AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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Requirements for the packaging and transport of pathology specimens and associated materials

Fifth Edition

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Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

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Contents

National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards and initiate and promote education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) leads and coordinates national improvements in health care safety and quality. The Commission works in partnership with patients, carers, clinicians, the Australian state and territory health systems, the private sector, managers, healthcare organisations, colleges and professional organisations to achieve a safe, high-quality and sustainable health system.

The Commission's statutory functions include formulating model national schemes that provide for the accreditation of organisations that provide health care services and relate to healthcare safety and quality matters. [i]

The Commission is responsible for the administration of the National Pathology Accreditation Scheme on behalf of the Australian Government Department of Health and Aged Care (the Department). The Department retains responsibility for the regulation and funding of pathology in Australia.

[i] National Health Reform Act 2011 (Cth)

Scope

The *Requirements for the packaging and transport of pathology specimens and associated materials* (the *Packaging and transport standard*) is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for medical pathology services* (the *RMPS*).

The *RMPS* provides a framework for good medical pathology practice in laboratories where the primary consideration is patient safety, quality and welfare. The *RMPS* also supports the needs of patients, the laboratory workforce and referrers (both for pathology requests and inter-laboratory referrals) for effective, timely and good quality services being met.

References to standards in the *RMPS* and other NPAAC documents are provided to assist laboratories implement interrelated requirements.

The transport of pathology specimens and associated materials may require several modes of transport, each of which is covered in this document.

The following topics are outside the scope of this document:

- transport of medical waste – refer to relevant jurisdictional legislation
- requirements for the packaging of genetically modified organisms (GMOs) – see the *Guidelines for the transport, storage and disposal of GMOs* issued by the Office of the Gene Technology Regulator. [ii]

This document was written for the Australian context and includes requirements for international shipping.

[ii] https://www.ogtr.gov.au/resources/publications/guidelines-transport-storage-and-disposal-gmos

Definitions

Term	Description
Dangerous goods	means articles or substances that are capable of posing a risk to health, safety, property or the environment.
Dry ice	means solidified carbon dioxide that changes from a solid to a gas (sublimates) at normal atmospheric conditions. It is used primarily for cooling and due to its very low temperature (–79.5°C) Dry ice can cause severe burns to skin upon direct contact. The carbon dioxide gas can lead to the displacement of oxygen resulting in asphyxiation. If improperly packaged (i.e. gas cannot escape) the carbon dioxide gas will pressurise the container, potentially causing the container to explode. The United Nations (UN) number for dry ice is UN 1845.
Formalin	means, generically, a solution of formaldehyde gas dissolved in water.
Group F employee	means an employee of a shipper of dangerous goods whose duties include packing dangerous goods or supervising someone else whose duties include packing dangerous goods, in the course of the goods being consigned for transport on an aircraft. Under the definition of a Group F employee, a person packs dangerous goods if he or she does any of the following in relation to the goods: • encloses the goods in packaging • marks or labels the package or consignment • prepares a dangerous goods transport document for the consignment.
IATA Dangerous Goods Regulations	means a set of regulations published annually by the International Air Transport Association (IATA). These regulations are followed by all IATA member airlines worldwide.
Infectious substances	means substances that are known to contain, or are reasonably expected to contain, pathogens. Infectious substances are divided into categories A, B or Exempt Specimens, and are governed by various UN requirements (see Section 3.1 of this document for definitions of these categories).
Laboratory	A medical pathology practice.

Term	Description
Liquid nitrogen	means an inert, colourless, odourless, non-corrosive, non-flammable, and extremely cold element, with a boiling point of –150°C at standard temperature and pressure conditions.
Microbial cultures	means cultures that are the result of a process by which pathogens are intentionally propagated.
Outer packaging	means the outer protection of a combination packaging together with absorbent materials, cushioning and any other components necessary to contain and protect the primary receptacle and secondary packaging and make it capable of withstanding the rigours of transport.
Package	means the complete product of the packing operation consisting of all the packaging and their contents prepared for transport.
Patient specimens	means specimens that are collected directly from humans or animals (including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts) that are transported for purposes such as research, diagnosis, investigations, disease treatment and prevention.
Secondary packaging	means leak-proof packaging that provides additional protection for the primary receptacle(s); it may include absorbent material.
Surface transport	means any form of surface transport within the public domain. This includes vehicles or packages transported by water, foot or trolleys. (Regulation of sea transport is the responsibility of the Australian Maritime Safety Authority.)
Workforce	means all people working in a health service organisation, including clinicians and any other employed or contracted, locum, agency, student, volunteer, or peer workers. The workforce can be members of the health service organisation or medical company representatives providing technical support who have assigned roles and responsibilities for care of, administration of, support of, or involvement with patients in the health service organisation.

Introduction

This document, together with the Tier 2 document *Requirements for medical pathology services* (the *RMPS*), sets out the expected policies, procedures and practices laboratories are to use when packaging and transporting pathology specimens and associated materials.

This standard takes a risk-based approach to the provision of packaging laboratory specimens. Pathology specimens and associated materials must be transported and packaged safely to:

- protect the safety of everyone required to handle the specimens and package
- protect the integrity of the transported material
- ensure that the material is maintained under suitable conditions
- reduce the environmental risk due to specimen packaging materials.

The *Packaging and transport standard* is intended to serve as the expected level of practice. The *Packaging and transport standard* has been developed with reference to current best practice and available evidence.

The *Packaging and transport standard* should be read in conjunction with the National Pathology Accreditation Scheme including the current versions of the following NPAAC standards:

Tier 2

- *Requirements for medical pathology services*

Tier 3B

- *Guidelines for Approved Pathology Collection Centres (Requirements for medical pathology specimen collection)*

In addition to these standards, laboratories must comply with all relevant state and territory legislation (including any reporting requirements), including those pertaining to air or road transport.

The format of this standard has been simplified. Action items appear with numbers, for example 1.01. Only statements numbered in this way are considered requirements; all other material is provided as guidance.

The classification scheme for hazards used in this document is based on the International Air Transport Association (IATA) Dangerous Goods Regulations, Australian Standard on packaging of biological material for surface transport (AS 4834) and the Australian Dangerous Goods Code, Edition 7.

NPAAC documents can be accessed at the Australian Commission on Safety and Quality in Health Care website.

Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street
Sydney NSW 2001

Phone: 1800 304 056
Email: pathology@safetyandquality.gov.au
Website: https://www.safetyandquality.gov.au/our-work/accreditation/national-pathology-accreditation-scheme

1 Training

This standard should be read in conjunction with Standard 4 in the *Requirements for medical pathology services*.

Item	Action	
Access to training	1.01	A laboratory **must** ensure the workforce responsible for packaging and transport of pathology specimens are: a. trained b. routinely assessed in their competency to perform the activity
	1.02	Members of the laboratory workforce who pack exempt substances for transport **must** be trained in the IATA Dangerous Goods Regulations and/ or Australian Dangerous Goods Code before packaging hazardous substances
Transport packaging training	1.03	A laboratory that ships infectious substances or dry ice for air transport **must** ensure accredited training is completed and then updated to maintain competency every two years for: a. members of the laboratory workforce before packaging these substances b. members of the laboratory workforce supervising packaging and transport activities
Training records	1.04	A laboratory **must** maintain training records and make them available to the Civil Aviation Safety Authority of Australia on request

2 Hazard classification

Item	Action	
Classification of specimens	2.01	Members of the laboratory workforce **must** use the flowchart at Figure 2.1 to classify: a. infectious hazards b. biological hazards c. other hazards

Infectious hazards – Category A

A **Category A** substance is an infectious substance that is transported in a form that, when exposure to it occurs, is capable of causing permanent disability or a life-threatening or fatal disease in otherwise healthy humans or animals.

Classifying Category A hazards **should** be based on:

- known medical history and symptoms of the source human or animal
- endemic local conditions
- professional judgment concerning individual circumstances of the source human or animal

For shipping purposes, Category A hazards are labelled as:

- *Infectious substances, affecting humans*
- *Infectious substances, affecting animals*

The United Nations *Recommendations on the transport of dangerous goods, model regulations* are published online and provides indicative examples of infectious substances, including those in Category A.

Laboratories **should** consult the latest version of this publication when classifying infectious substances to be transported.

Category A hazards	2.02	Substances classified as infectious that cause disease in humans or both humans and animals **must** be assigned to UN 2814
	2.03	Substances classified as infectious that cause disease only in animals **must** be assigned to UN 2900

Item	Action

Biological hazards – Category B

A **Category B** substance is an infectious substance that does not meet the criteria of Category A.

Hazards meeting the criteria of Category B **should** be assigned to UN 3373. This applies to human or animal material being transported for research, diagnosis, investigation and disease treatment and prevention, including but not limited:

- Excreta and faeces
- Secreta
- Blood and its components
- Tissue and tissue fluids
- Body parts

Classify Category B hazards using Figure 2.1: Hazard classification flowchart and use IATA Packing Instruction 650 relating to air transport and the latest edition of the Australian Code for the Transport of Dangerous Goods by Road & Rail.

Category B hazards are labelled as *Biological substances, Category B* for shipping purposes.

Category B hazards	2.04	Substances classified as category B hazards **must** be assigned to UN 3373

Biological hazards – Exempt Specimens

An **Exempt Specimen** is a patient specimen with minimal likelihood that pathogens are present. These specimens are not subject to the IATA Dangerous Goods Regulations if they are transported in triple packaging that prevents leakage.

Exempt Specimens are labelled as *Exempt human specimens* or *Exempt animal specimens* for shipping purposes.

Unless a substance meets the criteria of another class, the following substances are not subject to the IATA Dangerous Goods Regulations:

- substances that do not contain infectious substances, or substances that are unlikely to cause disease in humans or animals
- substances containing micro-organisms that are non-pathogenic to humans or animals
- substances in a form where any present pathogens have been neutralised or inactivated such that they no longer pose a health risk
- environmental specimens (including food and water specimens) that are not considered to pose a significant risk of infection

Item	Action

- dried blood spots (collected by applying a drop onto absorbent material) or faecal occult blood screening tests, and blood or blood components that have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation, and any tissues or organs intended for use in transplantation

Use professional judgment to determine if a substance is an Exempt Specimen or if there is minimal likelihood that pathogens are present. Decision making **should** be based on:

- known medical history
- symptoms and individual circumstances of the source (human or animal)
- endemic local conditions

Examples of Exempt Specimens:

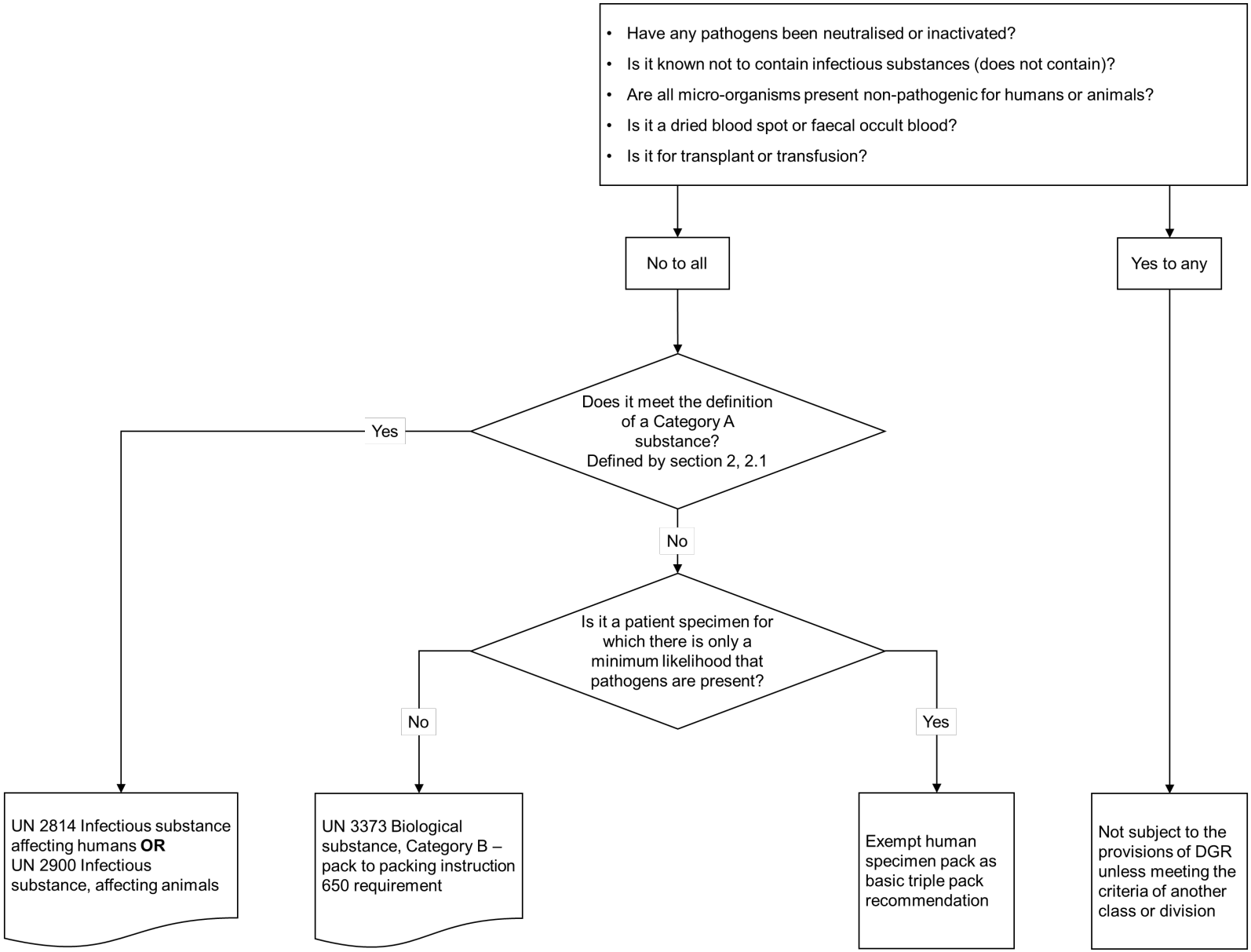
- fixed cytology smears
- specimens of blood or urine to be tested for antibodies, cholesterol, glucose, hormones, tumour markers, kidney or liver function, therapeutic drugs, non-therapeutic drugs and alcohol (the latter may have ‘chain of custody documents’)

Other hazards

Other hazards relevant to this document include:

- dry ice – covered by IATA Hazard Class 9, UN 1845 and IATA Packing Instructions 954
- flammable substances – covered by IATA Hazard Class 3
- corrosive substances – covered by IATA Hazard Class 8

Figure 2.1: Hazard classification flowchart



2.1 Hazard classification of common pathology substances

Table 2.1: Hazard classifications of some pathology substances

Specimen or substance type	Hazard classification
Any specimen with dry ice as a refrigerant	Classification as per Figure 2.1: *Hazard classification flowchart*; additional IATA Hazard Class 9 and IATA Packing Instruction 954 apply to the dry ice
Blood cultures	Most are Biological substances, Category B, unless the organism is or suspected to be an infectious substance according to the United Nations *Recommendations on the transport of dangerous goods, model regulations*, in which case they are Infectious substances, Category A
Cell cultures	Classification as per Figure 2.1: *Hazard classification flowchart*
Cervical specimen, liquid based	Included in packages containing Biological substances, Category B, provided transported in small numbers
Fixed-tissue specimen on glass slide	Exempt Specimen
Microbial cultures	Most are Biological substances, Category B unless known or suspected of being a Category A infectious substance.
Pap smears (glass slide type) – fixed	Exempt Specimen
Paraffin-embedded tissue specimen	Exempt Specimen
Patient specimen	Use Figure 2.1: *Hazard classification flowchart* to evaluate
Suspected serious infectious respiratory illness	
• Swab or nasopharyngeal aspirate	Category B, unless known to be or suspected of being infectious
• Bronchial washing/aspirate/lavage	Category B, unless known to be or suspected of being infectious

3 General packing requirements based on mode of transport

The following criteria should be read in conjunction with Standard 6A in *Requirement for medical pathology services*.

Item	Action	
Triple packaging	3.01	For transport of all pathology specimens and associated materials by air or surface transport methods, the packaging **must** consist of three components: a. primary receptacle b. secondary packaging c. outer packaging
Labelling and marking	3.02	The markings and labelling of packages for air or surface transport **must** comply with the relative Packing Instruction
	3.03	Packaging of pathology specimens **must** be suitable to the specimen and mode of transport

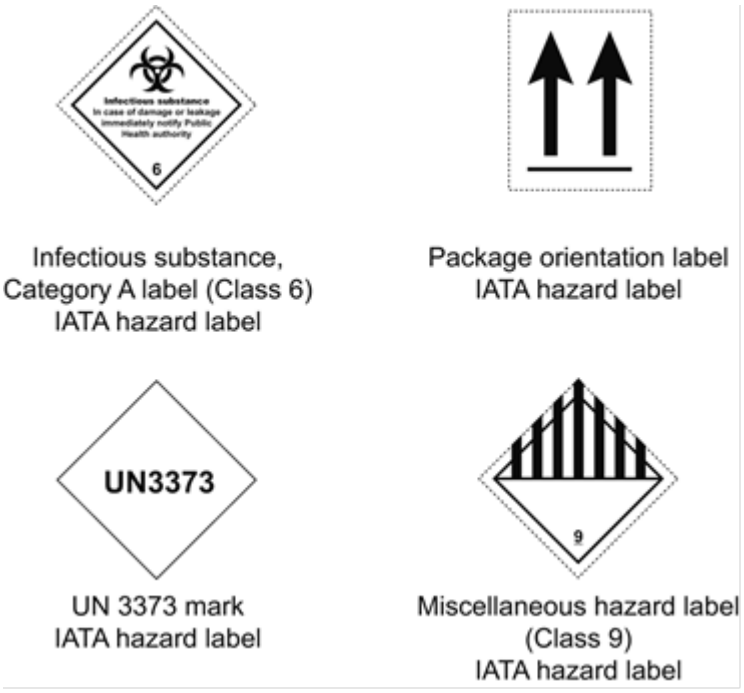


Figure 3.1: Labels used in packaging pathology specimens

3.1 Packaging requirements for biological and infectious substances

Shipment type	**Infectious substances, Category A – affecting humans, animals or both humans and animals**
UN or ID number	UN 2814 (human only) UN 2900 (animals only)
Proper shipping name	Infectious substances, affecting humans Infectious substances, affecting animals
IATA Hazard Class or Packing Instruction, or packaging group	Hazard Class 6.2 Packaging Instruction 620
Max net quantity passenger and cargo aircraft	50 mL or 50 g
Max net quantity cargo aircraft only	4 L or 4 kg
Marking and labelling and packaging	Infectious substance (Hazard Class 6.2) Packaging Instruction 620
Packaging requirements	Packaging Instruction 620

Shipment type	**Biological substances, Category B**
UN or ID number	UN 3373
Proper shipping name	Biological substances, Category B
IATA Hazard Class or Packing Instruction, or packaging group	Hazard Class 6.2 Packing Instruction 650
Max net quantity passenger and cargo aircraft	Liquid 4 L or solid 4 kg
Max net quantity cargo aircraft only	
Marking and labelling and packaging	Australian Code for the Transport of Dangerous Goods
Packaging requirements	Packaging Instruction 650

Shipment type	**Biological substances, Exempt Specimens**
UN or ID number	Not applicable
Proper shipping name	Exempt human specimens Exempt animal specimens
IATA Hazard Class or Packing Instruction, or packaging group	Not applicable
Max net quantity passenger and cargo aircraft	No limit Can carry as hand luggage or be in checked luggage
Max net quantity cargo aircraft only	
Marking and labelling and packaging	Australian Code for the Transport of Dangerous Goods Packaging Instruction 650
Packaging requirements	Packaging Instruction 650

Shipment type	**Dry ice**
UN or ID number	UN 1845
Proper shipping name	Dry ice or carbon dioxide, solid
IATA Hazard Class or Packing Instruction, or packaging group	Hazard Class 9 Packing Instruction 954
Max net quantity passenger and cargo aircraft	2.5 kg in cabin (airline approval must be obtained) 200 kg in cargo hold
Max net quantity cargo aircraft only	200 kg
Marking and labelling and packaging	• Miscellaneous (Hazard Class 9) • Dry ice • UN 1845 • Weight of dry ice in kg
Packaging requirements	Packaging Instruction 954

Shipment type	**Liquid nitrogen**
UN or ID number	UN 1977
Proper shipping name	Nitrogen, refrigerated liquid
IATA Hazard Class or Packing Instruction, or packaging group	Hazard Class 2.2 (no packaging group)
Max net quantity passenger and cargo aircraft	50 kg
Max net quantity cargo aircraft only	500 kg
Marking and labelling and packaging	Non-flammable gas or cryogenic liquid
Packaging requirements	Approved dewar cryogenic containers are usual for small quantities. Cylinders are required to be transported in an upright position.

4 Materials not covered in this Standard

Table 4.1: Transport guides for other materials related to pathology

Contents	Comments
Blood products for transfusion	Refer to the *Requirements for transfusion laboratory practice (Fifth Edition)*
Cooling tower water	Exempt Specimen Not classed as a hazardous substance Temperature control is important
Corrosive substances, solvents/stains, etc.	Refer to the material safety data sheet Substances containing corrosive material are IATA Hazard Class 8 Flammable substances usually contain methanol or other IATA Hazard Class 3 substances Shipment of small quantities may be possible under the relevant regulations
Drinking water specimen	Exempt Specimen Not classed as a hazardous substance Temperature control is important
Food specimens	Exempt Specimen
Laboratory reagents	Refer to material safety data sheet Temperature control is important
Medical waste	Clinical waste is a Division 6.2 dangerous good (Infectious Substances) and is identified by the number **UN3291.** A comprehensive guide to transport of medical waste is not within the scope of these guidelines; refer to relevant state/jurisdictional legislation Transport of medical waste by Australia Post is prohibited
Mercury, mercury compounds or mercury in manufactured items, such as thermometers	UN 3506 Packing Instruction 869 If it is necessary to transport mercury thermometers, they should be transported by surface transport, unless special permission is obtained

Contents	Comments
	IATA Hazard Class 8 Prohibited by Australia Post
Post-mortem specimens	Special Provision A189 Coronial and forensic cases are subject to ‘chain of custody’ processes — refer to state/jurisdictional legislation
Quality control specimens	Where of human or animal origin, treat as for patient specimens
Scientific instruments	IATA DGR 3.6.2.2.3.9
Suspected bioterrorist specimens	Contact state or territory government counterterrorism or chemical, biological, radiation and nuclear (CBRN) hazard unit for details on local arrangements. The state or territory Public Health Laboratory Network (PHLN) laboratory will usually be involved.
Vaccines	Not classed as hazardous substances Temperature control and monitoring are critical For vaccines guidelines, refer to the *Australian Immunisation Handbook*.

Appendix A — IATA Packing Instruction 620

Packing Instruction 620 has been reproduced with permission from the International Air Transport Association (IATA).

To obtain the latest version, visit the IATA website.

ⓘ The following location-specific requirements (State Variations), transport operator requirements (Operator Variations) or IATA Dangerous Goods Regulations may also apply for international shipments:

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

Operator Variations: 6O-02, 4C-04, 4M-04, AA-06, AM-06/10, AS-08, BR-14, BZ-07, CA-11, E9-03, FX-04, G3-02, HA-03, IP-03, JJ-04, KC-08, L7-04, LA-07, LH-05, LP-04, M3-40, M7-04, MS-06, OU-12, PX-08, SN-08, SV-12, TK-07, UC-04, WR-03, WS-03, XL-04

This instruction applies to UN 2814 and UN 2900.

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

General Requirements

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

The packagings must include:

a) **inner packagings**, comprising of:

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

b) an **itemised list of contents**, enclosed between the secondary packaging and the outer packaging; and

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

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

Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar). This primary receptacle or secondary packaging must also be capable of withstanding temperatures in the range of −40° to +°55°C.

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

- *flexible receptacles and flexible packagings,*
- *receptacles and packagings filled and closed under an absolute atmospheric pressure lower than 95 kPa.*

Additional Requirements

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

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided these substances meet the requirements of 2.7. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.

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

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

Specific Requirements

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

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

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

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

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

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

Appendix B — IATA Packing Instruction 650

Packing Instruction 650 has been reproduced with permission from the International Air Transport Association (IATA).

To obtain the latest version, visit the IATA website.

ⓘ The following location-specific requirements (State Variations) or transport operator requirements (Operator Variations) may also apply for international shipments:

State Variations: BHG-02, CAG-05, DQG-03, FRG-06, GBG-05, VCG-04

Operator Variations: 4C-04, 4M-04, 5X-01, AM-06/10, AR-02, AS-08, BR-14, BZ-07, CM-05, E9-03 FX-04, G3-02, IP-03, JJ-04, KC-08, KE-06, L7-04, LA-07, LH-05, LP-04, LU-04, M3-04, M7-04, MS-06, OS-05, OU-12, PX-08, SN-06/08, SV-12, TN-05, TR-05, UC-04, WR-03, WS-03, XG-05, XL-04, XQ-05

This instruction applies to UN 3373 on passenger and cargo aircraft and CAO.

General Requirements

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

The packaging must consist of three components:

a) a primary receptacle(s);

b) a secondary packaging; and

c) a rigid outer packaging.

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

Packages must be prepared as follows:

a) **For liquid substances**:

1. The primary receptacle(s) must be leak proof and must not contain more than 1 L;

2. The secondary packaging must be leak proof;

3. If multiple fragile receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;

4. Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be sufficient in quantity to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

5. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

6. The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen.

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

   - flexible receptacles and flexible packagings,

   - receptacles and packagings filled and closed under an absolute atmospheric pressure lower than 95 kPa.

b) **For solid substances**:

1. The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
2. The secondary packaging must be siftproof;
3. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
4. Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
5. If there is any doubt as to whether or not residual liquid may be presented in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

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

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

The completed package must be capable of successfully passing the drop test described in 6.5.1.1 except that the height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

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

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

- the overpack must be marked with the work “Overpack” in lettering at least 12 mm high; and
- the package markings must be reproduced on the outside of the overpack.

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

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

Specific Requirements

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

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

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

a) the name and address of the shipper and of the consignee must be provided on each package;

b) the name and telephone number of a person responsible must be provided on each package;

c) the classification must be in accordance to 3.6.2;

d) the incident reporting requirements in 9.6.1 and 9.6.2 must be met; and

e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

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

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

If an Air Waybill is used, the “Nature and Quantity of Goods” box must show “UN 3373”, the text “BIOLOGICAL SUBSTANCE, CATEGORY B” and the number of packages (unless these are the only packages within the consignment).

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

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3, 8 or 9 permitted as excepted quantities under 2.6 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.

Appendix C — IATA Packing Instruction 954

Packing Instruction 954 has been reproduced with permission from the International Air Transport Association (IATA).

To obtain the latest version, visit the IATA website.

ⓘ The following transport operator requirements (Operator Variations) or IATA Dangerous Goods Regulations may also apply for international shipments:

Operator Variations: 2K-07, 3K-05, 5X-01, AI-05, AM-09, AS-11, AV-07, B6-01, CA-08, FI-02, G3-09, GU-07, IP-06, KE-06, LR-07, OM-05, RH-05, TO-07, TA-07, TY-04, VN-11

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

The General Packing Requirements of Subsection 5.0.2 must be met.

Additional Packing Requirements

In packages:

a) must be in a 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;

b) the shipper must make arrangements with the operator(s) for each shipment, to ensure ventilation safety procedures are followed;

c) the Shipper's Declaration requirements of Subsections 8.1 and 10.8.1 only apply when the Carbon dioxide, solid (dry ice) is used as a refrigerant for dangerous goods that require a Shipper's Declaration or when Carbon dioxide, solid (dry ice) is used as a refrigerant for substances or articles not subject to these regulations is described on a Shipper's Declaration;

d) when a Shipper's Declaration is not required or used, the following information, as required by 8.2.3 for the Carbon dioxide, solid (dry ice) must be contained in the "Nature and Quantity of Goods" box on the Air Waybill when used, or in the appropriate location on alternate transport documentation. Where an agreement exists with the operator, the shipper may provide the information in EDP or EDI techniques. The information should be shown in the following order:

- UN 1845;
- proper shipping name (**Dry Ice** or **Carbon dioxide, solid**);
- the number of packages; and
- the net quantity of dry ice in each package.

e) the net weight of the Carbon dioxide, solid (dry ice) must be marked on the outside of each package. When packages are placed in an overpack, the overpack must be marked on the outside with the total net quantity of dry ice in the overpack.

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

a) may be shipped in a unit load device or other type of pallet prepared by a single shipper provided that the shipper had made prior arrangements with the operator and the following information must be contained in the "Nature and Quantity of Goods" box on the air waybill when used, or in the appropriate location on alternate transport documentation. Where an agreement exists with the operator, the shipper may provide the information in EDP and EDI techniques. The information should be shown in the following order:

- UN 1845;
- proper shipping name (**Dry Ice** or **Carbon dioxide, solid**);
- the number of packages and the net weight of dry ice in each package if the ULD includes the packages that contain dry ice; or
- the identification number of the ULD and the net quantity of dry ice in each ULD if the dry ice is placed in the dry ice bunker of the ULD or loose in the ULD.

b) the unit load device, or other type of pallet must allow the venting of the carbon dioxide gas to prevent a dangerous build up of pressure (the marking and labelling requirements of Section 7 do not apply to the unit load device);

Notes:

1. Refer to the relevant airline's loading procedures for Carbon dioxide, solid (dry ice) limitations.
2. For Air Waybill requirements see 8.2.3. For loading instructions see 9.3.12.
3. For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of Packing Instructions 954.

UN Number	Quantity per package Passenger aircraft	Quantity per package Cargo aircraft only
UN 1845 **Carbon dioxide, solid** or **Dry Ice**	200 kg	200 kg

References

This document uses the IATA regulations and the UN Model Regulations to categorise the substances being transported and makes recommendations regarding appropriate packaging, labelling and handling.

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

Australia Post. (2020). *Dangerous and prohibited goods and packaging guide*. https://auspost.com.au/sending/check-sending-guidelines/dangerous-prohibited-items

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AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au