious substance:

Name: Infectious Substance
 Minimum dimensions: 100 x 100 mm
 For small packages: 50 x 50 mm (black and white)



Hazard label for noninfectious genetically modified microorganisms and for carbon dioxide, solid (dry ice):

Name: Miscellaneous
 Minimum dimensions: 100 x 100 mm
 For small packages: 50 x 50 mm (black and white)



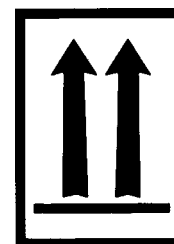
Hazard label for liquid nitrogen:

Name: Non-flammable gas
 Minimum dimensions: 100 x 100 mm
 For small packages: 50 x 50 mm (green and white)



Packages containing liquid cultures of infectious organisms and genetically modified microorganisms must be packed so that the closure(s) of the inner packaging(s) are upward; the upright position of the packaging must be indicated by two "Package Orientation" labels (black or red arrows). The labels must be affixed on opposite sides of the packaging. A label "THIS SIDE UP" or "THIS END UP" may also be displayed on the top cover of the package:

Name: Package Orientation
 Minimum dimensions: 74 x 105 mm (black or red and white)
 For small packages of infectious substances dimensions may be halved.



may be operated by a hospital, a laboratory, a health service or other approved agency or organisation.

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 a rack to maintain it in an upright position;
3. specimen containers and racks should be placed in robust, leak-proof plastic or metal transport boxes with secure, tight fitting covers;
4. the transport box should be secured in the transport vehicle;
5. each transport box should be labelled appropriately consistent with its contents;
6. specimen data forms and identification data should accompany each transport box;
7. a spill kit containing absorbent material, a chlorine disinfectant, a leak-proof waste disposal container and heavy duty reusable gloves should be kept in the transport vehicle.

Note: The practices 1–7 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, labelling 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 among 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 including investigating the need for an import permit;
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;
3. prepares necessary documentation including permits, dispatch and shipping documents;
4. 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;
2. provides advice to the sender about correct packaging;
3. assists the sender in arranging the most direct routing and then confirms the routing;
4. maintains and archives the documentation for shipment and transport;
5. monitors required holding conditions of the shipment while in transit;
6. notifies the sender of any anticipated (or actual) delays in transit.

The receiver

1. obtains the necessary authorisation(s) from national authorities for the importation of the material;
2. provides the sender with the required import permit(s), letter(s) of authorisation, or other document(s) required by the national authorities;
3. arranges for the most timely and efficient collection on arrival;
4. immediately acknowledges receipt to the sender.

Shipments should not be dispatched until:

- advance arrangements have been made between the sender, carrier and receiver
- the receiver has confirmed with the national authorities that the material may be legally imported
- the receiver has confirmed that there will be no delay incurred in the delivery of the package to its destination.

Detailed information on response and emergency safety measures in transport-associated accidents can be found in *Laboratory Biosafety Manual*, Second edition (1993). Geneva: World Health Organization: (pp. 52–54).

FIGURE A3.4. Standard shipment of infectious substances.

Shipper's Declaration for Dangerous Goods

Shipper: World Health Organization, 20, avenue Appia, CH-1211 Geneva, Switzerland

Air Waybill No. 117-4812'9550

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Shipper's Reference Number (optional)

Consignee: Karolinska Hospital, Clinical Microbiology, Stockholm 17176, Sweden, Attn: Dr Göran Kronvall, Tel: 468 51 77 4910/Fax: 468 308 099

Transport details: This shipment is within the limitations prescribed for: (delete non-applicable)

Passenger and Cargo Aircraft: Passenger Cargo

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

Shipment type: (delete non-applicable) Non-Radioactive ~~Radioactive~~

Nature and Quantity of Dangerous Goods (see sub-Section 8.1 of IATA Dangerous Goods Regulations)

Dangerous Goods Identification						
Proper Shipping Name	Class or Division	UN or ID No.	Pack- ing Group	Sub-idiary Risk	Quantity and type of packing	Pack- ing Inst. Authorization
Infectious substance, affecting humans (Streptococcus Pneumonia)	6.2.	UN 2814			1 fibreboard box x 2g	602

SPECIMEN

Additional Handling Information: Emergency contact: P Munger - Tel: 4122 791 2179. Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made.

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

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

Name/Title of Signatory: P Munger, Shipping and Logistics Unit, Place and Date: Geneva, 3 Jun 1995, Signature (see warning above)

Distribution: One copy to accompany AWS, One copy to be filed at airport of departure (with AWS-copy)

FIGURE A3.5. Shipment of infectious substances using dry ice.

Shipper's Declaration for Dangerous Goods							
Shipper World Health Organization 20, avenue Appia CH-1211 Geneva Switzerland				Air Waybill No. 117-4812'9550 Page 1 of 1 Page Shipper's Reference Number <i>(optional)</i>			
Consignee Karolinska Hospital Clinical Microbiology Stockholm 17176, Sweden Attn: Dr Göran Kronvall Tel: 468 51 77 4010/Fax: 468 308 099							
Transport details This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>				Warning Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.			
Airport of Departure:				Shipment type: <i>(delete non-applicable)</i> Non-Radioactive <input checked="" type="checkbox"/> Radioactive			
Airport of Destination:							
Nature and Quantity of Dangerous Goods <i>(see sub-Section 2.1 of IATA Dangerous Goods Regulations)</i>							
Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Streptococcus Pneumonia)	6.2	UN 2814			1 fibreboard box x 2g	602	
Dry Ice	9	UN 1845	III		10 kg	904	
OVERPACK USED							
SPECIMEN							
Additional Handling Information Emergency contact: P Munger - Tel: 4122 791 2179 Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made.							
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.					Name/Title of Signatory P Munger, Shipping World Logistics Unit Place and Date Geneva, 3 June 1995 Signature <i>(see warning above)</i>		
Two completed and signed copies of this Declaration must be handed to the operator							
Distribution: One copy to accompany AWB One copy to be filed at airport of departure (with AWB-copy)							