HSE National Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials 2023

Policy ☐ Procedure ☐ Protocol ☐ Guideline ☒ Clinical Guideline ☐

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Document Owner: Anne Marie Hoey **Document Owner email:** NHSF.Policyteam@hse.ie **Document Commissioner(s):** National Director of Human Resources **Document Approver(s):** National Director of Human Resources			
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Version No.	**Date approved**	**Section numbers changed**	**Author**
V2	September 2023	2.1 Packaging • Secondary Packaging- included note • 95 kPa pressure performance – removed note Outer packaging – Drop test – updated note	National Health and Safety Function
V2	September 2023	6.0 Roles and Responsibilities – Aligned to Corporate Safety Statement	National Health and Safety Function
V2	September 2023	Appendix II Inclusion of a note regarding the classification of Monkeypox virus	National Health and Safety Function
V2	September 2023	Appendix III - Minor updates to the air P650 instruction	National Health and Safety Function
V2	September	Appendix VII - Update of the air IATA	National Health and Safety Function

[1] Details the senior management roles involved in the development of the document.
[2] Details clear ownership for the document lifecycle and responsibility for timely review.
[3] Details the version number and section numbers with updated content.

	2023	dangerous goods declaration form	
V2	September 2023	Part B – updated the following sections: 1.1 Purpose 1.2 Scope 1.3 Objectives 1.6 Supporting evidence and publications 2.3 Resources necessary to implement the PPPG recommendations	National Health and Safety Function

PUBLICATION INFORMATION [4]
Title:
HSE National Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials 2023
Topic:
Preparation for Transport of Patient Specimens and other Biological Materials 2023
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National Health & Safety Function (policy team)
Short summary:
This guideline applies to all personnel involved in the preparation of patient specimens and other biological materials for transport.
Description:
The Guideline addresses the requirements for consigning and transporting patient specimens and other biological materials associated with human health care and provides guidance on the consignment of patient specimens and other biological materials associated with human healthcare for carriage by road, rail, sea or air. The Guideline must be used to develop written local procedures detailing the specific practices for a particular activity or facility.

[4] Details the document information required for publication on the HSE National Central Repository.

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Appendices to Part A

PART B: PPPG DEVELOPMENT CYCLE

PART A:

Guidelines for the Preparation for transport of Patient Specimens and other Biological Materials

This Guideline must be used to develop written local procedures detailing the specific practices for a particular activity or facility.

1.0 Procedure for the Classification of Biological Substances for Transport

In line with the requirements of the dangerous goods transport regulations, biological substances must be correctly classified to determine their status prior to being offered for transport. It is the responsibility of the consignor / shipper[5] to determine the correct classification. This requires knowledge of the nature of the sample material and the classification criteria.

The outcome of the classification process will result in substances being assigned to one of four groupings i.e.

1. Category B infectious substance;
2. Category A infectious substance;
3. Non-Infectious substance not regulated for transport; or
4. Non-infectious substance regulated for transport according to the decision tree in Figure 1.

In practice, given the disease profile in Ireland, the majority of patient specimens can be safely transported by default as Category B infectious substances. However, if establishing a new screening program or dealing with a material where there is any doubt as to its classification, then a reasoned classification assessment should be performed.

[5] Consignor means any person, organisation or government which prepares a consignment for transport. Shipper is an equivalent term that is used in air transport regulations. In the context of the HSE, this is the facility who is preparing the patient specimens / biological substances for transport.

Decision tree for categorisation of patient specimens and other biological material for transport

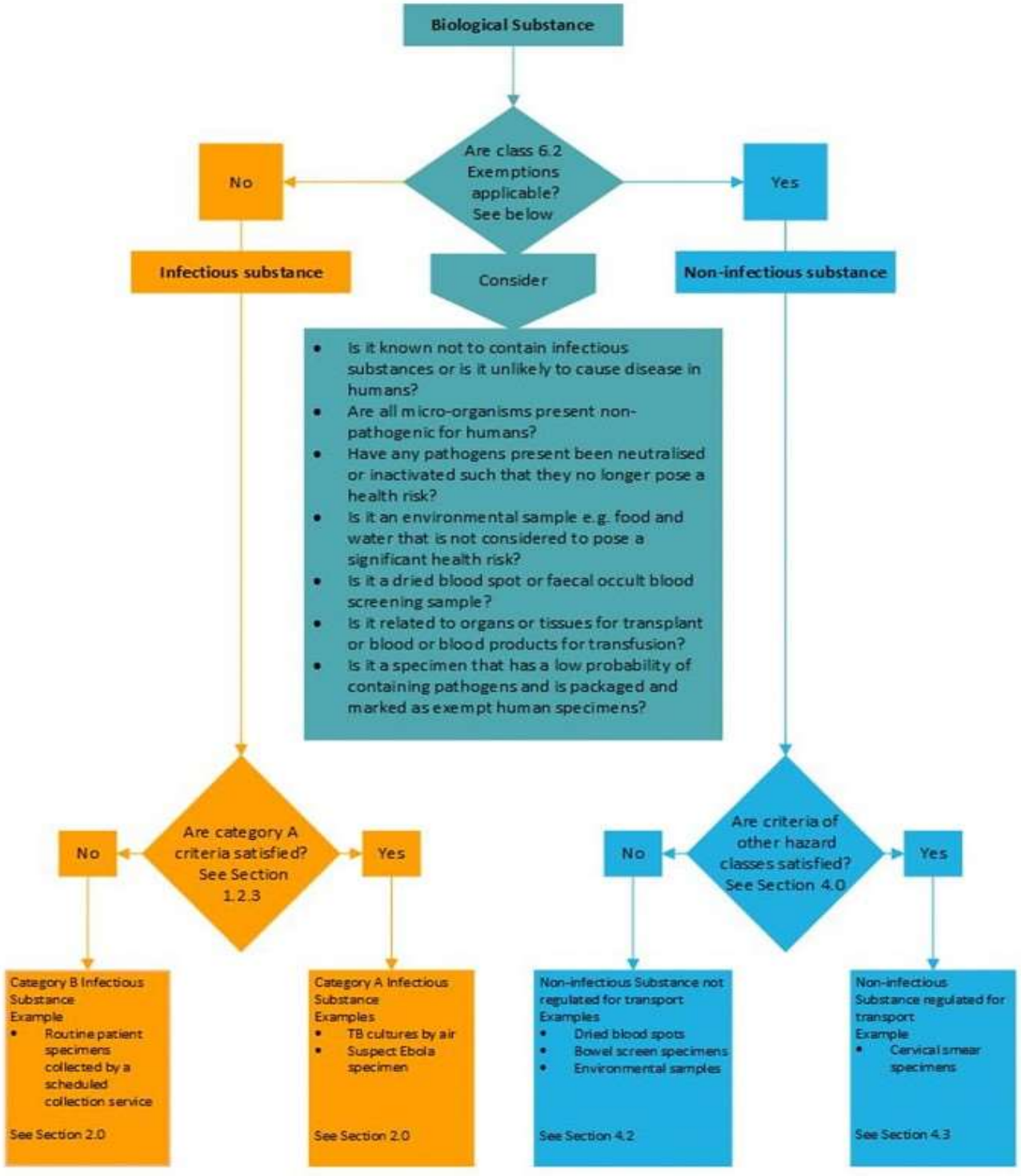


Figure 1. Decision tree for categorisation of patient specimens and other biological material for transport

1.1 Principles behind classification for transport

The rationale for classifying a biological substance as infectious under the transport regulations is different from that applied in the professional healthcare and laboratory environments. This is because transport workers do not normally come in direct contact with the transported material and consequently are not exposed to the same level of risk as healthcare professionals or laboratory staff who directly manipulate biological materials. Thus, healthcare professionals and laboratory staff operate on the principle of standard precautions where all biological specimens and associated materials are handled as potentially infectious. In contrast under transport regulations, it is only substances that are known or reasonably expected to contain pathogens that must be classified as infectious substances. Substances that do not contain pathogens, substances that have minimal likelihood that pathogens are present, and substances that may contain pathogens but which are unlikely to cause disease may all be regarded as non-infectious for the purposes of transport.

Table 1. Delineation between infectious and non-infectious substances for the purposes of transport

Infectious Substance for transport	Not an infectious substance for transport
• Substances known to contain pathogens • Substances reasonably expected to contain pathogens	• Substances known not to contain pathogens • Substances with minimal likelihood that pathogens are present • Substances that are unlikely to cause disease

1.2 Application of classification criteria

Application of classification criteria to determine if a biological material is an infectious substance for transport is essentially a process of elimination. The first step is to check if any of the exemptions detailed in Appendix I (Exemptions from the Dangerous Goods Regulations) are relevant and can be applied. **In practice this can be achieved by considering the following questions (Table 2) in relation to the material to be transported:**

Table 2. Questions to determine if a biological material is an infectious or non-infectious substance for transport

- Is it known not to contain infectious substances or is it unlikely to cause disease in humans?
- Are all micro-organisms present non-pathogenic for humans?
- Have any pathogens present been neutralised or inactivated such that they no longer pose a health risk?
- Is it an environmental sample e.g. food and water that is not considered to pose a significant health risk?
- Is it a dried blood spot or faecal occult blood screening sample?
- Is it related to organs or tissues for transplant or blood or blood products for transfusion?
- Is it a specimen that has a low probability of containing pathogens and is packaged and marked as an exempt human specimen?

Note: An element of professional judgement is required to determine if a substance may be shipped as an exempt human specimen. That judgement should be based on the known medical history, symptoms and individual circumstances of the source, and endemic local conditions, which effectively means that it may only be of practical benefit for shipment of individual samples.

Examples of specimens which may be carried under this exemption include:

- Blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA);
- Those required to monitor organ function such as heart, liver or kidney function for humans with non-infectious diseases, or for therapeutic drug monitoring; Those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol;
- Pregnancy test;
- Biopsies to detect cancer; and antibody detection in humans in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.)

Conversely this exemption should *not* be used in any of the listed scenarios if the specimen has been taken from an individual with a known infectious disease or the specimen is being transported for testing for a suspected infectious disease.

1.2.1 Non-infectious substance

If the answer in relation to any of the exemptions/questions is a definitive 'YES', then the substance is not an infectious substance. If there is any doubt as to whether an exemption can apply, then the material should be classified as an infectious substance.

The final step in the assessment of a non-infectious substance is to consider if it has been mixed with or contains substances that confer hazardous properties of other transport classes. In such circumstances the material will still be regulated for transport under the provisions applicable to that class. As an example, cervical screening samples are collected in a flammable alcohol solution which meets the classification criteria for assignment to Class 3 (Please refer to Appendix IX).

1.2.2 Infectious substance

If a negative response 'NO' applies to all the questions in Table 2, then the substance must be regarded as an infectious substance for transport purposes.

Note: A substance classified as infectious may be mixed with a maximum of 30 ml of dangerous goods belonging to classes 3, 8 or 9[6] without having to consider the hazards of these classes.

The final step is to determine if the substance meets the criteria of a Category A infectious substance.

1.2.3 Category A infectious substance

As per the definition those are substances that may contain pathogens that cause serious diseases that can be fatal, life-threatening or result in permanent disability and secondly that the pathogens have a very low infectious dose such that physical contact with the pathogen in the form in which it is carried may cause otherwise healthy humans or animals to succumb to the disease. i.e. Category A is reserved for infectious substances that may have both severe consequences and a high risk of infection as transported.

Indicative examples of substances that meet these criteria are given in Appendix II. This list should be used to assist in classification. However, the list is not intended to be exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the list but which meet the same criteria of severity and infectivity must be transported as Category A infectious substances. In addition, if there is any doubt as to whether

[6] Class 3 - Flammable
liquids Class 8 – Corrosives
Class 9 - Miscellaneous Dangerous Goods

or not a pathogen falls within this category, it must be transported as a Category A infectious substance.

From a review of the list, it will be seen that it is only exceptional cases that would warrant classification of patient specimens transported in Ireland as Category A infectious substances as the known viruses which require classification of patient specimens as Category A are not normally encountered in Ireland. Also, cultures of listed pathogens that are sent to reference labs for further diagnosis and to which note “a” applies, can be shipped by road or rail within Ireland as Category B infectious substances. However, if sending to an overseas reference laboratory, they will have to be shipped as Category A infectious substances as this provision does not apply to air or sea transport regulations. For example, shipment of *Mycobacterium tuberculosis* cultures to reference labs for identification of the strain of the bacterium, may travel as category B if the reference lab is within Ireland but must be shipped as Category A if sending to a lab overseas.

A Category A infectious substance must be identified in transport as **UN 2814 INFECTIOUS SUBSTANCE AFFECTING HUMANS**. For further detailed guidance, please refer to Section 3.0.

1.2.4 Category B infectious substance

Any infectious substance that does not meet the criteria of a Category A substance, must be assigned to Category B and identified in transport as **UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B**. Thus, the vast majority of patient specimens and related samples will transport as UN3373 shipments. For further detailed guidance, please refer to Section 2.0.

2.0 Requirements for UN 3373 Category B Biological Substances

UN 3373 Category B, biological substances must be packed and marked in accordance with packing instruction P650. No other transport provisions apply once this packing instruction is complied with. Thus, it is vital that the material is packed correctly before handing over for carriage as this is the only means of assuring safety during transport. This responsibility rests solely with the consignor / shipper unless part of the responsibility has been transferred under a contract of carriage.

Note: it is common practice for carriers that operate scheduled collection services to supply part of the packaging to complete a compliant package. Where such practices apply, it is recommended that this is explicitly documented in the service contract ("Contract of carriage") so that it is clear as to the extent to which responsibility has been transferred between the parties.

The requirements of packing instruction P650 as set out in the various modal dangerous goods regulations are consolidated in Appendix III.

2.1 Packaging

The key elements of packaging instruction P650 are as follows:

2.1.1 Minimum 3-layer construction

The packing must contain a minimum of three component layers of packaging consisting of a primary receptacle, secondary packaging and outer packaging.

2.1.2 Primary receptacles

Primary receptacles must be leak-proof for liquids or sift proof for solids.

Figure 2. Examples of primary receptacles

2.1.3 Secondary packaging

The secondary packaging must be leak-proof for liquids or sift proof for solids.

Note: As the packaging specification for liquids is of a higher standard to that of solids, and as most specimens are liquid it is advisable that packaging systems suitable for liquids are adopted as the standard for routine scheduled collections of both liquid and solids.

Figure 3. Examples of secondary packaging

Additional layers may be present. For example, most laboratories provide a plastic envelope with an attached request form into which the person in charge of taking the specimen places the primary receptacle (Figure 4). This may only be considered as a secondary packaging for (a) liquids if the plastic envelope has a leakproof seal and contains sufficient absorbent to absorb all the liquid present in the primary receptacle and (b) for solids if the plastic envelop is sift proof.

Figure 4. Examples of Laboratory request form

Note: If using fragile (glass) primary receptacles, which is not the norm, then each primary receptacle must be individually wrapped or separated to prevent contact within the secondary packaging.

2.1.4 95 kPa pressure performance

Either the primary or secondary packaging for liquids must be leak-proof at a pressure differential of 95 kPa.

A number of manufacturers offer non- fragile primary receptacles that have been shown to be leak-proof at this pressure differential. Similarly, a selection of secondary leak-proof packaging is available. This can range from rigid plastic containers with screw-on or clip-on closures to sealable plastic bags that may or may not meet the 95 kPa pressure differential standard. To ensure that these packaging requirements are fulfilled, it is recommended that when selecting a packaging system, copies of certification or statements of compliance are obtained from manufacturers and kept on file.

2.1.5 Absorbent for liquids

It is essential that sufficient absorbent material is present within the secondary leak-proof packaging to absorb all the liquid that may be present in the primary packaging.
It is recommended that information on the absorbent capacity of absorbent materials is obtained from suppliers in order to demonstrate that this requirement is satisfied.

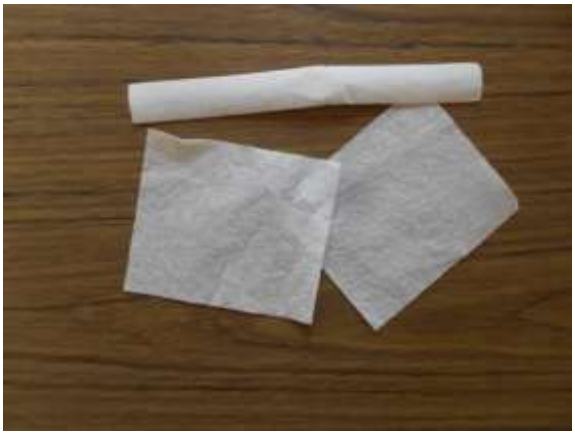


Figure 5. Examples of absorbent material

2.1.6 Outer packaging

The outer packaging must have one surface of minimum dimension 100 x 100 mm. A non-rigid outer packaging is acceptable for surface transport (road, rail, sea) provided a rigid secondary packaging is used. For air transport a rigid outer packaging is always required.

Figure 6. Examples of outer packaging

2.1.7 Drop test

The package as assembled must be capable of successfully passing a 1.2 m drop test as outlined in Appendix IV.

Suppliers offer a range of matched secondary and outer packaging combinations that have been established as capable of meeting the drop test requirements when used according to the manufacturer's instructions. They fall into two broad categories: courier-type box systems that are intended for repeated routine use and smaller packaging systems that are designed to hold fewer samples with more limited re-use capabilities. Manufacturer's instructions on the use of such systems should be available and followed.

If packaging systems are reused, they should be inspected before each use to verify that all elements of the system are still in place. They should be subject to periodic routine cleaning and inspection. Should a primary receptacle leak, any contaminated packaging must be decontaminated or replaced as appropriate before further use.

Note: Where hybrid systems are used (e.g. intermediate and outer packaging from different suppliers) the consignor must establish that the package as assembled is capable of passing the 1.2 m drop test requirement (See Appendix IV PACKAGE TESTING REQUIREMENTS FOR P650). The test may be carried out by consignors/shippers themselves as the use of accredited testing facilities is not required.

However, the advice and assistance of a Dangerous Goods Safety Advisor (DGSA) should be sought and a record of any testing must be retained for inspection.

2.2 Marking and labelling of packages

Each outer package must display the UN 3373 mark (minimum dimensions of diamond 50 x 50 mm) and the words “BIOLOGICAL SUBSTANCE, CATEGORY B" in letters ≥ 6 mm high as illustrated in Figure 7. The markings must not be obscured by address labels or tape as clear visibility is essential for communicating the potential hazards to emergency responders in the event of an accident. If the packages are covered by an outer envelope or container, the marking must be repeated on this outer surface. The marking should not be used on incomplete packages that do not comply with all relevant aspects of packing instruction P650.

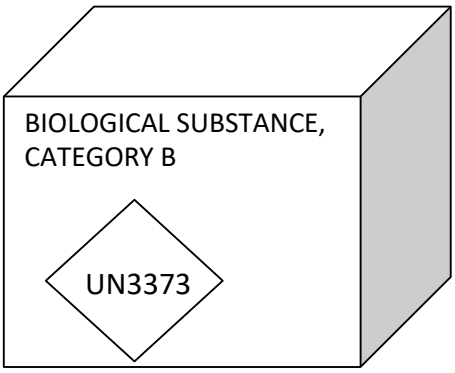
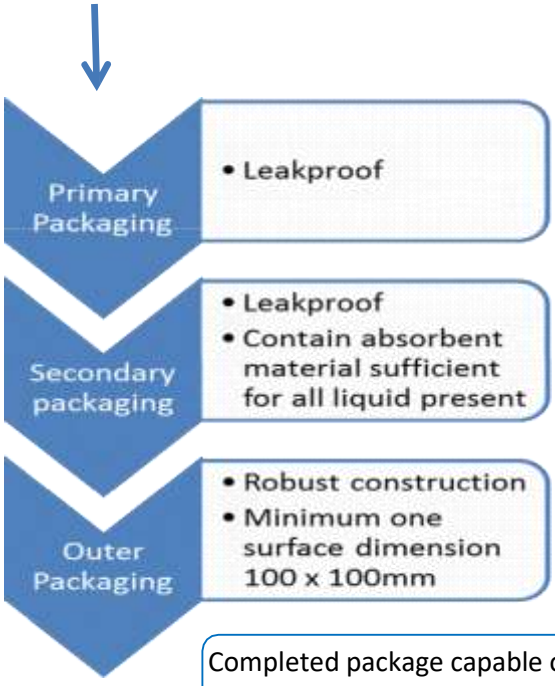


Figure 7. Marking of a package for surface transport

The requirements for shipping UN 3373 Category B Biological Substance liquids by road and sea are summarised in Figure 8.

Summary of Requirements for UN 3373 Category B - Biological substances (liquids by road and sea)

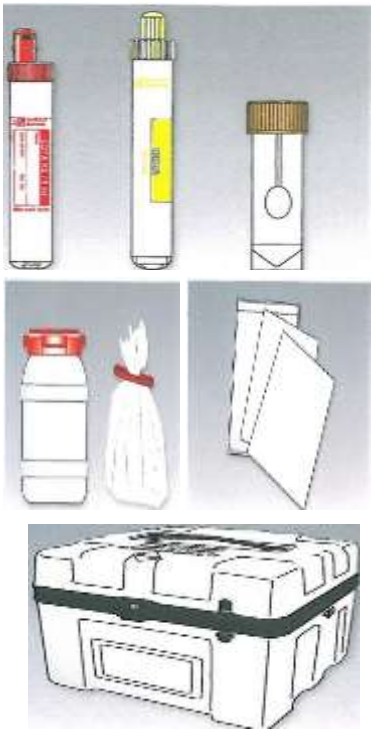
Minimum 3 Layer Packaging System



Either primary or secondary packaging to withstand internal pressure of 95kPa

Either secondary or outer packaging must be rigid

Completed package capable of withstanding a 1.2 m drop test



Example of Packaging systems

Outer packaging markings

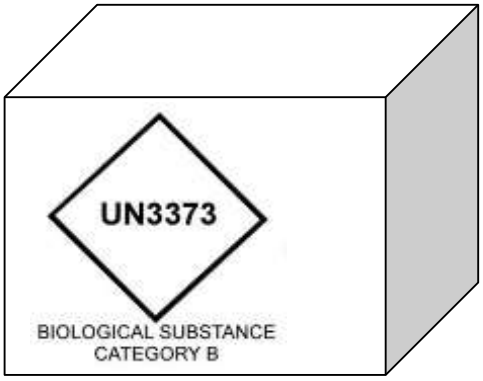
Packaging must

- Display **UN3373 Mark**

(Diamond minimum dimension 50 x 50 mm)

- Display the wording **'Biological Substances Category B'**

(Characters ≥ 6mm High)



Transport

No additional requirements for the carrier

For additional information on mail, air or refrigerated / frozen packaging requirements (if deemed necessary), please refer to sections 2.3, 2.4 & 2.5

Note: the above packaging system is also suitable for the transportation of solids

Figure 8. Summary of Requirements for UN 3373 Category B, Biological substances (Liquids by road and sea)

2.3 Additional requirements for mail shipments

UN 3373 P650-packages may be sent by mail with An Post within Ireland. However, both the shipper and the recipient must be officially recognised as "senders" by An Post or the sender's competent authority. In practice An Post recognise the HSE and the regulatory authorities for healthcare professions as competent bodies, which effectively means that specimens may only be sent by personnel employed in the healthcare sector, not members of the general public. The shipper's return address must be shown on the top left-hand corner of the surface bearing the consignee address.

Note: Packages that contain dry ice, and UN 3373 P650-packages for destinations outside Ireland, are prohibited by An Post.

2.4 Additional requirements for shipments by air.

The outer packaging must be rigid for air shipments.

There are volume limits of 1 L per primary receptacle and 4 L per package for liquids or 4 kg for solid. These restrictions are unlikely to have any practical impact.

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

The name and address of the shipper and consignee must be provided on each package.
The name and telephone number of a responsible person must be provided on the package or on the Air Waybill (if used) – the responsible person can be a member of the shipper's or consignee's staff (See Figure 9 for an illustration of a package bearing all the required marking for air transport, see Appendix V for an illustration of an Air Waybill).

If the completed package is placed in a courier envelope such that the marking on the package is no longer visible, then the marking must be repeated on the outside of the envelope together with the word "OVERPACK" in characters 12 mm high.

There is no requirement for a dangerous goods declaration. However, an Air Waybill is normally required by the courier service, in which case the "Nature and Quantity of Goods" box must show the text "UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B" and the number of packages. See Appendix V for an illustration of an Air Waybill.

Note: UN 3373 specimens cannot be carried in person either as carry-on or checked baggage or on the person.

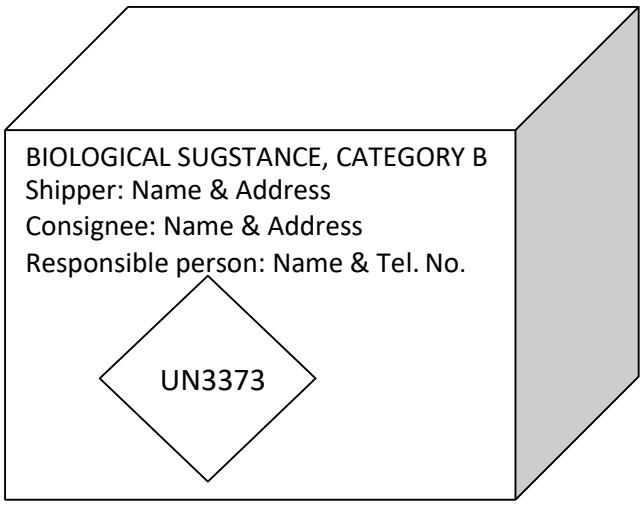


Figure 9. Marking of a package for air transport

2.5 Refrigerated or frozen specimens additional requirements

Courier services within Ireland offer vans with refrigerated and freezer compartments for transport of samples requiring temperature control. Such services in combination with insulated packaging and cool packs can usually avoid the need for other coolants such as dry ice for transport within Ireland.

2.5.1 Dry Ice

Dry ice is the most common coolant for shipping frozen specimens by air. Dry ice must never be placed within the secondary packaging as this will result in the build-up of pressure as carbon dioxide gas is released which in turn may lead to a destructive explosion. The packaging within which the dry ice is placed must be designed and constructed to permit the release of carbon dioxide (CO_2) gas. This can be either the outer packaging or an overpack and usually consists of an insulated polystyrene box in an outer fibreboard box. The inner packagings should be secured such that they maintain their orientation in the outer packaging should all the dry ice have melted.

In addition to the markings required for a non-refrigerated air shipment of UN 3373 the outer packaging must display the UN number, proper shipping name and net quantity of dry ice used together with the Class 9 hazard label as illustrated in Figure 10.

The Air Waybill must show “UN 1845 DRY ICE Net Qty” in the “Nature and Quantity of Goods” box in addition to the information required for a non-refrigerated UN 3373 shipment.

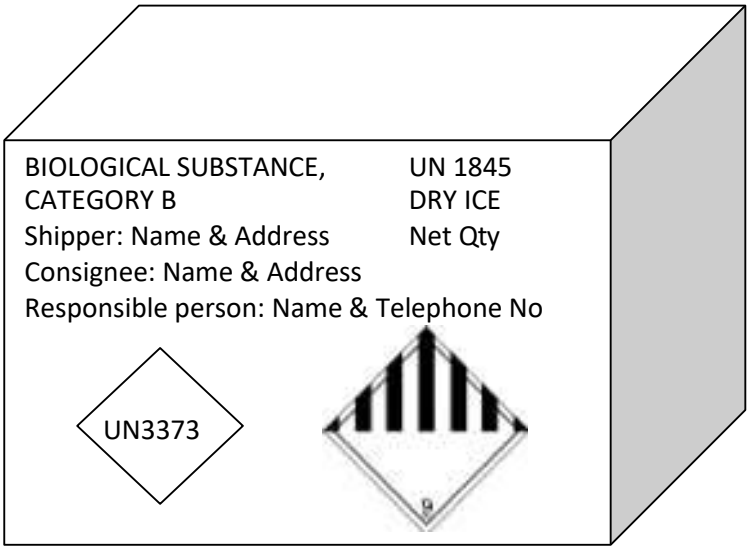


Figure 10. Marking and labelling requirements for an air shipment of UN 3373 containing dry ice

Carriage by road to the airport must be in a load compartment that has adequate ventilation so that the CO_2 level will not exceed 0.5% and the oxygen level will not go below 19.5%. Alternatively, there must be no gas exchange between the load compartment and the drivers cab and all access doors to the load compartment must display the following warning sign (Figure 11).

DRY ICE
AS COOLANT

Figure 11. Dry Ice as Coolant

2.6 Training Requirements

Personnel involved in preparing or handling P650 packages for transport should receive function specific training relevant to the tasks that they perform i.e. training on the packaging system(s) in use and specific local procedures on the transport of specimens as appropriate. Training records should be retained locally. Carriers should be aware of what to do in an emergency – this could be as basic as knowing who to contact to being able to respond to a spillage. General awareness training as specified in Chapter 1.3 of the transport regulations is not required.

2.7 Spill Response

Spillage arising during the preparation of a shipment should be managed in accordance with local spill response procedures.

During transport when the appropriate packaging is used correctly, experience is that the likelihood of a spill is quite remote, as the packaging is intended to withstand the normal shocks and loadings encountered during transport. Should a spill occur, it is most likely to be discovered at the point of loading or unloading, where staff are available with the necessary training, PPE and experience to handle the materials. Thus, the facilities spill response procedures should be followed, taking account of the all the hazards that may be present (i.e. biological, chemical).

If a spill results from a serious road traffic accident where the packaging is crushed, then the emergency services should follow their response procedures.

All incidents occurring at HSE facilities must be reported and managed in accordance with the HSE Incident Management Framework. ADR reporting requirements do not apply.

3.0 Requirements for UN2814 Category A Infectious Substances

The requirements for packaging and transport of Category A infectious substances are much more stringent compared to a Category B infectious substance as there is a significant risk of infection should the substance escape from the packaging. Thus, all elements of the transport regulations apply including the use of UN-certified packaging, dangerous goods declarations, fully equipped vehicles, certified drivers, trained personnel, DGSA appointments and security plans. The basic requirements are summarised in Figure 12.

3.1 Packaging

Category A infectious substances must be packaged according to packing instruction P620. The relevant text is shown in Appendix VI. This requires UN certified packaging that has been constructed and tested in accordance with Chapter 6.3 of the ADR/IMDG regulations (chapter 6.5 of the IATA regulations). Although it uses the same 3-layer principle as P650 packaging, it is constructed to a much higher standard so as to be capable of surviving a significant impact as reflected in test specifications that include a 9 metre drop test and ability of the secondary packaging to resist penetration by a steel rod. Such packaging is easily identified by the presence of the United Nations packaging symbol and the text "Class6.2" in the packaging approval code which must be displayed on the outer packaging layer. Examples of such marking are as follows

 4G/Class 6.2/15/GB/….  4H2U/Class 6.2/08/USA/….

Packaging is normally supplied as integrated systems consisting of cushioning and absorbent material for the primary receptacle, the secondary receptacle and the outer packaging. Component parts of different P620 packaging systems must not be interchanged. The packaging must be used according to the manufacturer's instructions, which must be consulted. It is also necessary to verify that the primary receptacles are covered under the authorisation – for example, a packaging system that is approved for use only with specimen tubes of maximum capacity 10 ml could not be used with 20 ml universal containers. Note however, that a "U" in the packaging code indicates that all types of primary receptacle are allowed subject to any limitations that will be specified in the approval certificate or manufacturer's instructions. It is good practice that copies of packaging certification and instructions for use are obtained from the suppliers and maintained on file.

Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure.
Where multiple receptacles are shipped, each primary receptacle must be individually wrapped or separated so as to prevent contact.

An itemised list of contents must be placed between the secondary and outer packaging. This should include the UN number and proper shipping name supplemented by the name of the infectious agent if known, or the words "suspected Category A infectious substance" if the infectious substances to be carried are unknown, but suspected of meeting the criteria for inclusion in Category A. This can be part of or separate from any request form that may be in use by the consignee. A quantity limit of 4 L or 4kg per package applies to air shipments, excluding body parts.

Summary of Requirements for UN 2814 Category A Infectious Substances

Minimum 3 Layer Construction Packaging

Primary Packaging
- Leakproof
- Secured closures
- Individually separated

Secondary packaging
- Leakproof
- Puncture proof
- Contain sufficient absorbent material for any liquid present

Either primary or secondary packaging to withstand internal pressure of 95kPa

Outer Packaging
- UN certified for Class 6.2
- Minimum surface dimension 100 x 100mm
- Contain Itemised list of contents

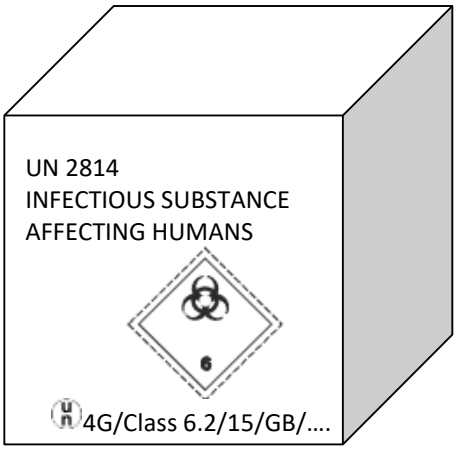
Matched secondary & outer packaging

Example of Packaging systems

Marks & labels

Packaging must

- Display **Class 6.2 Label** (Diamond dimension 100x100 mm)
- Display the UN Number (Characters ≥ 6mm High)
- Display the Proper Shipping Name (if going by sea or air)
- Bear the UN packaging approval marking



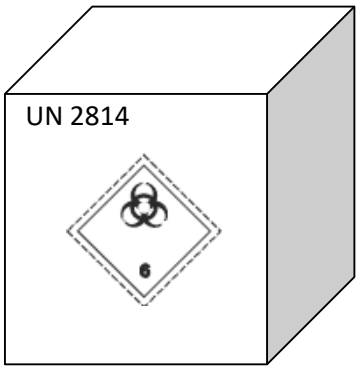
Transport

- Accompanied by a transport document/dangerous goods declaration
- Vehicle to display orange plates
- Vehicle driven by an ADR trained & certified driver

Figure 12. Summary of Requirements for UN 2814 Category A Infectious Substances

3.2 Marking and labelling of packages

As a minimum packages for land transport must display the UN number (UN 2814) and a class 6.2 infectious label as illustrated in Figure 13. If individual primary receptacles contain more than 50 ml of liquid then orientation marks must be displayed on opposite sides of the package.



Orientation

Figure 13. Minimum marking and labelling requirements for land transport

3.2.1 Sea Transport

For sea transport, the proper shipping name "INFECTIOUS SUBSTANCE AFFECTING HUMANS" must be displayed in addition to the markings and labels required for land transport (Figure 14). The technical name should not be included in brackets on the outer packaging as this could be of assistance to potential terrorists.

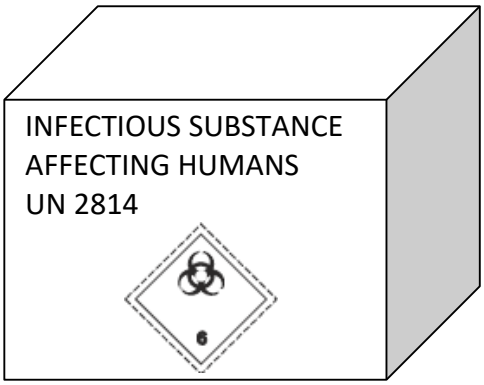


Figure 14. Minimum marking and labelling requirements for sea transport

3.2.2 Air Transport

Packages for air transport must, in addition to all the marks and labels for sea transport, display the name and address of the shipper and consignee, and the name and telephone number of a responsible person (Figure 15).

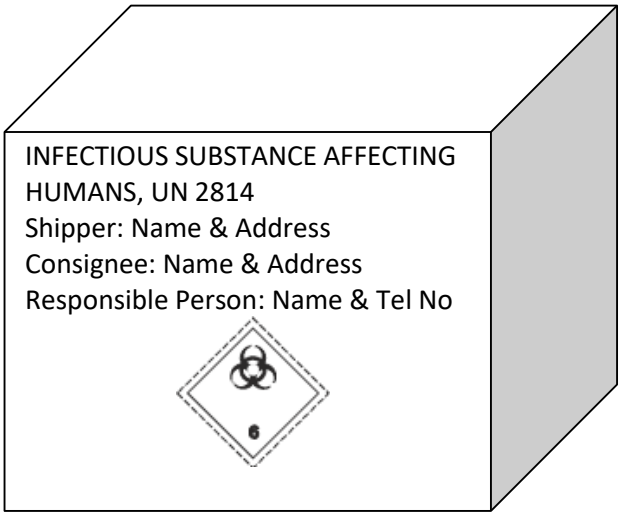


Figure 15. Minimum marking and labelling requirements for air transport

If a shipment contains packages with non-identical contents, then the net quantity as a volume or weight must be shown on each individual package.
If a package contains more than 50 ml or 50g of infectious substances then a cargo only label must be displayed (Figure 16).

Figure 16. Cargo only aircraft label

Air shipments containing dry ice will additionally need to display a class 9 label and the proper shipping name, UN number and net quantity of dry ice, the same as for a Category B package.

Note: Manufacturers usually pre-print the outer packaging in accordance with the air requirements. Orientation labels are printed by default and text is included in the Class 6.2 label as required by some airline operators. While the standard dimensions of the class label are 100 x 100 mm, they also often avail of the allowance to use dimensions of 50 x 50 mm when the package is of a size not large enough to accommodate the standard label dimension.

The schematic in Figure 17 summarises the components, marking and labelling requirements for a typical non-refrigerated air shipment.

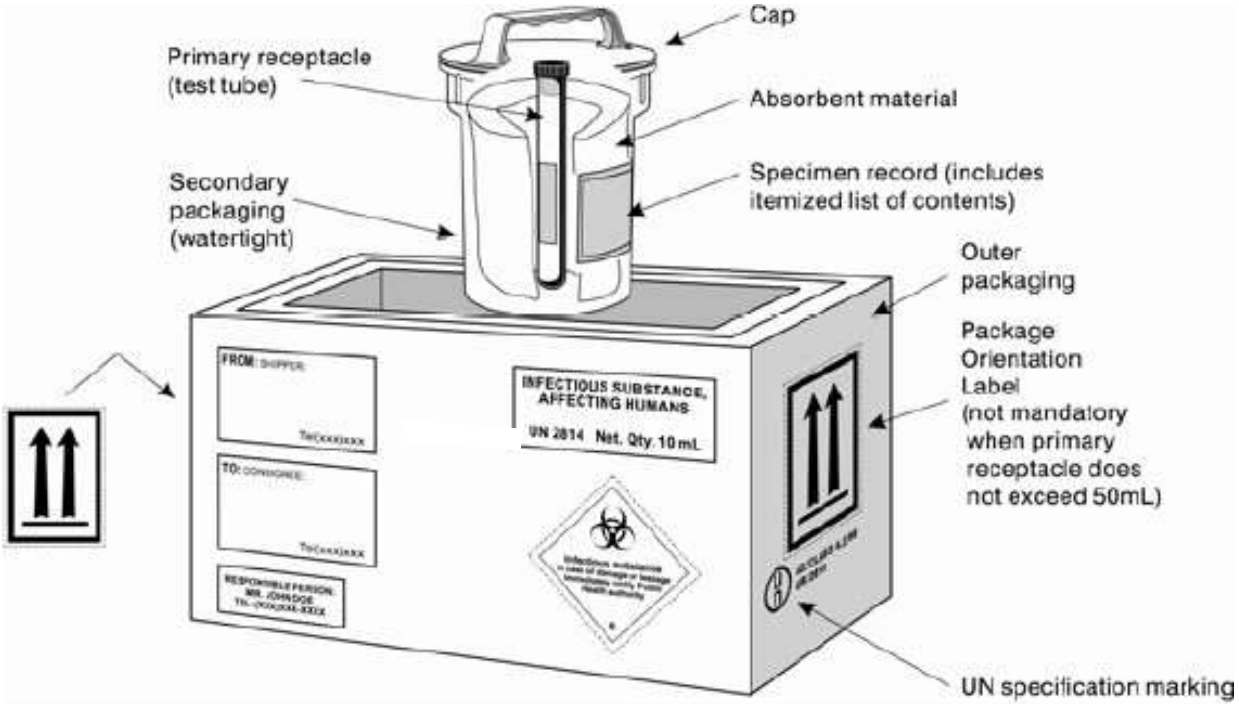


Figure 17. Schematic of a UN 2814 package for air transport.

3.3 Documentation

For land transport the shipper must prepare a transport document and hand over to the carrier with the shipment. A specific format is not required but the document must contain the following information:

- The name and address of the consignor/shipper
- The name and address of the consignee
- The name and telephone of a responsible person i.e the person shipping the sample with knowledge of the specimen, who can be contacted in case of emergency
- The identification of the goods by UN number, proper shipping name, class division and tunnel code as per the following example
  UN 2814 INFECTIOUS SUBSTANCE AFFECTING HUMANS (e.g.Ebola virus), 6.2, (-)
- The number and description of the packages e.g. 1 fibreboard box
- The total quantity of dangerous goods by volume or weight as appropriate

Copies of the transport document must be retained by the consignor and carrier for a minimum of three months.

For air shipments a specific format shipper's declaration with red hatchings down the sides must be completed. An illustration of a completed declaration is provided in Appendix VII. Two copies with original signatures must be provided to the carrier.

3.4 Training Requirements

Personnel preparing shipments and declarations must be trained. This training must include transport regulations, general awareness, safety, security and function-specific elements. Training must be refreshed as appropriate with records of training maintained. For further advice on training requirements contact your local DGSA.

In the case of air shipments, personnel must complete an air-specific training course which includes a test to verify the effectiveness of the training. Refresher training must be completed every two years. Training courses should be approved. For further information and list of approved trainers please refer to: https://www.iaa.ie/commercial-aviation/flight-operations/dangerous-goods/training-requirements-for-personnel.

Drivers of vehicles must hold an ADR Driver Training Certificate (also known as Hazchem License) and both the consigner and carrier organisations must have a certified Safety Adviser (DGSA) appointed to access DGSA Services please refer to: https://healthservice.hse.ie/staff/health-and-safety/dangerous-goods/

3.5 Security

As infectious substances have been used by terrorists, all participants involved in the transport chain must have written security plans that detail the measures necessary to minimise the risk of infectious substances falling into the hands of terrorists. The elements of such a plan are outlined in Appendix VIII. The plan should address measures to provide physical protection and limit access to information on the goods, which should be based on a risk assessment of potential vulnerabilities and the threat level. Further guidance on the preparation of a security plan is available from the UK department of transport website at: https://www.gov.uk/government/publications/security-requirements-for-moving-dangerous-goods-by-road-and-rail

Carriers, consignors and consignees should co-operate with each other and with competent authorities to exchange threat information, apply appropriate security measures, respond to security incidents and ensure that security plans dovetail when goods or information are transferred between participants e.g. procedures to ensure that only an identified driver can pick up a package.

3.6 Vehicle Equipment & Documentation

Vehicles carrying UN 2814 packages must display orange plates front and back of the vehicle.
The vehicle must also have on board

- One 2 kg powder fire extinguisher (ABC type)
- One wheel chock;
- Two self-standing warning signs (triangles, cones or flashing beacons);
- Eye rinsing liquid
- Protective gloves for each crew member
- Eye protection for each crew member
- Portable lighting apparatus (torch) for each crew member

- Warning vest (hi viz EN471) for each crew member
- A copy of the Instructions in Writing
- The transport document
- Photographic means of identification for all crew members
- The driver's training certificate

Spot checks of equipment should be completed by a nominated person within the facility, particularly when there is a change in driver or vehicle.

3.7 Spill Response

Spillage arising during the preparation of a shipment should be managed in accordance with relevant spill response procedures and reported and managed in accordance with the HSE incident management framework.

During transport, considering the packaging specifications applying to Category A samples, a spill should only occur if the package is crushed in a serious road traffic accident for example. As per the "Instructions in Writing" (the ADR standardised emergency response card) the driver is advised not to touch the spilled material, inform the emergency services and keep others away. Considering the fact that category A material has a high infection risk that can result in serious or fatal disease, emergency responders are required to follow relevant emergency response procedures. The accident will have to be reported to and investigated by the carrier's DGSA and an accident report submitted to the HSA.

4.0 Requirements for Biological Samples that are not classified as infectious substances

4.1 Exempt Human Specimens (Class 6.2 - Exemption 8 in Appendix I)

If shipping a specimen as an "EXEMPT HUMAN SPECIMEN" the following requirements apply:

(a) The packaging consists of three components:

(i) a leak-proof primary receptacle(s);

(ii) a leak-proof secondary packaging; and

(iii) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm and bearing the words "EXEMPT HUMAN SPECIMEN";

(b) For liquids, absorbent material in sufficient quantity to absorb the entire contents is placed between the primary receptacle(s) and the secondary packaging so that, during carriage, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles are placed in a single secondary packaging, they are either individually wrapped or separated to prevent contact between them.

The following scenario illustrates how a satisfactory level of safety and compliance with the above requirements can be achieved.
E.g. A blood specimen is taken in a 95kPa rated non-fragile primary blood tube.
The tube is then placed in the request form plastic envelope with absorbent and sealed to create the secondary leakproof packaging.
This is then placed in a suitably strong envelope marked with the words "EXEMPT HUMAN SPECIMEN".

4.2 Samples not subject to transport regulations (Class 6.2 - Exemption 1, 2, 3, 4, 5, 6 and 7 in Appendix I)

There are no specific requirements as regards packaging of samples that are not subject to transport regulations. However, good practice dictates that appropriate packaging must be used so that the sample can arrive at its destination in good condition allowing for the shocks and stresses normally encountered during transport. If using An Post, prior agreement is required so that the nature of the material is identified on the package in a manner satisfactory to An Post. Please refer to Appendix I for further information on Exemptions from Class 6.2.

4.3 Samples subject to transport provisions of other classes (Appendix IX Examples of biological substances that may be shipped as non-infectious)

If the material satisfies the criteria of another transport class, then account must be taken of any requirements of that class. Usually, such materials can be shipped as Limited Quantity packages to avoid the more rigorous provisions for fully regulated dangerous goods packages. Examples are as follows.

4.3.1 Cervical Screening Samples

Sampling kits for collection of cervical screening samples requires distribution of specimen containers containing a Class 3 flammable liquid. To comply with the requirements for Class 3, the specimen containers are packed as Limited Quantity packages in a box with the limited quantity mark plus orientation arrows on two opposite sides as illustrated in Figure 18.

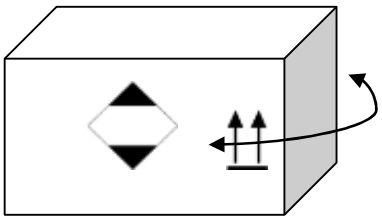
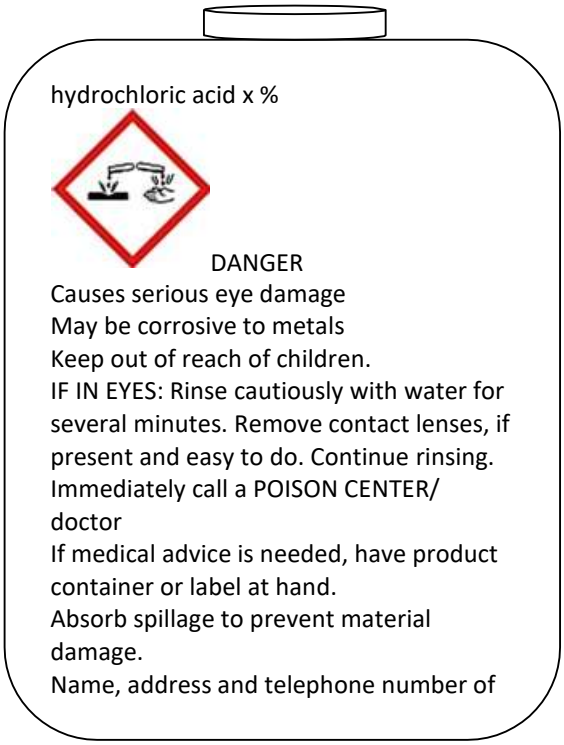


Figure 18. Limited Quantity package markings for cervical screening samples

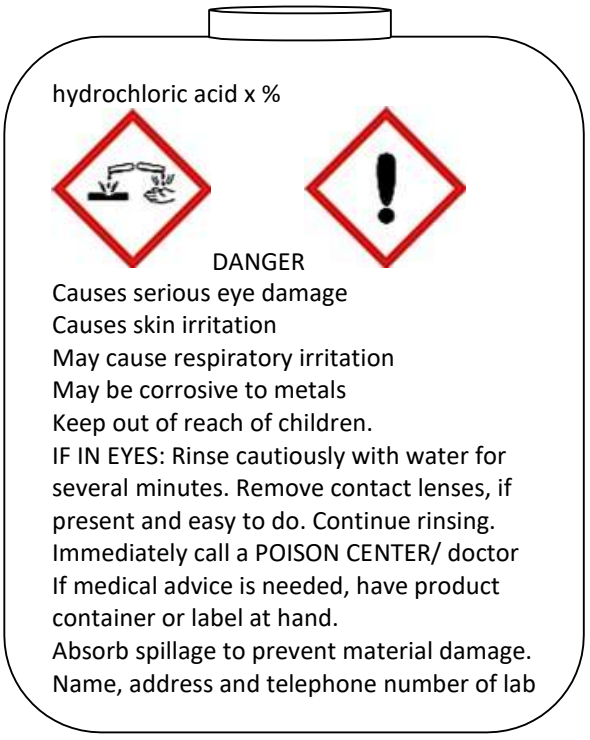
4.3.2 Acidified Urine Collections

Similarly hydrochloric acid (HCl) solutions provided in a container for collection of a 24-hour urine will satisfy the criteria for Class 8 corrosive substances. These may be placed in a suitable outer box or bag to constitute a limited quantity combination package, which should be marked as shown in the Figure 19.

Note: The primary containers will have to bear labels displaying relevant CLP labelling as illustrated in Figure 19.



Concentration range 1 – 10 % HCl
(0.27 – 2.74 N)



Concentration range 10 – 25 % HCl
(2.74 – 6.85 N)

Figure 19. CLP Labelling requirements for acidified urine containers

Note: Non-regulated samples may be included in UN 3373 packages for convenience provided they then comply with the packaging requirements for UN 3373.

4.4 Provisions for coolants

4.4.1 Dry ice

If dry ice is used as a coolant for non-infectious substances, then the requirements for coolants will apply the same as outlined in the previous section covering frozen infectious substances.

4.4.2 Liquid Nitrogen

Liquid nitrogen is also used as a coolant for shipping non-infectious frozen samples such as semen by air. Special “dry shipper” insulated containers are available that contain an absorbent designed to absorb the liquid nitrogen and thus eliminates the risk of free liquid nitrogen spilling from the container. Shipment of dry shippers is exempt from the dangerous goods transport regulations. All that is required is that the words “not restricted as per special provision A152” is included in the description on the Air Waybill.

Note: Liquid nitrogen may also be used when shipping infectious materials but its use is not addressed in this guidance.

5.0 Glossary of Terms & Definitions used in this guideline

Patient specimens	Patient specimens are human materials, collected directly from humans, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being carried for purposes such as research, diagnosis, investigational activities, disease treatment and prevention
Infectious substances	For the purposes of transport, infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans
Cultures	Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human patient specimens as defined in the previous paragraph
Biological products / Biological materials	Biological products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines
Medical or clinical wastes	Medical or clinical wastes are wastes derived from the medical treatment of humans or from bio-research
Biological substance	Biological substance refers to any substance that contains material derived from living organisms and includes patient specimens, cultures and biological products
RIMD	Reusable Invasive Medical Device
Category A infectious substance	An infectious substance which is carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans. Category A infectious substances shall be assigned to UN No. 2814.
Category B infectious substance	An infectious substance which does not meet the criteria for inclusion in Category A. Category B Infectious substances shall be assigned to UN No. 3373
Dangerous goods	For the purposes of transport, dangerous goods means those substances and articles the carriage of which is prohibited by the dangerous goods transport regulations, or authorized only under the conditions prescribed therein
Sift proof	Means the packaging is impermeable to dry contents during transport
Class	Class refers to the hazard class to which dangerous goods are assigned for the purposes of transport. Dangerous goods are assigned to one of nine classes according to the hazard or the most predominant of the hazards they present
Class 6.2	Class 6.2 is the class and division to which infectious substances are assigned
Limited Quantities	Limited Quantities refers to dangerous goods which when packed according to restrictions on the quantity of dangerous goods per package and per primary receptacle are exempt from a number of provisions of the dangerous goods regulations

CLP	Refers to the Classification, Labelling and Packaging of substances and mixtures
Consignor	Consignor means any person, organisation or government which prepares a consignment for transport. Shipper is an equivalent term that is used in the IATA dangerous goods regulations
Carrier	Carrier means the enterprise which carries out the transport operation with or without a transport contract
Consignee	Consignee means any person, organisation or government which is entitled to take delivery of a consignment
Packer	Packer means any enterprise which puts dangerous goods into packagings, including large packagings and intermediate bulk containers (IBCs) and, where necessary, prepares packages for carriage
Contract of carriage	Contract of carriage means a written contract for the carriage of dangerous goods by road in which one or more of the parties have identified themselves as a particular participant with specific obligations as set out chapter 1.4 of the ADR
UN Number	UN number means the four-figure identification number of a substance or article which is used to identify it during transport
Proper Shipping Name (PSN)	Proper shipping name refers to the standardized name assigned to a substance or article which in conjunction with its UN number is used to identify it during transport
Air Waybill (AWB)	An air waybill is a document used by airline carriers to serve as evidence of receipt and a contract of carriage for transport of air cargo

6.0 Roles and Responsibilities

With specific reference to the Guideline for the preparation of patient specimens and other biological materials for transport, the following responsibilities apply:

6.1 Chief Executive Officer (CEO)

The CEO has overarching responsibility to ensure, so far as is reasonably practicable the safety, health and welfare at work of all employees and others affected by HSE activities by:

6.1.1 Ensuring compliance with this Guideline.

6.1.2 Delegating operational responsibility for the day-to-day discharge of statutory duties under the ADR Regulations (i.e. duties of consignor[7] and packer), and the Safety, Health and Welfare at Work Act, 2005 to the Executive Management Team, Senior Management Team, Senior Managers and Line Managers for all matters within their control.

6.2 Responsibilities of Hospital Group Chief Executive Officers, Chief Officers Community Health Organisations

6.2.1 Ensure there are adequate and appropriate arrangements in place for the successful implementation, monitoring, evaluation, audit and review of this guideline throughout respective areas of responsibility.

6.2.2 Ensure necessary resources are allocated and are available for the implementation of this Guideline.

6.2.3 In line with the Framework Agreement for National Dangerous Goods Safety Adviser Services (Ref: HSE14605), ensure access is provided to competent dangerous goods advice.

6.2.4 Integrate performance indicators in relation to preparation of patient specimens and other biological materials for transport.

6.3 Responsibilities of the Senior Manager e.g. Hospital Manager and Service Managers

6.3.1 Ensure this Guideline is brought to the attention of, and implemented by all relevant employees and others as appropriate.

6.3.2 Ensure that all hazards and the risks associated with the preparation of patient specimens for transport and biological materials are undertaken and reviewed at least annually (more frequently if necessary) by responsible persons.

6.3.3 Ensure written protocols for the preparation of patient specimens and biological materials for transport are developed in line with this Guideline.

[7] With reference to the duties of the consignor, these exclude those assigned to the Healthcare Risk Waste Contractor under the agreed contract of carriage (Reference: Contract Book & User Guide Provision of Hazardous Healthcare Risk Waste Services to the Health Services Executive for the Acute Hospitals, Non Acute Locations. HSE Ref: HSE 2661)

Note: Detailed duties of the consignor are available in the ADR Carriage of Dangerous Goods by Road, A Guide for Business, available at https://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/New_ADR_Guide_for_Business.pdf

6.3.4 Ensure employees, contractors and agency personnel are trained commensurate with their delegated roles and responsibilities.

6.3.5 Ensure training records are maintained and are easily accessible.

6.3.6 (i) Ensure incidents are reported and managed in line with the HSE Incident Management Framework.

6.3.7 Identify for your area of responsibility, those responsible as packer, consignor, and or carrier as appropriate.

6.3.8 Engage with the relevant external contractor(s) to ensure compliance with this guidance document as appropriate.

6.3.9 Ensure that where courier services participate in completion of a compliant P650 package (see Appendix III P650 Packaging Instructions), the details of the responsibilities that are transferred from the consignor/shipper to the carrier/courier are clearly documented in the service contract agreement i.e. inclusion of a "Contract of carriage" (refer to Appendix III).

6.3.10 Monitor, Audit and Review the implementation of this Guideline.

6.4 Line Manager Responsibilities

6.4.1 Develop written protocols for the preparation of patient specimens and biological materials for transport in line with this Guideline.

6.4.2 Ensure this Guideline and local written protocols are brought to the attention of, and implemented by all employees and others as appropriate.

6.4.3 Ensure all specimens are classified, packaged, marked and labelled in line with the requirements of this Guideline.

6.4.4 Ensure that all hazards and the risks associated with the preparation of patient specimens and biological materials for transport are identified and assessed, and ensure appropriate measures put in place to eliminate, control or minimise the risk.

6.4.5 Ensure employees, agency personnel are trained commensurate with their delegated roles and responsibilities, refresher training made available as appropriate and training records are maintained.

6.4.6 Ensure all incidents are reported and managed in accordance with the HSE Incident Management Framework.

6.4.7 Monitor and review implementation of the guideline and local protocol to ensure all measures are effective and continue to meet the requirements of the guideline.

6.5 Responsibilities of Employees

6.5.1 Take reasonable care of their own safety, health and welfare and that of others

6.5.2 Adhere to this guideline, associated risk assessments and local protocols.

6.5.3 Co-operate in the regular review of the risk assessments and control measures to ensure that they are valid and are being effectively implemented and/or updated as required.

6.5.4 Attend relevant training as appropriate.

6.5.5 Report incidents, , in line with the HSE Incident Management Framework

6.6 Responsibilities of the Contractor

The responsibilities of the contractor will vary depending on their role as agreed in a service level agreement or contract of carriage. Where the contractor acts as a carrier of completed P650 packages (taxi service) the only requirement specified in the regulations is that they must have provisions to clean up/disinfect a load compartment, where a spill has occurred. Where the contractor is involved in the completion of P650 packages or the transport of Category A specimens they must have procedures and training commensurate with their activities as follows:

6.6.1 To have in place written emergency procedures which address the procedures to be followed in the event of an incident or emergency during carriage

6.6.2 Ensure that written procedures are in place to cover any activities and responsibilities that are inherent in their role or have been transferred under a contract of carriages

6.6.3 Ensure that relevant staff are suitably trained appropriate to their roles and responsibilities

Appendix I Exemptions from the Dangerous Goods Transport Regulations

Exemptions from Class 6.2

Because of the low hazard they present, the following substances of biological origin are exempted from classification as dangerous goods of class 6.2:

Text of exemption	Commentary/explanation
1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals, unless they meet the criteria for inclusion in another class.	This is a broad ranging exemption and provides a basis for some of the more specific exemptions that follow. Under the first clause substances / materials are exempt if they do not contain any infectious agent – this flows directly from the definition of an infectious substance, since to be considered an infectious substance a material must be known or reasonably expected to contain a pathogen/infectious agent. Under the second clause a substance could contain an infectious agent, but still be considered exempt on the basis that it is unlikely to transmit the disease by virtue of the nature or the substance, the level of infectious agent or other consideration. E.g. it is recognised that uncooked poultry meat can be contaminated with Salmonella These exemptions are conditional on the material not satisfying the criteria for inclusion in another dangerous goods class. An example of how this could occur is if a specimen is collected in alcohol. The alcohol will have a disinfecting effect on any infectious agent that may be present in the specimen so that it will no longer belong to Class 6.2. However, the presence of the alcohol could mean that it would satisfy the criteria for Class 3 flammable liquids and still be subject to the transport regulations applicable to that class.
2 Substances containing microorganisms which are non-pathogenic to humans or animals, unless they meet the criteria for inclusion in another class.	This exemption flows directly from the definition of an infectious substance which is based on the possibility of the presence of pathogens, not non-pathogenic organisms. Examples of such material include pro-biotic yogurts or yeast breads. The provision that the substance does not contain other components that would result in assignment to another class applies.
3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk, unless they meet the criteria for inclusion in another class. NOTE: Medical equipment which has been drained of free liquid is deemed to	This exemption follows on from the second clause of exemption 1. A substance that may contain pathogens can be considered exempt if measures have been taken to inactivate or neutralise the infectious agent such that it is no longer capable of causing disease. Examples of this include positive control sera supplied with diagnostic kits for detection of infectious diseases, which

meet the requirements of this paragraph and is not subject to the provisions of the Dangerous Goods transport regulations.	may be heat treated or treated with chemicals to inactivate any pathogens that would be present in the source material or tissue specimens that have been “fixed” in formalin. The condition that the substance does not meet the criteria for another dangerous goods class applies.
4 Substances where the concentration of pathogens is at a level naturally encountered (including foodstuff and water samples) and which are not considered to pose a significant risk of infection, unless they meet the criteria for inclusion in another class.	This exemption is also based on the second clause of exemption 1. It can be applied to samples taken for routine environmental and hygiene monitoring as such samples may contain low levels of pathogens that are unlikely to cause infection. Application of the exemption would not be appropriate when tracing the source of an infection outbreak if there is a risk that significant risk of infection either by virtue of elevated levels of pathogen or mode of transmission.
5 Dried blood spots, collected by applying a drop of blood onto absorbent material	This exemption is without qualification and can be applied to all dried blood spots transported for routine screening on the basis that even if a specimen contained a pathogen, the form and quantity in which it is transported poses minimum risk that the transmission of infection will occur.
6 Faecal occult blood screening samples.	This exemption is without qualification and is used for collection of samples under the national bowel screen programme.
7 Blood or blood components which 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 as well as samples drawn in connection with such purposes.	This exemption applies to both the donated materials and any samples that may be taken in connection with the process such as blood samples taken to confirm disease free status or compatibility with recipients. The pre-donation questionnaires provide assurance that there is minimum likelihood that such materials will transmit disease.
8 Human specimens for which there is minimal likelihood that pathogens are present if the specimen is carried in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen"	This exemption is intended to allow the transport of specimens exempt from the dangerous goods regulations in cases where there is no reason to suspect that the sample may contain pathogens and the specimen is packaged and marked as an exempt specimen. This requires an element of professional judgement which should be based on the known medical history, symptoms and circumstances of the individual. It does not require absolute certainty that pathogens are not present. This exemption should not be used for specimens that are being transported to test for infectious diseases.

Exemptions based on the nature of the activity

Transport on foot

Transport on foot is not subject to the dangerous goods transport regulations as the ADR regulations only apply to carriage in or on a motor vehicle.

Transport of specimens by health professionals in the course of their work

Transport of specimens collected from patients in the course of visiting their residence may be regarded as an ancillary activity which is exempt from any of the provisions of ADR under clause 1.1.3.1(c). Nevertheless, measures must be taken to prevent any leakage of contents in normal conditions of carriage. This exemption should not be applied where a health professional is making a journey just for the purpose of transporting samples.

Appendix II Indicative examples of infectious substances included in category A in any form unless otherwise indicated

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 haemorrhagic fever virus
Dengue virus (cultures only)
Eastern equine encephalitis virus (cultures only)
Escherichia coli, verotoxigenic (cultures only) [a]
Ebola virus
Flexal virus
Francisella tularensis (cultures only)
Guanarito virus
Hantaan virus
Hantavirus 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[8]
Mycobacterium tuberculosis (cultures only) [a]
Nipah virus
Omsk haemorrhagic fever virus

[8] Expert medical opinion has judged that recent outbreaks of Monkeypox virus in Europe do not meet the definition of a Category A infectious substance and thus, with the agreement of the HSA, specimens containing or suspected of containing the virus may be transported as UN 3373 Biological Substance, Category B within the state.

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) [a]
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)

When the cultures are intended for diagnostic or clinical purposes, they may be classified as infectious substances of Category B when transported by road or rail. This provision does not apply when cultures are transported by air or sea.

Appendix III Consolidated text of packing instruction P650

Additional requirements/guidance for air shipments only are shown in italics.

P650 PACKING INSTRUCTION

This packing instruction applies to UN No. 3373.

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

(2) The packaging shall consist of at least three components:

(a) a primary receptacle;

(b) a secondary packaging; and

(c) an outer packaging of which either the secondary or the outer packaging shall be rigid. *(IATA: the outer packaging must be rigid)*

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

(4) For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with minimum dimensions of 50 mm by 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.

(IATA; An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.)

(5) At least one surface of the outer packaging shall have a minimum dimension of 100 mm × 100 mm.

(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in 6.3.5.2 at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

(7) For liquid substances:

(a) The primary receptacle(s) shall be leakproof; *(IATA: and must not contain more than 1 L)*

(b) The secondary packaging shall be leakproof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;

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

(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar). *(IATA:*

> *Note for Air shipments only— The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:*
>
> *— flexible receptacles and flexible packagings;*
>
> *— receptacles and packagings filled and closed under an absolute atmospheric pressure lower than 95 kPa.*
>
> *The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold)*

(8) For solid substances:

(a) The primary receptacle(s) shall be siftproof;

(b) The secondary packaging shall be siftproof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;

(IATA: 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)

(d) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during carriage then a packaging suitable for liquids, including absorbent materials, shall be used.

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

(a) When dry ice or liquid nitrogen is used as a coolant, the requirements of 5.5.3 shall apply. When used, ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position. If ice is used, the outside packaging or overpack shall be leakproof.

(IATA: If dry ice is used the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent the build up of pressure that could rupture the packagings.)

(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

(10) When packages are placed in an overpack, the package marks required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.

(IATA: the overpack must be marked with the word "overpack" in lettering at least 12 mm high)

(11) Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirements.

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

(13) Other dangerous goods shall not be packed in the same packaging as Class 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. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements of the transport regulations need be met.

(14) If any substance has leaked and has been spilled in a cargo transport unit, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

IATA:

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

b) The name address and telephone number of a person responsible must be provided on the air waybill or on the package

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.*

If an air way bill 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 they are the only packages within the consignment).

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

Appendix IV Package testing requirements for P650

I. Samples must be subjected to free-fall drops onto a rigid, non-resilient, flat, horizontal surface from a height of 1.2 metres. Where the samples are in the shape of a box, five must be dropped in sequence:

1) flat onto the base;
2) flat onto the top;
3) flat onto the longest side;
4) flat onto the shortest side;
5) onto a corner.

Where the samples are in the shape of a drum, three must be dropped in sequence:

6) diagonally onto the top chime, with the centre of gravity directly above the point of impact;
7) diagonally onto the base chime;
8) flat onto the side.

Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s), which must remain protected by absorbent material in the secondary packaging.
Note: While the sample must be released in the required orientation, it is accepted that for aerodynamic reasons the impact may not take place in that orientation.

II. If the test sample includes an outer packaging constructed of fibreboard, the sample must be subjected to a water spray that simulates exposure to rainfall of approximately 5 cm per hour for at least one hour. It must then be subjected to the test described in i. above.

III. If the test sample includes an inner or outer packaging constructed of plastic, the sample must be conditioned in an atmosphere of –18°C or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in i. above. Where the sample contains dry ice, the conditioning period may be reduced to four hours.

IV. Where the packaging is intended to contain dry ice, a test additional to that specified in i., ii. or iii. must be carried out. One sample must be stored so that all the dry ice dissipates and then be subjected to the test described in i. above.

Appendix V Sample Air Waybill

Appendix VI Packing Instruction P620

This instruction applies to UN Nos. 2814 and 2900.

The following packagings are authorized provided the special packing provisions of 4.1.8 are met:

Packagings meeting the requirements of Chapter 6.3 and approved accordingly consisting of:

(a) Inner packagings comprising:

(i) leakproof primary receptacle(s);

(ii) a leakproof secondary packaging;

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

(b) A rigid outer packaging:

Drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1, 1H2, 1D, 1G);

Boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2);

Jerricans (3A1, 3A2, 3B1, 3B2, 3H1, 3H2).

The smallest external dimension shall be not less than 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2; such an overpack may contain dry ice.

2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:

(a) Substances consigned at ambient temperatures or at a higher temperature: Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;

(b) Substances consigned refrigerated or frozen: Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.3. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;

(c) Substances consigned in liquid nitrogen: Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually.

Provisions for the carriage of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;

(d) Lyophilised substances may also be carried in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C.

4. Other dangerous goods shall not be packed in the same packaging as Class 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. These small quantities of dangerous goods of Classes 3, 8 or 9 are not subject to any additional requirements of the regulations when packed in accordance with this packing instruction.

The relevant special provisions referred to in the packing instruction are as follows:

4.1.8 Special packing provisions for infectious substances (Class 6.2)

4.1.8.1 Consignors of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during carriage.

4.1.8.2 The definitions in 1.2.1 and the general packing provisions of 4.1.1.1 to 4.1.1.17, except 4.1.1.10 to 4.1.1.12 and 4.1.1.15 apply to infectious substances packages. However, liquids shall only be filled into packagings which have an appropriate resistance to the internal pressure that may develop under normal conditions of carriage.

4.1.8.3 An itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be carried are unknown, but suspected of meeting the criteria for inclusion in Category A, the words "suspected Category A infectious substance" shall be shown, in parenthesis, following the proper shipping name on the document inside the outer packaging.

4.1.8.4 Before an empty packaging is returned to the consignor, or sent elsewhere, it shall be disinfected or sterilized to nullify any hazard and any label or mark indicating that it had contained an infectious substance shall be removed or obliterated.

4.1.8.5 Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within a secondary packaging are allowed without the need for further testing of the completed packaging:

(a) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

(i) the primary receptacles are of similar design to the primary receptacle tested (e.g. shape: round, rectangular, etc.);

(ii) the material of construction of the primary receptacles (e.g. glass, plastics, metal) offers resistance to impact and stacking forces equivalent to or better than that of the primary receptacles originally tested;

(iii) the primary receptacles have the same or smaller openings and the closure is of equivalent design (e.g. screw cap, friction lid, etc.);

(iv) sufficient additional cushioning material is used to take up empty spaces and to prevent significant movement of the primary receptacles; and

(v) primary receptacles are oriented within the secondary packagings in the same manner as in the tested package;

(b) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in (a) above, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

Appendix VII Example shipper's declaration for dangerous goods by air

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Hospital Laboratory Address	Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number *(optional)*
Consignee Reference Laboratory Address	
Two completed and signed copies of this Declaration must be handed to the operator.	**WARNING** **Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.**
TRANSPORT DETAILS This shipment is within the limitations prescribed for : *(delete non-applicable)* PASSENGER AND CARGO AIRCRAFT / ~~CARGO AIRCRAFT ONLY~~ Airport of Departure (optional):	
Airport of Destination (optional):	Shipment type : *(delete non-applicable)* ~~NON-RADIOACTIVE~~ / ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (subsidiary hazard)	Packing Group			
UN 1814	INFECTIOUS SUBSTANCE AFFECTING HUMANS (suspected Category A infectious substance)	6.2		1 Fibreboard box x 10 ml	620	
UN 1845	DRY ICE	9		20 kg Overpack used	954	

Additional Handling Information
Responsible Person: Mr. Expert Tel: 353 1 1234567

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 labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.	Name A. N. Other Date 4th May 2022 Signature *A N Other* *(See warning above)*

Appendix VIII Elements of a Security Plan

The security plan shall comprise at least the following elements:
(a) Specific allocation of responsibilities for security to competent and qualified persons with appropriate authority to carry out their responsibilities;

(b) Records of dangerous goods or types of dangerous goods concerned;

(c) Review of current operations and assessment of security risks, including any stops necessary to the transport operation, the keeping of dangerous goods in the vehicle, tank or container before, during and after the journey and the intermediate temporary storage of dangerous goods during the course of intermodal transfer or transhipment between units as appropriate;

(d) Clear statement of measures that are to be taken to reduce security risks, commensurate with the responsibilities and duties of the participant, including:

- training;
- security policies (e.g. response to higher threat conditions, new employee/employment verification, etc.);
- operating practices (e.g. choice/use of routes where known, access to dangerous goods in intermediate temporary storage (as defined in (c)), proximity to vulnerable infrastructure etc.);
- equipment and resources that are to be used to reduce security risks;

(e) Effective and up to date procedures for reporting and dealing with security threats, breaches of security or security incidents;

(f) Procedures for the evaluation and testing of security plans and procedures for periodic review and update of the plans;

(g) Measures to ensure the physical security of transport information contained in the security plan; and

(h) Measures to ensure that the distribution of information relating to the transport operation contained in the security plan is limited to those who need to have it. Such measures shall not preclude the provision of information required elsewhere in the transport regulations (e.g. provision of transport documents).

Appendix IX Examples of biological substances that may be shipped as non-infectious

Cervical screening sample tests –These are collected in alcohol which will have an inactivating effect on any organisms present. Thus, specimens do not have to be assigned to Class 6.2. However, they will be subject to requirements for Class 3 Flammable Liquids because of the alcohol, which are addressed by applying the provisions for Limited Quantities.

Sperm & Embryos for fertility treatment – these fall under exemptions 1 & 7 respectively as there are general screening procedures to minimise the risk of transmission of infection. If frozen, transport regulations around the use of coolants may apply.

Fixed / stained histology specimens and slides – inactivation by the fixing process avoids assignment to Class 6.2. CLP labelling may be required to communicate the hazards of the fixing agent, if present.

Commercial control sera / Positive controls – measures are normally employed to minimise the risk of infection as stated in the product leaflet by a combination of screening of the starting material and/or inactivation procedures. Note: The advice is usually to handle in the laboratory as if potentially infectious, but this does not require that they are transported as infectious.
Note: External Quality Control Samples are normally transported as Class 6.2 infectious substances as there is minimal processing of such materials.

Bowel Screen samples – the faecal occult blood exemption applies (Exemption 6, Appendix I).

Acid preserved 24-hour urine samples – urine generally carries a lower risk of infection compared to other biological specimens and acidification is likely to inactivate any organisms that may be present so that the second clause of exemption 1 applies. The acid in the sample container will satisfy the criteria for a Class 8 Corrosive substance, and depending on the volume of urine collected, the acid may not be sufficiently diluted to eliminate the corrosive hazard. Application of Limited Quantity provisions can address this hazard.

Part B

1.0 Initiation

1.1 Purpose

The Guideline:

- Addresses the requirements for consigning and transporting patient specimens and other biological materials associated with human health care
  and
- Provides guidance on the consignment of patient specimens and other biological materials associated with human healthcare for carriage by road, rail, sea or air.

The Guideline must be used to develop written local procedures detailing the specific practices for a particular activity or facility.

1.2 Scope

This guideline applies to all personnel involved in the preparation of patient specimens and other biological materials for transport.

Out of Scope

The guideline does not apply to:

- The transport of Healthcare Waste or contaminated Reusable Invasive Medical Devices (RIMDS) to or from HSE facilities

- Transport of Cadavers

Section 38 and Section 39 agencies are required to adopt or develop a Guideline which is consistent with this Guideline.

1.3 Objective(s)

- To provide a framework for managers with responsibility for the preparation of patient specimens and other biological materials for transport

- To ensure that all patient specimens and other biological materials shipped or received by HSE personnel are transported in compliance with the applicable provisions of the relevant dangerous goods transport regulations

- To ensure a standardised approach across the HSE and reduce variation in practice

- To outline clear roles and responsibilities.

1.4 Outcome

This guideline provides a process to enable managers to be fully compliant with the applicable provisions of the relevant dangerous goods transport regulations.

1.5 PPPG Development Group

Please refer to Appendix XI.

1.6 Supporting Evidence

The following legislation is pertinent and was referred to during the development of this guideline:

- ADR: Agreement Concerning the International Carriage of Dangerous Goods by Road –a softcopy may be downloaded by navigating from the webpage at http://www.unece.org/trans/welcome.html
- European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations, (current version) – apply the ADR regulations to national and international road transport within Ireland. A consolidated version is available at https://www.hsa.ie/eng/your_industry/adr_-carriage_of_dangerous_goods_by_road/adr_general_information/legislation/si_349_of_2011_consolidated_to_2021.pdf
- RID: Regulations concerning the International Transport of Dangerous Goods by Rail – a soft copy may be downloaded from http://otif.org/en/
- IMDG Code: International Maritime Dangerous Goods Code
- ICAO TI: International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air – the legally enforceable regulations for air transport
- IATA DGR: International Air Transport Association Dangerous Goods Regulations - a practical industry standard incorporating the ICAO TIs that must be complied with in order to ship dangerous good by air on member-operators' aircraft.
- Safety, Health and Welfare at Work (General Application) (Amendment) (No. 3) Regulations 2016 – SI 370 of 2016

The following documents were also consulted:

- An Post Terms and Conditions for Universal Services - Single Piece Mail.
- An Post Guidelines for Posting to International Destinations.
- An Post letter of agreement on the transport of cervical screen samples, dated 11.01.2019.

- Carriage of Dangerous Goods by Road 2021 – A HSA Guide for Businesses available through https://www.hsa.ie/eng/publications_and_forms/publications/chemical_and_hazardous_substances/carriage_of_dangerous_goods_by_road_2021.html

- ST/SG/AC.10/C.3/2004/99,available through http://www.unece.org/trans/welcome.html

2.0 Development of PPPG

2.1 Literature Review

The objective of the literature review was to determine the legal requirements, establish current evidence and best practice in relation to the preparation and consignment of patient specimens and other biological materials for transport.

The guideline is based on the requirements set out in the ADR Regulations and other pertinent legislation as detailed in Section 1.6

2.2 Method of appraising evidence

The process outlined in this document is based on a review of the relevant legislation, codes of practice and relevant publications as documented in section 1.6

2.3 Resources necessary to implement the PPPG recommendations

The guideline document consolidates existing practices and line managers are required to review existing practices and procedures to ensure they are aligned to the requirements set out in this guideline.

2.4 PPPG Steps/Recommendations

Please refer to Part A of this Guideline.

3.0 Governance and Approval

3.1 Formal Governance Arrangements

Please refer to Appendix XII

3.2 Copyright/permission sought

Copies of conflict of interest forms and PPPG checklist are held with the master copy and retained on file with the National Health & Safety Policy Team.

4.0 Communication and Dissemination

4.1 The guideline will be disseminated by the National HR Division for immediate implementation by relevant services, in line with the agreed HSE protocol. The guideline will also be communicated through national and local newsletters; twitter and email notifications.

5.0 Implementation

5.1 Managers (Responsible Persons)

Managers (Responsible Persons) are responsible developing an implementation plan, including identification of responsible person(s), specifying the actions to implement the guideline and timeframes for implementation.

5.2 Education & Training

To support implementation of this guideline, any queries, requests for training can be made through the National Health and Safety Function, Helpdesk.
www.hse.ie/eng/staff/safetywellbeing/

6.0 Monitoring, Audit and Evaluation

6.1 Managers are required to monitor and audit the implementation plan supporting this guideline using the audit checklist in Appendix XIII.

6.2 Implementation of this guideline shall be audited periodically at national level and by the local Dangerous Goods Safety Advisor (DGSA).

7.0 Revision/Update

7.1 The guideline shall be reviewed at national level every three years or earlier if circumstances require it e.g. change in legislation etc.

8.0 Appendices

Appendix X Signature Sheet

Appendix XI Membership of the PPPG Development Group

Appendix XII Membership of the Approval Governance Group {

Appendix XIII Audit Checklist

Appendix X Signature Sheet

I have read, understand and agree to adhere to this Policy, Procedure, Protocol or Guideline:

Print Name	Signature	Area of Work	Date

Appendix XI Membership of the PPPG Development Group

Name	Title
JJ Tobin ChemHaz Solutions (HSE National Dangerous Goods Adviser)	
Michael Joyce C/O ChemHaz Solutions (HSE National Dangerous Goods Adviser)	
Bríd Cooney National Health & Safety Advisor (Policy Team)	
Chairperson: Margo Leddy National Health & Safety Manager (Policy Team)	

Appendix XII Membership of the Approval Governance Group

Anne Marie Hoey, National Director HR	Signature:  Date: 26.09.2023
Katrina Dempsey, Head of the National Health and Safety Function	Signature:  Date: 26.09.2023

Appendix XIII Audit Checklist for Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials 2023

Audit on the Implementation of the Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials, 2023		Recommendation	Follow up actions	Agreed Imp Date	Responsible Person
1	Is there a system in place for the appropriate circulation/communication of this guideline and local protocol to all relevant employees?				
2	Do all relevant departments have a copy of this guideline?				
3	Has a risk assessment for the preparation for transport of patient specimens and biological materials been undertaken and reviewed at least annually?				
4	Have local protocols been developed in line with this guideline and controls measures identified through the risk assessment process?				
5	Are all patient specimens and biological substances classified in accordance with this guideline?				
6	Does the packaging in use meet the requirement of this guideline?				
7	Has appropriate information, instruction, supervision and training been provided based on risk assessment?				
8	Is there a procedure in place for reporting, managing and reviewing all incidents?				