

Guidance on regulations  
for the

**transport of  
infectious  
substances 2019–  
2020**

Applicable from 1 January 2019



Country Health Emergency  
Preparedness & IHR

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## ABBREVIATIONS AND ACRONYMS

|         |   |
|---------|---|
| ADR     | European agreement concerning the international carriage of dangerous goods by road |
| CAO     | cargo aircraft only   |
| DGD     | dangerous goods declaration   |
| DGR     | dangerous goods regulations   |
| DGTD    | dangerous goods transport document  |
| EDI     | electronic data interchange   |
| EDP     | electronic data processing  |
| GMO     | genetically modified organism   |
| GMMO    | genetically modified microorganism  |
| IAEA    | International Atomic Energy Agency  |
| IATA    | International Air Transport Association   |
| ICAO    | International Civil Aviation Organization   |
| IMO     | International Maritime Organization   |
| RID     | International carriage of dangerous goods by rail                                   |
| SOLAS   | Safety of Life at Sea   |
| UN      | United Nations  |
| UNCETDG | United Nations Committee of Experts on the Transport of Dangerous Goods             |
| UPU     | Universal Postal Union  |
| WHO     | World Health Organization   |

## SECTION 1: TRANSPORT REGULATIONS

### 1.1 INTERNATIONAL REGULATIONS

Work with biological agents plays a key role in the detection and prevention of outbreaks of emerging and highly infectious disease, and in the reduction of other risks to international health security. Such work includes diagnostic activities, biomedical research and pharmaceutical manufacturing. Facilities handling biological agents have a responsibility to ensure that biological agents are identified, and safely stored and controlled in adequately equipped facilities, according to best practices.

While materials containing biological agents are being transported, there is the possibility of exposure for the people and the environment through which the material passes. To appropriately control and reduce this risk, various international groups have developed recommendations or regulations (or both) that outline the way in which infectious substances should be packaged, marked, labelled and documented, to ensure safety and containment throughout the transport process.

One of the most widely known and referenced set of recommendations is the “Recommendations on the transport of dangerous goods – model regulations (20th revised edition)” (referred to here as the “UN model regulations”). These recommendations are made by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods (UNCETDG), a committee of the United Nations Economic and Social Council that comprises expert advisors from various countries, nongovernmental organizations and specialized agencies, including World Health Organization (WHO) representatives. The recommendations are continuously reviewed, in 2-yearly cycles, and are updated by the committee in light of technical progress, the introduction of new substances or materials, modern pressures on transport systems, and emerging safety requirements for people, property and the environment.

The UN model regulations provide a minimum set of provisions to follow, to safely transport any dangerous goods, including infectious substances. The aim of using this set of provisions as a basis across various national and international regulations is to provide conformity and harmonization across them all. However, the UN model regulations provide a certain degree of flexibility, so that the basic regulations may be adapted to fit local needs and special requirements for overcoming barriers in transport. Adapted versions may then be adopted by governments or international organizations as mandatory or legally binding regulations for the transport of dangerous goods. The subsequent implementation of, and compliance with, adopted regulations may be overseen by independent bodies or national authorities, as designated by the relevant governing body.

### 1.2 MODAL AGREEMENTS

Although the UN model regulations are general enough to cover all modes of transport, they are most commonly reflected in international law through international modal agreements, which adapt and publish guidelines or regulations specialized for a specific mode of transport. Some of the most common modal agreements for the transport of dangerous goods are described in Table 1.1. References and online links to these agreements can also be found in [Annex 1](#) of this document.

**Table 1.1. A summary of the modal agreements containing relevant dangerous goods regulations.**

| Mode of transport | International modal agreements  |
|-------------------|---|
| <b>Air</b>        | <p>The <i>Technical instructions for the safe transport of dangerous goods by air</i> (referred to here as the “ICAO technical instructions” – ICAO being the International Civil Aviation Organization) are a detailed set of instructions deemed necessary for the safe international transport of dangerous goods by air. Published by ICAO, these legally binding international regulations apply on all international flights. They are regularly reviewed and updated based on comments received from states and interested international organizations, including WHO, or based on recommendations of the UNCETDG or the International Atomic Energy Agency (IAEA).</p> <p>The International Air Transport Association (IATA) also publishes dangerous goods regulations (DGR) that incorporate the ICAO provisions, and may add further restrictions stemming from operational considerations. DGR also present state and operator variations. The IATA DGR are applicable to its members and some other airlines, as well as all shippers and agents that offer consignments of dangerous goods to these operators.</p> <p>For national flights (i.e. those within one country), national civil aviation authorities may apply national legislation. This is normally based on the ICAO provisions, but may incorporate variations. State and operator variations are published in both the ICAO technical instructions and in the IATA DGR.</p> |
| <b>Rail</b>       | <p><i>International carriage of dangerous goods by rail</i> (RID) is a set of regulations created by the Intergovernmental Organisation for International Carriage by Rail (OTIF). These regulations apply to countries in Europe, the Middle East and North Africa, and to domestic transport in the European Union through Council Directive 2008/68/EC.</p>  |
| <b>Road</b>       | <p>The <i>European agreement concerning the international carriage of dangerous goods by road</i> (ADR) applies to 49 countries. In addition, modified versions of the convention are being used by countries in South America and South-East Asia. ADR also applies to domestic transport in the European Union through Council Directive 2008/68/EC.</p>  |
| <b>Sea</b>        | <p>The <i>International maritime dangerous goods code</i> is published by the International Maritime Organization (IMO). It is of mandatory application for all contracting parties to the International Convention for the Safety of Life at Sea (SOLAS).</p>  |
| <b>Post</b>       | <p>The <i>Letter post manual</i>, published by the Universal Postal Union (UPU), reflects the UN model regulations by using the ICAO technical instructions as the basis for shipments.</p> <p>Some infectious substances considered to be of a high-risk category (known as “Category A infectious substances”) will not be accepted for shipment through postal services. Some infectious substances in lower risk categories (e.g. “Category B infectious substances” and “Exempt human and exempt animal specimens”) may be shipped by registered air mail. For more information on infectious substances categories, see <a href="#">Section 5.2</a>.</p> <p>Local and international restrictions may also be in force. Prior contact should therefore be made with the national public operators for registered mail, to ascertain</p>  |



|  |   |
|--|---|
|  | whether the packaged material will be accepted by the postal service in question. |
|--|---|

### 1.3 NATIONAL REGULATIONS

Many countries adopt the UN model regulations in their entirety to stand as their national dangerous goods legislation, whereas others apply variations that suit local conditions and requirements (an example of such a variation is shown in Fig. 1.1). National authorities should be able to provide details of their own national requirements to relevant users.

Where national regulations do not exist, the international modal agreements described above should be followed. Should multiple regulations apply to a single shipment of infectious substances, the most stringent ones should be applied.

|                     |   |                    |
|---------------------|---|--------------------|
| <b>VU — VANUATU</b> |   |                    |
| VU 1                | The marking of packages and overpacks and the Dangerous Goods Transport Document accompanying dangerous goods consignments must be in English or French. If the State of Origin requires another language each shall be given equal prominence.   | 5;2.5<br>5;4.1.6.3 |
| VU 2                | Infectious substances are prohibited from entry to Vanuatu without prior approval from the Vanuatu Government Department of Health. Requests for approval should be addressed to:<br><br>Director of Health<br>P.O. Box 102, Port-Vila<br>Vanuatu | 1;1.2              |

**Fig. 1.1. An example of a national variation requirement**

Source: ICAO technical instructions.

### 1.4 OPERATOR/CARRIER VARIATIONS

Transport of infectious substances is of international concern because of the public health impact and needs. Much of the transport and logistics chain, however, is not a public health service, and includes industries of a commercial nature. Often, safety is a key factor, for reasons of reputability and trust rather than for health concerns. Hence, although there are modal agreements and national regulations to appropriately address safety procedures, companies operating commercial enterprises (e.g. airlines and couriers) may enforce additional safety requirements for shipments in their carriage, aiming to achieve a high level of accountability for their clients. Although such variations are not usually legally binding, failure to comply with such variations may result in a refusal of service between that enterprise and the person trying to send the infectious substances. Failure to comply with operator/carrier variations is generally the most common reason for delayed or refused shipments. Furthermore, a commercial enterprise that does not wish to carry particular dangerous goods is under no legal obligation to do so, even if compliance with applicable regulations is met.

ICAO and IATA list the main operator/carrier restrictions in force among airlines. Some airlines will not carry dangerous goods at all, while others will carry only a limited range of goods. An example of one such restriction can be seen in Fig. 1.2. As carrier restrictions for the different modes of transport are not published centrally, harmonization between stakeholders is essential.

| VA — VIRGIN AUSTRALIA |       |   |           |
|-----------------------|-------|---|-----------|
| ≠                     | VA-01 | Petrol powered equipment such as chainsaws, brush cutters, generators or the like, either new or used, are forbidden in carry-on or checked baggage. Such items will only be accepted as cargo if they are packaged and shipped in accordance with the IATA Dangerous Goods Regulations. Where Special Provision A70 applies to internal combustion or fuel cell engines, these items may be accepted for transport as cargo provided operator approval has been granted. | Table 8-1 |
| +                     | VA-02 | Dangerous goods listed in the list of high consequence dangerous goods will not be accepted for carriage.   | Table 1-7 |
| +                     | VA-03 | Not used.   |           |

**Fig. 1.2. An example of an operator/carrier variation**

Source: ICAO technical instructions.

## 1.5 SUPPLEMENTARY REGULATIONS

Particularly where international transport is concerned, regulations over and above those for safety in transport may apply. Examples of such regulations include those for import or export licensing; licensing to carry, hold or store certain biological agents; and agricultural and environment safety regulations.

Supplementary regulations may be applied by a variety of government departments, or by several different agencies. It is the responsibility of the shipper (i.e. the person sending the shipment) to ensure that they are aware of, and comply with, all applicable regulations.

## 1.6 SPECIAL PROVISIONS

“Special provisions” is a term used to describe certain circumstances or procedures that are not covered in standard regulations. These provisions supplement or modify the original regulations, indicating how to appropriately ship the dangerous good to which they apply.

Tables listing special provisions applicable to dangerous goods can be found in most international regulation documents, including the UN model regulations. A shortlist of special provisions that may be applicable to infectious substances shipments is also provided in [Annex 2](#) of this document.

## SECTION 2: TRANSPORT STAKEHOLDERS

From the time an infectious substance is packed until it reaches its destination, it is likely that many different stakeholders will participate in the transport process. The efficient transfer of infectious substances requires good coordination and harmonization between all parties involved in the shipment, including the person or institution sending the substance, the commercial entities involved in carrying the package, and the person or institution receiving the substance.

This section provides an overview of the responsibilities of some of the primary stakeholders involved in the transport process.

### 2.1 THE SHIPPER

The shipper of the infectious substance:

- may also be known as the consigner or the sender;
- ensures the correct classification, packaging, labelling and documentation of all infectious substances destined for transport;
- ensures that packaging selected is suitable and compliant for the substances being shipped;
- confirms with the national authorities that the material may be legally exported;
- makes themselves aware of all regulations applicable to their shipment, based on the place of origin, transit, destination and mode of transport, as applicable;
- explores whether additional approvals are required (e.g. export permits);
- makes primary contact with the receiver of the package to ensure that the receiver is able and prepared to receive the shipment;
- ensures that the package is prepared in accordance with the instructions from the package manufacturer;
- makes advance arrangements with the carrier to ensure that:
  - there are no additional operator variations applicable to the shipment;
  - the shipment will be accepted for appropriate transport;
  - the shipment is undertaken by the most direct routing (direct transport if possible);
- prepares necessary documentation, including permits, dispatch and shipping documents, retaining a copy of each;
- notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time; and
- ensures that the package and documentation is prepared in compliance with the regulations, in addition to any advice received from the carrier.

#### Definitions

**Consigner:** The person responsible for sending the shipment, also known as the shipper or sender.

**Consignee:** The person responsible for receipt of the shipment, also known as the receiver or buyer.

**Consignment:** A package or group of packages (shipment) destined for delivery.

### 2.2 THE PACKAGING SUPPLIER

The supplier of the packaging for the infectious substance:

- manufactures and tests lines of packaging materials, according to applicable regulations;
- makes available test reports and results on request to users of their packages, and to national competent authorities;
- provides instructions to users regarding the procedures to be followed, and additional components needed, to ensure that the packaging materials meet performance requirements; and
- if required, is registered with a quality assurance programme, as directed by national competent authorities.

### 2.3 THE OPERATOR/CARRIER

The operator/carrier of the infectious substance:

- may include logisticians, courier companies, airline freight forwarders or other transport operators;
- provides advice to the sender regarding the necessary shipping documents, and instructions for their completion;
- provides advice to the sender about correct packaging;
- assists the sender in arranging the most direct routing, then confirms the routing; and
- maintains and archives copies of the documentation for shipment and transport.

### 2.4 THE RECEIVER

The receiver of the infectious substance:

- may also be known as the consignee, importer or buyer;
- confirms with the national authorities that the substance may be legally imported;
- obtains the necessary authorization(s) from national authorities for the receipt of the substance (e.g. importation permits) – these may need to be provided to the sender, where applicable;
- arranges for the most timely and efficient collection on arrival; and
- acknowledges receipt to the sender.

## SECTION 3: TRAINING

Before a consignment of dangerous goods is offered for transport, all relevant persons involved in its preparation must have received training to enable them to carry out their responsibilities. Where the organization responsible for preparing the shipment does not have appropriately trained personnel the “relevant persons” may be interpreted as those contracted to act on the shipper’s behalf and undertake the shipper’s responsibilities in the preparation of the shipment; where this is the case, those people must still be able to fulfil applicable training requirements.

Personnel should be trained in a manner that corresponds to their contractual responsibilities. Therefore, the content of the training should be based on an analysis of the recipient’s assigned roles and responsibilities (as given in their job description). In some cases, this should be determined by the employer, but in other cases it will be stipulated or governed by national competent authorities. Employees should only ever carry out functions for which the required training has been provided; otherwise, they should be appropriately supervised and signed off by another competent individual.

### Stakeholders requiring training

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

- the people or organizations undertaking the responsibilities of the shipper;
- personnel of transport operators (e.g. drivers, pilots and captains);
- ground handling agencies that act on behalf of the operators/carriers to accept, handle, load and unload dangerous goods packages;
- individuals involved in the transferring, processing or screening of cargo or mail (e.g. security personnel);
- freight forwarders; and
- designated postal operators.

The ICAO technical instructions provide a more detailed overview of the various aspects of dangerous goods transport that various types of personnel should be familiar with if they are to be considered competent to ship dangerous goods.

### 3.1 AREAS OF TRAINING

According to the UN model regulations, all individuals involved in the transport of dangerous goods should be trained in general awareness and familiarization, safety and specific functions, as outlined below.

#### 3.1.1 GENERAL AWARENESS AND FAMILIARIZATION TRAINING

General awareness and familiarization training should involve familiarization with the general provisions of dangerous goods transport requirements, including:

- description of the classes of dangerous goods;
- labelling, marking and placarding;
- packaging;
- segregation;
- compatibility of dangerous goods;
- purpose and content of dangerous goods documentation; and

- descriptions of available emergency response documents.

---

### 3.1.2 SAFETY TRAINING

Safety training includes:

- methods and procedures for avoiding accidents (e.g. proper handling, including equipment use, and methods of stowage);
- emergency response information and how to use it;
- general dangers and hazards of the various dangerous goods classes;
- prevention of exposure to hazards, including the use of personal protective equipment; and
- procedures to be followed in the event of release or exposure to any dangerous goods.

---

### 3.1.3 FUNCTION-SPECIFIC TRAINING

Function-specific training will depend on the specific job functions of the individual. For example, a shipper of a public health institution will probably need to be trained on the details of classification, packing, labelling, marking and documenting dangerous goods, whereas a carrier is more likely to require training on handling, stacking, stowing and logistics procedures. Function-specific competencies should be appropriately supervised until competency is assured, which may require the completion of approved training courses or passing of examinations.

## 3.2 TESTING AND VERIFICATION

Most modal agreements include provisions that require the testing and verification of an individual's knowledge and competency in the aforementioned areas for any person involved in dangerous goods transportation. For example, the UN model regulations stipulate that anyone involved in the shipment of high-risk categories of infectious substances (known as Category A infectious substances) must undertake appropriate training and be willing to provide records of that training on request.

Records of training conducted should be kept by the employer, who should be able to make these available when asked to do so by the employee or a national competent authority, because they may need to be verified if a person takes up a new appointment or acquires new responsibilities. Training should be supplemented with retraining, as deemed necessary by the competent authority. Typically, training and competency testing should be repeated at least every 2 years (24 months), but the frequency will vary for different modes of transport. Training programmes on dangerous goods may be subject to review and approval by the relevant national competent authorities.

## SECTION 4: DEFINING A MATERIAL FOR TRANSPORT

For the purpose of transport, infectious substances are materials or products that contain, or are reasonably expected to contain, biological agents that cause disease in humans or animals (i.e. pathogens). In this context, the terms “infectious substances”, “infectious materials” and “infectious products” are considered to be synonymous.

Before beginning the transportation process, it is important to define what is being shipped, and whether this is, in fact, an infectious substance. This section discusses several products that may fall under the definition of an infectious substances, under certain circumstances.

### 4.1 CULTURES

Culture is a method by which biological agents are intentionally propagated, under controlled laboratory conditions, inside a designated medium or in animals. This results in a concentrated collection of cultivated biological agents known as cultures, which may be used in research and diagnostics, or stored in culture collections. Any cultured biological agent capable of causing disease in humans or animals falls under the definition of infectious substances.

### 4.2 PATIENT SPECIMENS

Patient specimens are products or materials that are collected directly from humans or animals for the purpose of research or diagnostic investigations. They may also be referred to as “patient samples”, “diagnostic specimens” or “diagnostic samples”. Examples of such specimens are body fluids (e.g. excreta, secreta and blood or blood products); and tissues or body parts collected in containers, on swabs or submerged in preservative media. As with cultures, if the patient specimen contains biological agents capable of causing disease in humans or animals, it will be defined as an infectious substance.

### 4.3 BIOLOGICAL PRODUCTS

Biological products are substances or materials that are derived from living organisms (e.g. bacteria, fungi, viruses, animals and humans) and are extracted or purified for use as a preventive, therapeutic or diagnostic tool. Examples include antitoxins, vaccines and vaccine components. It is important to note that due to their importance in disease treatment and prevention, some biological products may be governed by special requirements or licensing agreements set out by national authorities. In this case, their manufacture and distribution could be subject to regulations that differ from, or be in addition to, those set out for infectious substances.

#### **Transport of live animals**

Live animals (including those that have been genetically modified) that have been infected with a biological agent must be transported in accordance with appropriate regulations in the country of origin, transit and destination. Such regulations are usually associated with proper animal care; hence, infectious substances transport regulations will not generally be applicable. Live animals must NOT be used as a means to transport biological agents, unless this cannot be done by any other measure.

A live animal that has been intentionally infected and is known or suspected to contain an infectious substance may only be transported by air under terms and conditions approved by the appropriate national authority of the states of origin, transit, destination and operator.

### **Genetically modified organisms or microorganisms**

Genetically modified organisms (GMOs) or genetically modified microorganisms (GMMOs) are animals, plants, biological agents or cellular materials that have been subject to a genetic modification that is different from their natural state.

If, after this modification, the organism or microorganism is capable of causing disease in humans or animals, then the GMO or GMMO, or any material contaminated with it, will be classified as an infectious substance.

If it does not meet the definition for an infectious substance, the GMO or GMMO is assigned to dangerous goods Class 9 and given a UN number (UN 3245). Section 5 of this document provides an introduction to UN numbers and other dangerous goods classes, and the UN model regulations have more detailed information on non-infectious GMOs and GMMOS.

#### **4.4 MEDICAL OR CLINICAL WASTES**

In treating patients (humans or animals) and conducting laboratory activities, consumables are used and waste is generated that is contaminated by reagents, liquids, tissues, cultures and other products. If this waste contains biological agents capable of causing disease in humans or animals, then this medical or clinical waste is an infectious substance.

#### **4.5 MEDICAL DEVICES OR EQUIPMENT**

Similar to medical or clinical wastes, medical devices or equipment that have been contaminated by biological agents during patient treatment or laboratory processes may be defined as infectious substances, should the biological agents contained within them be capable of causing disease in humans or animals.

#### **4.6 EXEMPTIONS**

There are some circumstances where, although the material or product being shipped falls under one of the definitions above, it will not meet the definition for an infectious substance owing to the confirmed absence of biological agents, or because any biological agents present are known to be incapable of causing disease in humans or animals (i.e. they are non-pathogenic, or have been inactivated or neutralized through a decontamination process). In such cases, the materials or products are not considered to pose a health risk and are therefore not subject to transport regulations, unless they meet the criteria for “dangerous goods” in another class. Specific examples of complete exemptions include:

- cultures where the biological agent is non-pathogenic to humans or animals;
- patient specimens for faecal occult blood screening samples, or for testing using a dried blood spot;
- biological products such as blood or blood products for transfusion, or body parts for transplant;



- medical or clinical waste that has been appropriately decontaminated using inactivation methods such as autoclaving or incineration;
- medical equipment that has been drained and confirmed to be free of any contaminated liquid (note: certain packaging requirements apply); and
- samples (e.g. food, soil or water) shipped for investigational purposes that are not thought to pose a risk of infection to humans or animals.

Where goods that meet these exemptions need to be transported by air, UN model regulations stipulate that they **must** be transported using a basic triple packaging system, comprising a leakproof primary receptacle, a leakproof secondary packaging and an outermost layer with adequate strength for the mass or capacity of its intended use. In the case of liquid specimens, absorbent materials must also be placed between the primary and secondary layers to prevent leakage, and must be able to absorb any and all of the specimen, should it escape the primary receptacle. Once contained in an appropriate triple packaging system, exempt specimens are not subject to any other infectious substances regulations. For more detailed information on the components of an appropriate triple packaging system, see [Section 6.1](#).

---

#### 4.6.1 EXEMPT HUMAN OR ANIMAL SPECIMENS

Exempt human or animal specimens are specimens for which there is a low or minimal likelihood that pathogenic biological agents are present. This special type of exemption includes specimens being transported for testing

|   |
|---|
| <p><b>Exemption from definition</b></p> |
|---|

|   |
|---|
| <p>This definition does not apply to medical or clinical wastes with a low likelihood of pathogenic biological agents being present. Such wastes should continue to be subclassified as infectious substances under the applicable nomenclature described in <a href="#">Section 5.2.2</a>.</p> |
|---|

that is unrelated to infectious disease; for example, testing for blood or urine markers (e.g. cholesterol, glucose, hormones, pregnancy, drugs and alcohols), biopsies (e.g. antigenic markers for certain cancers) and immunological investigations (e.g. vaccine-induced immunity or autoimmune responses) where infection is not suspected. Sound professional judgement is required to determine whether a specimen may be exempted under this definition, based on known medical history, symptoms, and endemic and individual circumstances surrounding the source of the specimen.

Samples that have been professionally defined as exempt human or animal specimens must be contained in the same basic triple packaging system as described for air transport for other types of exemption, irrespective of the mode of transport being used. More information on the basic triple packaging system can be found in [Section 6.1](#).

The outermost layer of the package must be marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate. Exempt human specimens and exempt animal specimens that have been appropriately marked and labelled would then be considered safe for transport, and not subject to further infectious substance regulations.

#### 4.6.2 USED MEDICAL DEVICES OR EQUIPMENT

Medical devices or equipment potentially contaminated with or containing infectious substances, which are being transported for disinfection, cleaning, sterilization, repair or evaluation, must be packaged in such a way that, under normal transport conditions, they cannot break, be punctured or leak their contents.

Packagings must be marked with the words “USED MEDICAL DEVICE” or “USED MEDICAL EQUIPMENT”, as appropriate.

Examples of situations where used medical devices or equipment will not fall under this definition and are subject to additional regulations are given in Table 4.1.

#### Relevant sections of UN model regulations

More detailed explanations of the type of packaging appropriate for used medical devices or equipment can be found in the following sections and sub-sections of the UN model regulations:

- 4.1.1.1 and 4.1.1.2: General provisions for the packing of dangerous goods in packagings, including IBCs [intermediate bulk containers] and large packagings;
- 6.1.4: Requirements for packagings (*type specific*); and
- 6.6.5: Test requirements for large packagings.

**Table 4.1. Examples of situations where used medical devices or equipment are subject to different regulations**

| Exceptions   | Requirements   |
|--|--|
| Medical or clinical wastes (i.e. material for disposal)  | For the applicable packaging requirements, refer to <a href="#">Section 5.2.2</a> .  |
| Medical devices or equipment contaminated with high-risk pathogens (i.e. biological agents that will be classified as Category A)                  | For the applicable packaging requirements, refer to <a href="#">Section 5.2.1</a> .  |
| Medical devices or equipment contaminated with material (other than infectious substances) that are classified as dangerous goods of other classes | For more information on dangerous goods classes, see <a href="#">Section 5.1</a> .<br>For more information on packaging requirements for other classes, see the relevant sections of the UN model regulations. |

## SECTION 5: CLASSIFICATION OF INFECTIOUS SUBSTANCES

Should professional judgement find that the material to be shipped is reasonably expected to contain biological agents capable of causing disease in humans or animals, and the material cannot be defined as an exemption, it is an infectious substance. The substance must then be classified, based on the materials composition and the level of risk it poses to human or animal health. It is this classification that will be used to assign the substance a **proper shipping name** and a **UN number** that will be used in all aspects of the package preparation, including its packaging composition, marking, labelling and documentation.

### 5.1 DANGEROUS GOODS CLASSES AND DIVISIONS

The first step of classification is to assign a class and division. An overview of the various dangerous goods classes is given in Table 5.1.

*Table 5.1. An overview of dangerous goods classes and divisions*

| <b>Dangerous goods class</b>   |
|--|
| <b>Class 1: Explosives</b>   |
| <b>Class 2: Gases</b>  |
| <b>Class 3: Flammable liquids</b>  |
| <b>Class 4: Flammable solids; Substances liable to spontaneous combustion; Substances which, in contact with water, emit flammable gases</b> |
| <b>Class 5: Oxidizing substances and organic peroxides</b>   |
| <b>Class 6: Toxic and infectious substances</b><br><b>Division 6.1: Toxic substances</b><br><b>Division 6.2: Infectious substances</b>       |
| <b>Class 7: Radioactive material</b>   |
| <b>Class 8: Corrosive substances</b>   |
| <b>Class 9: Miscellaneous dangerous substances and articles, including environmentally hazardous substances</b>                              |

*Divisions for classes other than Class 6 are not listed in this table. More detailed information on other dangerous goods classes and divisions is given in the UN model regulations.*

All infectious substances are assigned to Dangerous Goods Class 6, Division 6.2. For transport purposes, infectious substances should never be packaged together with goods from other classes. However, in some cases, substances from other classes may be employed for the purposes of cooling or preservation; examples of such substances are flammable liquids (e.g. ethanol, methanol and pyridine, included in Class 3), or dry ice (solid carbon dioxide, included in Class 9). More details about how to treat these substances when shipped together with an infectious substance are given in [Sections 6.5](#) and [6.6](#).

## 5.2 INFECTIOUS SUBSTANCE CATEGORIES

Once it has been classified as a dangerous good under Class 6, Division 6.2, the material must then be further subclassified based on its composition, the type of biological agent present, and the severity or harm that may be caused by that biological agent. This section provides an overview of the various subclassifications of infectious substances, including the official nomenclature (i.e. proper shipping name and UN number) that should be assigned to them for transport purposes. A summary of how to classify and subclassify infectious substances is provided in Fig. 5.1.

### 5.2.1 CATEGORY A

An infectious substance is classified as Category A if it is transported in a form that, when exposure to it occurs, could cause permanent disability, or life-threatening or fatal disease in otherwise healthy humans or animals. In other words, if the substance were released from the craft carrying it or from the protective packaging used during the transportation, it could have severe consequences on the health of any humans or animals that came into contact with it.

Any of the materials discussed in [Section 4](#) (cultures, patient specimens, biological products and medical or clinical wastes) may be subclassified as Category A should the material be known to contain, or reasonably expected to contain, a biological agent that meets the criteria given above. Indicative lists of the biological agents that may meet the criteria for a Category A infectious substance are provided in many transport regulations and modal agreements. A copy of the indicative list from the UN model regulations is provided in [Annex 3](#) of this document; however, many of the biological agents in that list will only meet the definition for a Category A infectious substance when being transported as cultures.

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

- Infectious substances capable of causing disease in humans, or both humans and animals, are assigned to **UN 2814**, and given the proper shipping name of **Infectious substance affecting humans**.
- Infectious substances capable of causing disease only in animals are assigned to **UN 2900**, and given the proper shipping name of **Infectious substance affecting animals only**.

#### Forms of a substance

Not all “forms” of an infectious substance are capable of causing infection in exposed individuals, even when the same biological agent is present. For example, *Mycobacterium tuberculosis* is only considered capable of causing severe harm to exposed individuals if it is transported in the form of cultures.

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

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

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

Ultimately, accurate subclassification of an infectious substance as Category A, and assignment of the appropriate UN number and proper shipping name, requires sound professional judgement. New or emerging pathogens may not appear in indicative lists, even though their biological characteristics are similar to those of pathogens associated with Category A.

A pathogen risk assessment must be performed, to determine whether the unknown biological agents within the infectious substance are capable of causing such severe harm to humans or animals (or both), based on known medical histories, symptoms, endemic local conditions, and the source or origins of the infectious substance. If there is any uncertainty around whether the infectious substance meets the criteria for Category A, a cautious approach should be taken, and Category A assigned.

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### 5.2.2 CATEGORY B

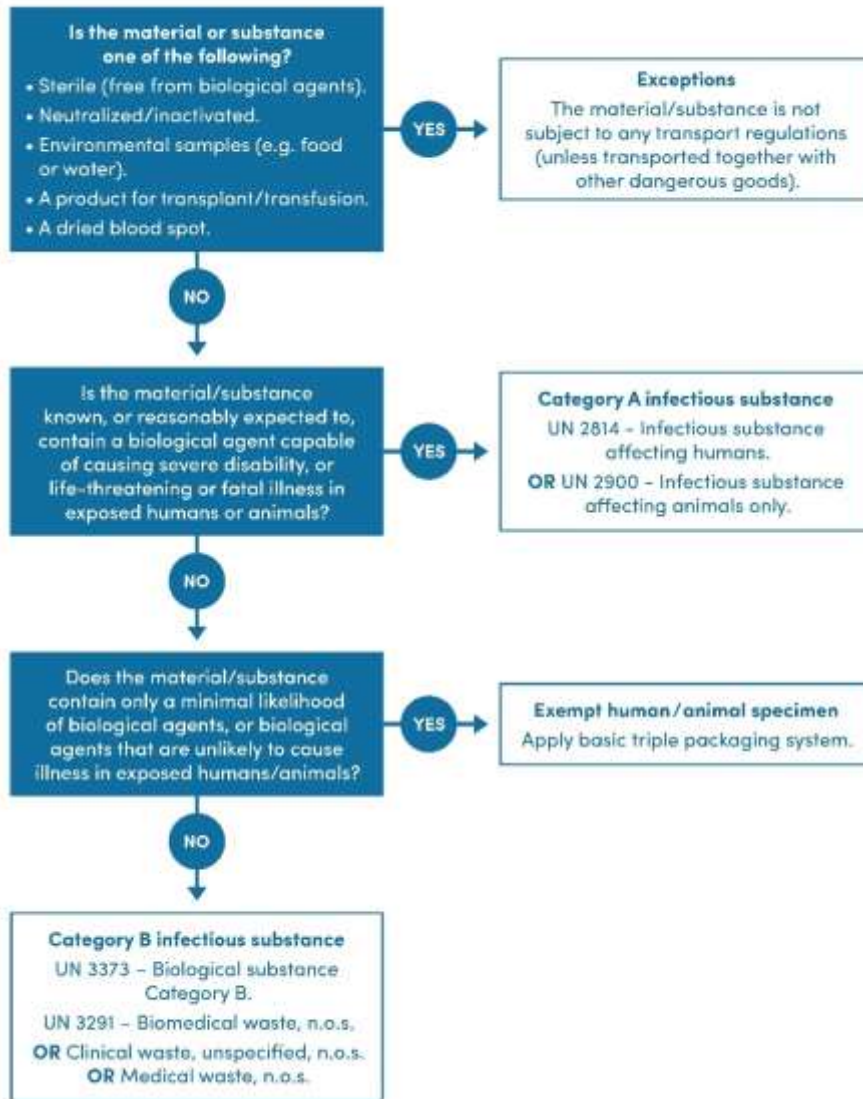
Infectious substances are subclassified as Category B when they contain biological agents capable of causing infection in humans or animals, but NOT meeting the criteria for Category A; that is, the consequences of an infection are not considered severely disabling or life-threatening.

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

- The UN number and proper shipping name for most shipments of Category B infectious substances is UN 3373, Biological substance, Category B.
- If the infectious substances are defined as clinical or medical wastes, and contain an infectious biological agent (or there is even a minimal likelihood that they do so) that does not fit the criteria for Category A, they must be assigned to UN 3291 and given a proper shipping name that reflects their contents or origin (or both). According to the UN model regulations, proper shipping names may include:
  - Clinical waste, unspecified, n.o.s.
  - Biomedical waste, n.o.s.
  - Regulated medical waste, n.o.s.

#### **Not otherwise specified**

N.O.S. is the abbreviation for “not otherwise specified”. Other proper shipping names for medical or clinical wastes may be applicable to shipments for other modes of transport. Applicable regulations should be consulted to establish the correct proper shipping name to use.



**Fig. 5.1. Overview of the process of defining and classifying infectious substances**

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

## SECTION 6: PREPARING PACKAGING REQUIREMENTS

When a package of infectious substances is moved between the point of origin, cargo transport units, warehouses and its destination, it can be subject to challenges, including movement, vibrations, changes of temperature, humidity and pressure. It is therefore essential that the packaging used to contain infectious substances during transport is of good quality and is strong enough to withstand the various challenges that could be faced. Hence, infectious substances must be contained in a triple-layer packaging system, where redundant layers of packaging and sufficient amounts of absorbent material can be used to control leakages or breaches of containment.

### Air transport

The carriage of infectious substances as hand carriage on passenger aircraft – even in diplomatic pouches – is strictly prohibited.

### Exempt specimens

For the purpose of transport, any material defined as “Exempt human specimen” or “Exempt animal specimen” can be transported in a triple-layer packaging system such as the one described here without being subject to any further infectious substance regulations. This also applies to other exemptions when substances are being transported by air.

There is no limit to the quantity of exempt human or animal specimen that may be carried per package, on any mode of transport.

A basic triple packaging system, described in [Section 6.1](#), can be used to compliantly transport exempt human specimens and exempt animal specimens by all modes of transport, and to transport other exemptions by air. Triple packaging systems with more specific and detailed requirements are required for infectious substances subclassified as Category A, Category B, or medical or clinical wastes under UN 3291. These additional requirements ensure safe containment in various modes of transport, and help stakeholders in being able to verify that the packaging material used is of an appropriate strength and quality. Further specifications for the triple packaging system may also be required if other dangerous goods are present (e.g. when dry ice is used as a coolant).

The UN model regulations, as well as other modal agreements, provide information sheets that outline the detailed packaging requirements for various classifications and subclassifications of dangerous goods. These instruction

sheets are generally referred to as “packing instructions”, and three of these may be applicable to the shipment of infectious substances:

- P620 for Category A infectious substances;
- P650 for Category B infectious substances assigned to UN 3373; and
- P621 for medical or clinical wastes containing a Category B infectious substance (assigned to UN 3921).

The ICAO technical instructions also provide a packing instruction – P1954 – for the use of dry ice as a coolant. This instruction may be applicable to infectious substances being transported by air.

[Sections 6.2](#) to [6.8](#) provide an overview of some of the contents of these packing instructions, and [Section 7](#) provides specific information on marking and labelling requirements.

## 6.1 A BASIC TRIPLE PACKAGING SYSTEM

As the name suggests, any triple packaging system used to contain an infectious substance must comprise three layers:

- a primary receptacle;
- a second, watertight and leakproof or siftproof packaging to enclose and protect the primary receptacle; and
- a third, outer layer of packaging that is used to protect the secondary packaging from physical damage while in transit.

The system is illustrated in Fig. 6.1.

### 6.1.1 PRIMARY RECEPTACLE

The primary receptacle, containing the infectious substance, must be watertight, and impermeable to the substance held within; that is, it must be leakproof if the substance is a liquid or siftproof if the substance is a solid. The primary receptacle should be appropriately labelled as to its contents.

The primary receptacle must not become punctured, broken, weakened or affected by contact with the infectious substance. For example, the primary receptacle should not be corroded by the preservation media used to hold a patient specimen.

If the infectious substance is in a liquid or semi-liquid form, the primary receptacle must be wrapped in enough absorbent material to absorb all the fluid in the event of a breakage or leakage.



**Fig. 6.1. Examples of basic triple packaging materials**

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

### 6.1.2 SECOND LAYER

A second, watertight and leakproof or siftproof packaging is used to enclose and protect the primary receptacle, and its absorbent material.



Several primary receptacles may be placed in a single secondary packaging, provided they contain infectious substances of the same class. If the primary receptacle is fragile, each must be wrapped and placed in the secondary packaging individually, or in a way that prevents contact between them. Cushioning material may be required to secure the primary receptacles within the secondary packaging.

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### 6.1.3 THIRD LAYER

A third, outer layer of packaging is used to protect the secondary packaging from physical damage while in transit. Hence, this layer must be of an appropriate strength for the weight, size and composition of the inner packages, to ensure that those packages are protected. The smallest external dimension must be at least 100 mm.

Specimen data forms, letters, supplementary documentation and other types of information that identify or describe the infectious substance should be placed between the secondary packaging and outer layers of packaging. If necessary, these documents may be taped to the secondary packaging.

## 6.2 PACKING INSTRUCTION P650 (CATEGORY B INFECTIOUS SUBSTANCE REQUIREMENTS)

Packing instruction P650 provides a slightly more detailed set of triple packaging requirements than is the case for the basic triple packaging system. Infectious substances subclassified as Category B (UN 3373) and packaged in accordance with P650 may be considered safe and compliant for all modes of transportation. Such substances

are not subject to any other packaging requirement outlined in the UN model regulations, such as the more detailed testing and approval processes that are required for packaging of Category A infectious substances. Thus, it is generally feasible to source P650 compliant packaging materials from local manufacturers or suppliers. In this case, the manufacturers or suppliers should provide clear instructions for the user (shipper, sender or consignee) on how to correctly fill and close the package to ensure full compliance with P650. An example of triple packaging materials that may be used to comply with P650 for Category B infectious substances is shown in Fig. 6.2.

### Quantity limits (Category B)

For shipments being carried by air (passenger or cargo aircraft), the primary inner receptacle must not contain more than 1 L and the outer packaging must not contain more than 4 L of material. This excludes any quantity of coolants used, such as dry ice or liquid nitrogen.

For shipments being carried via surface transport (road, rail or maritime), there are no quantity limits per package.

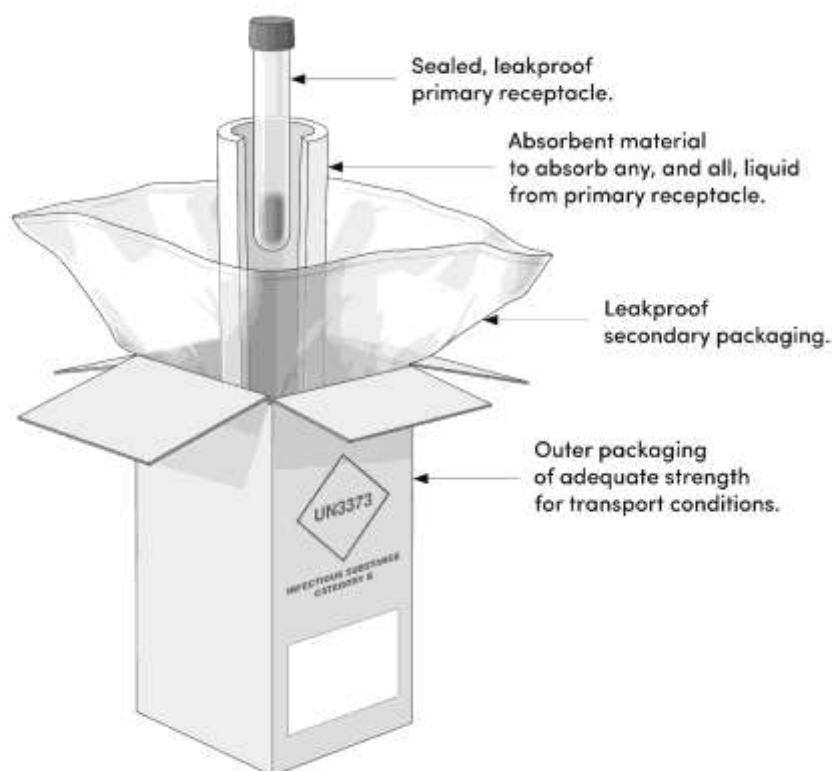
There is no comprehensive list of suppliers of packagings that comply with packing instructions P650 or P620. However, an online search (using terms such as “UN packaging” and “UN infectious substance packaging”) generally provides appropriate information, as well as access to national regulations. Carriers and forwarding agents (couriers or logistics companies) should also be able to supply details of local suppliers or local companies that can provide relevant information.

In addition to the basic triple packaging system, stipulations outlined in P650 include the following:

- For surface transport, either the secondary or outer packaging must be rigid; that is, if the outer packaging is soft, the secondary packaging must be rigid, or if the secondary packaging is soft, the outer packaging must be rigid. The latter is the most commonly applied arrangement, because a rigid outer packaging is always required for air transport.
- The complete triple package must be capable of passing a 1.2 m drop test, to prove that it is of an appropriate strength and quality.
- Either the primary receptacle or the secondary packaging must be capable of withstanding an internal pressure of 95 kPa (0.95 bar). This must be tested using an appropriate methodology that is based on the receptacle or packaging type being used (e.g. internal hydraulic or pneumatic pressure gauges, or external vacuum testing).

#### Test requirements

Further details on test requirements (e.g. for drop-testing and pressure differential testing) are given in subsection 6.3.5.3 of the UN model regulations.



**Fig. 6.2. Example of triple packaging materials that may be used to comply with P650 for Category B infectious substances**

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

### 6.3 PACKING INSTRUCTION P620 (CATEGORY A PACKAGING REQUIREMENTS)

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

---

### 6.3.1 PRIMARY RECEPTACLE

- Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging must be capable of withstanding a pressure differential of not less than 95 kPa, as well as temperatures in the range of  $-40\text{ }^{\circ}\text{C}$  to  $+55\text{ }^{\circ}\text{C}$ .
- When the shipment is being carried at ambient temperature (or above), the primary receptacle must be glass, metal or plastic. A positive means of ensuring a leakproof seal should be provided (e.g. a heat seal, skirted stopper or metal crimp seal). If screw caps are used, they should be secured by positive means (e.g. paraffin sealing tape, tape or manufactured locking closure).
- Lyophilized substances may also be transported in primary receptacles that are flame-sealed ampoules or rubber-stoppered glass vials fitted with metal seals.

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### 6.3.2 SECONDARY PACKAGING

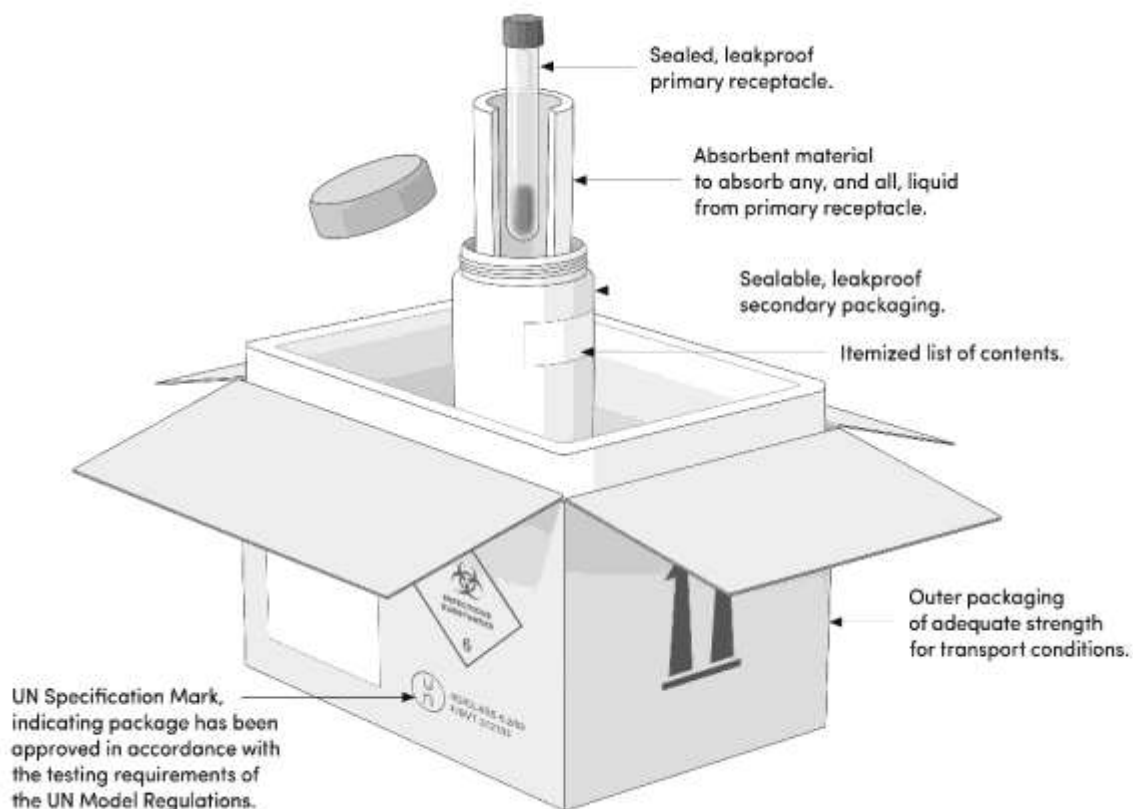
- As stated above, either the primary receptacle or this secondary packaging must be capable of withstanding a pressure differential of not less than 95 kPa, and temperatures in the range of  $-40\text{ }^{\circ}\text{C}$  to  $+55\text{ }^{\circ}\text{C}$ .

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### 6.3.3 THIRD, OUTER PACKAGING

- The outer packaging must be rigid.
- The smallest dimension of the package shall not be less than 100 mm.
- An itemized list of contents shall be enclosed between the secondary packaging and outer packaging, including the proper shipping name and technical name in brackets ("suspected Category A infectious substance" if the technical name is unknown) of the biological agent present in the infectious substance.

An example of triple packaging materials that may be used for Category A infectious substances is shown in Fig. 6.3.



**Fig. 6.3. Example of triple packaging materials that may be used for Category A infectious substances**

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

**Quantity limits (Category A)**

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

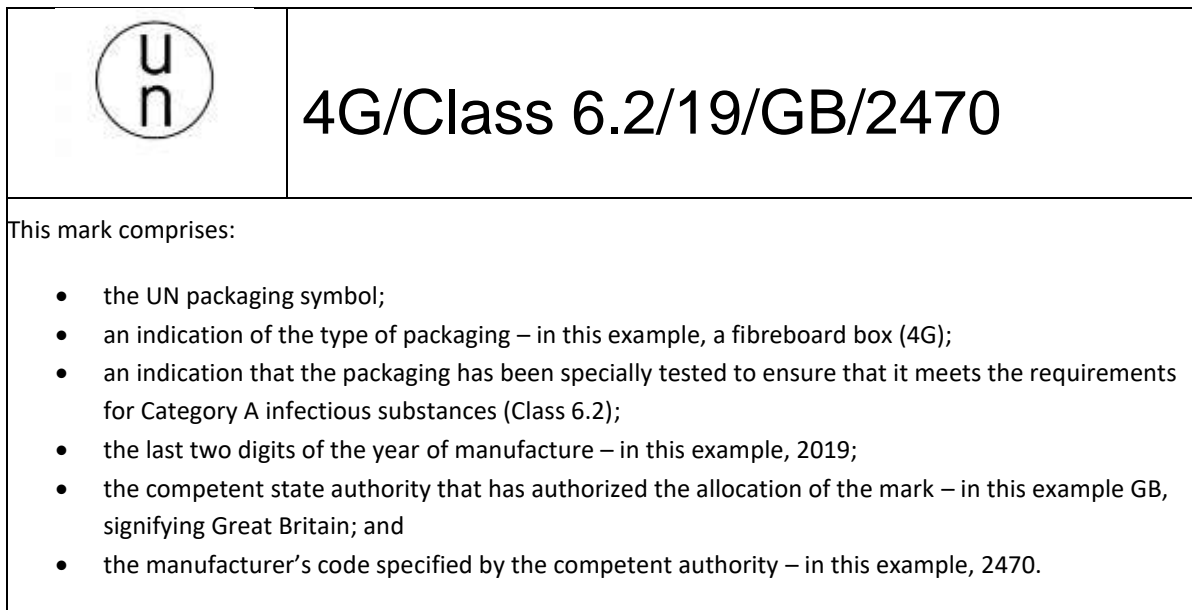
For shipments being carried on a cargo only aircraft, no more than 4 L or 4 kg of Category A infectious substance per package is allowed.

For shipments being carried via surface transport (e.g. road, rail or maritime), there are no quantity limits per package.

It is also necessary to verify the ability of packagings for Category A infectious substances to meet the requirements outlined above. The UN model regulations stipulate that Category A infectious substances must only be transported in a triple packaging system that has been tested according to the Requirements for the construction and testing of packagings for Division 6.2 infectious substances of Category A. The requirements detail the challenges and conditions that must be applied to the complete triple packaging system in order to verify the material quality (e.g. dropping, stacking and puncture tests, and the application of pressure, water spray and cold or high temperatures). Sub-section 6.3.5.3 of the UN model regulations provides details on the specific testing requirements.

Given the detailed and technical nature of the testing required, the manufacture of Category A “approved” packagings is generally performed by dedicated packaging specialists, and is governed by a quality assurance programme, overseen by a competent authority. Manufacturers should be able to demonstrate compliance with the requirements, by providing documentation and evidence of the methods used, and results obtained from package testing. Packagings that have been manufactured (and approved) in accordance with the UN model regulation requirements are

then to be marked with the UN packaging symbol, followed by a series of numerals and symbols that provide information on how, when and where the packaging was manufactured and approved.



**Fig. 6.4. Features of the UN specification mark for Category A infectious substances packaging (for UN 2814 and UN 2900)**

#### 6.4 PACKING INSTRUCTION P621 (MEDICAL OR CLINICAL WASTE REQUIREMENTS)

Medical or clinical waste that contains biological agents consistent with classification of Category B infectious substances is assigned to UN 3291. In turn, UN 3291 is subject to the packaging requirements outlined in the UN model regulations P621 (PI622 in ICAO and IATA documents).

Medical or clinical waste classified under UN 3291 does not have to conform to a triple layer of packaging. Thus, packagings for UN 3291 may comprise various types including drums, boxes, jerricans or composites, provided that these packagings conform to the general provisions outlined in the UN model regulations for a “Packing group II” level of performance. Packing group II performance levels may differ for liquid or solid infectious substances, but infectious substances containing liquid must be packed with sufficient absorbent material to absorb all liquid present.

Finally, UN 3291 infectious substances that may contain sharp objects (e.g. broken glass or needles) must be puncture resistant and suitably “leakproof”, as outlined in testing requirements for general dangerous goods packages in Chapter 6.1. of the UN model regulations.

#### 6.5 PACKING WITH COOLANTS

A coolant (also known as a refrigerant) is a substance that is used to maintain a cool temperature around the dangerous goods, to preserve their integrity until they reach their final destination. Many of the most commonly used coolants are themselves dangerous goods of other classes. Therefore, in addition to following the

requirements of the relevant packing instructions for infectious substances (i.e. P620, P621 and P650), other packaging requirements specific to these substances may need to be observed.

Some of the general requirements for packaging used to contain infectious substances together with a coolant material are as follows:

- Packaging used must be capable of maintaining integrity at the temperature afforded by the coolant.
- The coolant must be placed between the secondary packaging and outer packaging, or in an overpack used to transport multiple packages together (for more information on overpacks, see [Section 6.7](#)).
- Persons handling the packages should be appropriately trained on the coolants in use.
- Coordination between the shipper and carrier should ensure that the cargo transport unit being used to carry the packages is well ventilated for the coolants in use. In the case of air transport, it is especially important to ensure that ventilation safety procedures are followed. The carrier may also need to ensure that cargo transport units are appropriately marked with warning and hazard labels.

**Special provisions applicable to the use of dangerous goods as coolants are provided in Section 5.5.3 of the UN model regulations.**

The remainder of this section provides an overview for some of the more specific packing requirements for the commonly used coolants: wet ice, dry ice, liquid nitrogen and dry shippers. Additional requirements necessary for the marking, labelling and documentation of packages containing coolants are covered briefly in [Section 7](#). For detailed information, the relevant chapters of the UN model regulations should be consulted.

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#### 6.5.1 WET ICE

Wet ice is the term used to describe frozen, solid water. It is not considered a dangerous good and is therefore not assigned a proper shipping name or UN number. If wet ice is used, consideration should be given to a leakproof outer container to prevent water leakage, because ice may melt over time.

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#### 6.5.2 DRY ICE

Dry ice is one of the most commonly used coolants for the transport of infectious substances. It belongs to Dangerous Goods Class 9: Miscellaneous dangerous substances and articles, including environmentally hazardous substances. It is assigned the proper shipping name “Dry ice” or “Carbon dioxide, solid” and the UN number UN 1845.

Both P620 and P650 include packaging requirements for infectious substances shipped with dry ice. These instructions describe the importance of ensuring that the outer packaging must comprise a material that permits the release of carbon dioxide gas, such as Styrofoam. This is because dry ice will dissipate over time, turning from carbon dioxide solid into carbon dioxide gas, which is heavier than air and can create a build-up of pressure that could lead to an explosion if not effectively released. Hence, adequate ventilation safety procedures should be followed by the cargo transport unit carrying the package. Inserts or supporting material for the secondary packaging should be considered, to ensure that the container remains secure inside the outer package even once the dry ice has dispersed.

#### **Use of dry ice in air transport**

The ICAO technical instructions provide a specific packing instruction, PI954, which describes the necessary requirements for any dangerous goods shipment containing dry ice when transported by air.

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### 6.5.3 LIQUID NITROGEN

Liquid nitrogen is also commonly used in the transport of infectious substances. It belongs to Dangerous Goods Class 2: Gases, and is assigned the proper shipping name “Nitrogen refrigerated liquid cryogenic liquid” and the UN number UN 1977. Liquid nitrogen is used when extremely low temperatures are required to maintain the integrity of the shipment. Hence, both the primary and secondary packaging must be able to withstand extremely low temperatures without damage.

Because of the detail and complexity of the regulations, this document does not provide further guidance on the regulations applicable to shipments of liquid nitrogen (except for the use of liquid nitrogen as part of dry shippers, as described in [Section 6.5.4](#)). For more detailed information about shipments using free liquid nitrogen as a coolant, see the UN model regulations or other applicable modal agreements.

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### 6.5.4 DRY SHIPPERS

A dry shipper is a specialized outer packaging material that is insulated with a layer of liquid nitrogen fully absorbed into a porous material. This design ensures that liquid nitrogen is kept well contained inside the walls of the outer layer, even when its orientation is changed, and that pressure is prevented from building up inside.

Liquid nitrogen contained in a properly manufactured dry shipper is not subject to any other dangerous goods requirements. Thus, the package is not subject to the detailed requirements of free liquid nitrogen, but nevertheless maintains the extremely low temperatures that liquid nitrogen can provide.

The dry shipper must be appropriately marked and labelled to indicate the presence of infectious substances inside. More information on marking and labelling is given in [Section 7](#). The use of a dry shipper also needs to be indicated appropriately in shipment documentation, as described in [Section 8](#).

## 6.6 PACKING WITH STABILIZERS

A stabilizer is a chemical substance that is placed together with the infectious substance in the primary receptacle, to maintain viability, prevent degradation or preserve antigen integrity. Stabilizers commonly used with infectious substances include sorbitol, fetal bovine serum (FBS), alcohols, alcohol solutions or formaldehydes.

As with coolants, stabilizers may themselves be dangerous goods assigned to dangerous goods classes. However, certain stabilizers in Dangerous Goods Class 3 (alcohols), Class 8 (formaldehydes) or Class 9 meet the special provisions for “Dangerous goods packed in excepted quantities”. In this case, stabilizers present in the primary receptacle in a quantity of 30 mL or less are not subject to any other requirements of their dangerous goods class, so long as they are packed in accordance with either P620 or P650. For more detailed information on excepted quantities of dangerous goods, see Chapter 3.5 of the UN model regulations.

### **Inactivation by stabilizers**

Depending on the susceptibility of each biological agent, some stabilizers may cause inactivation of the biological agent, removing its ability to cause infection in humans or animals. In this case, sound professional judgement may be used to reclassify the substance as an exemption.

## 6.7 PACKING IN OVERPACKS

The term “overpack” describes several packages being combined to form one unit and sent to the same destination by a single shipper. If dry ice is used to protect contents, the overpacks may comprise insulated vessels or flasks, to allow dissipation of carbon dioxide gas.

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

## 6.8 REUSED PACKAGING

Packaging materials can be returned or reused. Before empty packaging is returned to the consigner, or sent elsewhere, it must be disinfected or sterilized to nullify any hazard; also, any label or mark indicating that it contained an infectious substance must be removed or obliterated. If the packaging is being reused, the shipper must ensure that all marks and labels reflect the substances actually being shipped and not the substance the packaging was used for previously.

Reused packaging must maintain its ability to comply with relevant quality testing procedures for Category A and Category B packaging. If packaging material becomes damaged or reduced in strength, it should no longer be used.



## SECTION 7: MARKING AND LABELLING

Once the correct packaging materials have been assembled, they must be properly marked and labelled to provide information about the contents of the package, the nature of the hazard and the packaging standards that have been applied. All marks and labels must be placed in such a way that they are clearly visible and not covered by any other label or mark.

### 7.1 MARKS

Marks that may be applicable to infectious substances shipments are provided in Table 7.1.

The following marks must be provided on the outer package of all infectious substances:

- the shipper's (sender's or consigner's) name and address;
- the receiver's (consignee's) name and address;
- the UN number of the infectious substance, followed by the proper shipping name of the substance (technical names do not need to be shown on the package); and
- when a coolant (e.g. dry ice) is used, the UN number and the proper shipping name of the coolant, followed by the words "AS COOLANT". In addition, the net quantity of coolant present should be given.

#### Net quantity

Net quantity refers to the total amount of a substance placed inside the package, not including the weight of excess substances such as the packaging or coolant materials.

The net quantity of dry ice may be particularly important for handling of the shipment as, along with the thermal capabilities of the packaging, it will determine how long a cool temperature can be maintained for preserving or stabilizing the infectious substance

in transit. In some cases, the net quantity of dry ice may need to be replenished while in transit to maintain cold chain through a long journey.

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

Additional marks may need to be used, depending on the infectious substance classification.

#### 7.1.1 ADDITIONAL MARKS FOR CATEGORY A INFECTIOUS SUBSTANCES

For Category A infectious substances, the following additional marks must be displayed:

- the UN packaging symbol and certification marks (numerals and letters, as shown in Fig. 6.4) – however, if an overpack is being used, the UN packaging symbol and certification marks should not be repeated on the overpack; and
- the name and telephone number of a responsible person, knowledgeable about the shipment.

### 7.1.2 ADDITIONAL MARKS FOR CATEGORY B INFECTIOUS SUBSTANCES

For Category B infectious substances, the mark shown in Fig. 7.1 must be displayed, as follows:



**Figure 1 Fig. 7.1 Example of the UN number format that must be used for Category B infectious substances**


- Specifications:** the width of the line forming the square must be at least 2 mm, and the letters or numbers must be at least 6 mm high. For air transport, each side of the square shall have a minimum dimension of 50 mm × 50 mm.
- Colour:** no colour is specified; however, the mark must be displayed on the outer packaging, on a background of contrasting colour, and be clearly visible and legible.


The proper shipping name (biological substance, Category B) in letters at least 6 mm high must be displayed adjacent to the mark.

### 7.1.3 MARKS ASSOCIATED WITH SHIPPING OF INFECTIOUS SUBSTANCES

Table 7.1 illustrates the various marks that are associated with shipping of infectious substances. Some marks are required on all packages, and others are specific to Category A or Category B packages.

**Table 7.1. Marks associated with infectious substances shipments**

|  |   |  |  |
|--|---|--|--|
| <p><b>SHIPPER</b><br/>PETER PAN<br/>TIMELY LOGISTICS<br/>BP 102<br/>I-0956666 NOLAND</p> <p><b>RECEIVER</b><br/>AB NORMAL<br/>FRANKENSTONE LAB<br/>RUE DE L'ESSAI<br/>F-9867 ADIEU</p> | <p>“To” and “From” marks, showing the name and address of the shipper and receiver; these are required for all packages</p> | <p><b>Infectious Substance Affecting Humans</b><br/><b>UN2814</b></p>                        | <p>The UN number and proper shipping name marks (for Category A packages)</p>                            |
|  <p><b>BIOLOGICAL SUBSTANCE</b><br/><b>CATEGORY B</b></p>   | <p>The UN number and proper shipping name marks (for Category B packages subclassified as UN 3373)</p>                      | <p><b>EMERGENCY CONTACT 24H/24H</b><br/><b>Dr RED PEPPER:</b><br/><b>+67 56 45 34 23</b></p> | <p>A 24-hour emergency contact person must be marked on all Category A infectious substance packages</p> |

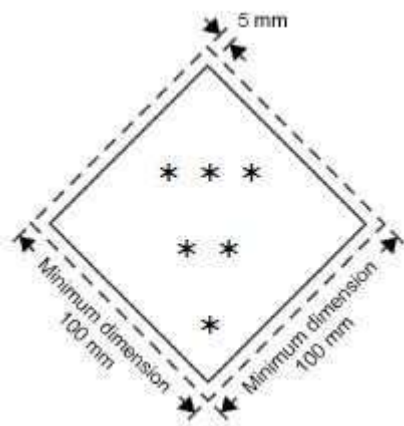
|   |  |               |                                  |                   |                 |
|---|--|---------------|----------------------------------|-------------------|-----------------|
|  <p><b>4G/CLASS<br/>6.2/19/GB/2470</b></p> <p>UN classification mark, indicating that the outer packaging has been tested according to UN standard, is required for all Category A infectious substance packages</p> | <table border="1" data-bbox="863 230 1091 499"> <tr><td><b>UN1845</b></td></tr> <tr><td><b>CARBON<br/>DIOXIDE, SOLID</b></td></tr> <tr><td><b>AS COOLANT</b></td></tr> <tr><td><b>Net 3 kg</b></td></tr> </table> <p>The UN number, proper shipping name followed by the words "AS COOLANT" should be used; the net quantity of coolant present should also be given</p> | <b>UN1845</b> | <b>CARBON<br/>DIOXIDE, SOLID</b> | <b>AS COOLANT</b> | <b>Net 3 kg</b> |
| <b>UN1845</b>   |  |               |                                  |                   |                 |
| <b>CARBON<br/>DIOXIDE, SOLID</b>  |  |               |                                  |                   |                 |
| <b>AS COOLANT</b>   |  |               |                                  |                   |                 |
| <b>Net 3 kg</b>   |  |               |                                  |                   |                 |

## 7.2 LABELS

There are two types of labels that may need to be used for packages of infectious substances – hazard labels and handling labels – as discussed below.

### 7.2.1 HAZARD LABELS

Hazard labels are always presented in the form of a square set at an angle of 45° (diamond shaped), as shown in Fig. 7.2. The minimum dimensions are 100 mm × 100 mm. If the package is very small, the label size may be reduced proportionately, provided that all elements of the label are easily visible.






**Fig. 7.2. An example of the diamond shape required to form any kind of dangerous goods hazard label**

Source: UN model regulations

There should be one hazard label affixed to the package for each dangerous good in the package (unless specifically exempted). This means that more than one hazard label may be required if the infectious substance is being shipped with a coolant (e.g. dry ice.).

Examples of hazard labels applicable to infectious substances shipments are given in Table 7.2.

**Table 7.2. Hazard labels applicable to infectious substances shipments**




|   |   |
|---|---|
|    | <p><b>Infectious substances hazard label.</b></p> <p><b>Required for:</b> Compulsory for all packages containing Category A infectious substances.</p> <p><b>Specifications:</b> The upper half of the diamond must display three crescents superimposed on a black circle. The lower half of the diamond should bear the inscriptions: “INFECTIOUS SUBSTANCE” and “In case of damage or leakage immediately notify Public Health Authority” in black colour. A number ‘6’ must be displayed in the bottom corner.</p> <p><b>Colour:</b> White background, black writing.</p> |
|   | <p><b>Miscellaneous dangerous good hazard label.</b></p> <p><b>Required for:</b> Infectious substance packages containing Class 9 substances (i.e. dry ice) as coolant.</p> <p><b>Specifications:</b> The upper portion must contain seven vertical stripes, and an underlined number ‘9’ must appear in the bottom corner.</p> <p><b>Colour:</b> White background, black writing.</p>  |
|  | <p><b>Non-flammable, non-toxic gas hazard label.</b></p> <p><b>Required for:</b> Infectious substances packages containing a Class 2, Division 2.2 compressed gas as a coolant (i.e. liquid nitrogen).</p> <p><b>Specifications:</b> Must show a symbol of a gas cylinder, with the number ‘2’ in the bottom corner.</p> <p><b>Colour:</b> Green, with writing in black or white.</p>   |

Source: all illustrations from IATA Infectious Substances Shipping Guidelines

### 7.2.2 HANDLING LABELS

Handling labels have various shapes, and can be affixed either alone or in addition to hazard labels, depending on the nature and quantity of dangerous goods present. Examples of these labels are shown in Table 7.3.

**Table 7.3. Handling labels that may be applicable to infectious substances shipments**

|  |  |
|--|--|
| <br> | <p><b>Orientation arrow labels.</b></p> <p><b>Required for:</b> Indicating the presence of a liquid in the package, requiring that the packages only be handled in the upright position to prevent leakage. For infectious substances, orientation arrows are required for all packages containing &gt;50 mL of infectious substance. These labels are not required for UN 3373 packages.</p> <p><b>Specifications:</b> The label must show two arrows pointing in the correct upright direction. The arrows must be rectangular and of a size that is clearly visible, commensurate with the size of the package. The label must appear on two opposite vertical sides of the package. A rectangular border around the arrows is optional.</p> <p><b>Colour:</b> Black or red arrows on a white, or suitably contrasting, background.</p> |
|    | <p><b>Cargo aircraft only (CAO) label.</b></p> <p><b>Required for:</b> Indicating that a package of infectious substances contains more than the quantity limits for passenger aircraft and is therefore eligible for transport by cargo aircraft only.</p> <p><b>Specifications:</b> Minimum dimensions of the label are 120 mm on the horizontal axis and 110 mm on the vertical axis. For small packages, these dimensions may be reduced by half.</p> <p><b>Colour:</b> Orange background, black writing.</p>  |
|   | <p><b>Cryogenic liquid warning label.</b></p> <p><b>Required for:</b> Infectious substances packages that are being transported by air and contain cryogenic liquids (deeply refrigerated liquefied gases) as a coolant (e.g. liquid nitrogen). This label must be used in addition to the hazard label for non-flammable, non-toxic gases. This label is <b>not</b> required if a specialized insulated packaging for liquid nitrogen (i.e. dry shipper) is used.</p> <p><b>Specifications:</b> Minimum dimensions of 75 mm on the horizontal axis and 105 mm on the vertical axis. The words <i>“Caution – may cause cold burn injuries if spilled or leaked”</i> may be included.</p> <p><b>Colour:</b> Green background, white writing.</p>  |

Source: red arrows from IATA infectious substances shipping guidelines, black arrows from UN Model regulations

## SECTION 8: DOCUMENTING SHIPMENTS

In most cases, the person preparing the infectious substance for shipment (i.e. the shipper, sender or consigner) will not be the person who transports and delivers the package to the final destination. Therefore, it is important that the person preparing the substance for shipment prepares any documentation required by applicable regulations, to inform those who will be carrying the package (i.e. the carrier, courier or logistician) about how the package was prepared and the dangerous goods that it contains.

Any information provided in transport documents should be easy to read and resilient (e.g. permanent ink that cannot be easily removed). If the document is more than one page, then pages should be consecutively numbered. Copies of any transport documents must be retained by the sender for a minimum of 3 months following the shipment, although different time periods may be required under certain modal agreements or variations. If both dangerous and non-dangerous goods are being recorded on the same document, the dangerous goods must always be listed first.

In some instances, shipping of an infectious substance requires certificates of approval from national competent authorities. Generally, these certificates do not need to accompany a shipment, but the shipper must be able to make them available on request. For international shipments where different approvals are required of the various countries involved, the UN number and proper shipping name provided in the transport document must be in accordance with the certificate of the country of origin of design.

### Electronic data

In some cases, electronic data processing (EDP) or electronic data interchanges (EDI) may be used as an alternative to paper documentation, but this must only be done with the pre-approval of the carrier. Where electronic data are used, electronic signatures and initials for certifications or declarations will be acceptable. However, the shipper must always be able to produce a paper document copy of all information on request.

This section describes some of the mostly commonly required documents for the shipment of infectious substances; that is, a dangerous goods transport document, a spill clean-up procedure and an air waybill.

### 8.1 DANGEROUS GOODS TRANSPORT DOCUMENT

As outlined in the UN model regulations, a certain minimum set of information should be recorded for any infectious substance in the form of a “Dangerous goods transport document” (DGTD). A DGTD is required for all shipments of Category A infectious substances (UN 2814, UN 2900) and for medical or clinical wastes (UN 3291). However, Category B infectious substances assigned to UN 3373 that are packaged according to P650 are said to no longer be subject to these requirements of the UN model regulations, meaning that a DGTD is not required.

According to the UN model regulations and ICAO technical instructions, the DGTD may take any form, provided that the minimum information requirements (as outlined below) are met. However, modal agreements or national regulations may also stipulate their own formats for this document, such as the commonly used “Dangerous goods declaration (DGD)” form used for air transport. Equivalent variations may be required for shipments by road, sea or rail, as described in the relevant modal agreements.

The following information is considered the minimum to meet the UN model regulation requirements for a DGTD for documenting a shipment of infectious substances. However, it is important to ensure that other regulations

for documentation applicable to the shipment are also consulted, so that any other essential information stipulated by these regulations is also included. For example, shipments by air may require additional information such as departure and arrival airport information, and reference numbers for other transport documents (e.g. an air waybill). Shippers should check with their carrier/operator to ensure that the correct form of the document is used, and for any special instructions that must be followed to ensure that it is filled in correctly.

The following information needs to be included:

- the sender and receiver;
- the date;
- a description of the dangerous goods;
- the type and net quantity of dangerous goods for each package;
- handling requirements;
- emergency response information; and
- certification (shipper's declaration).

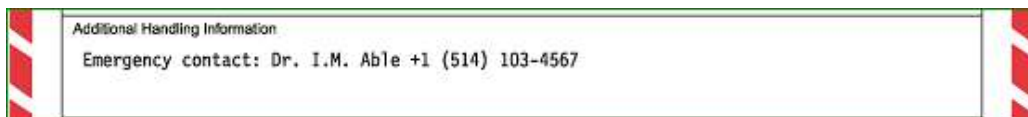
The requirements for each of these types of information are discussed below.

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#### 8.1.1 SENDER AND RECEIVER INFORMATION

The name and address of the shipper (consignor) and the receiver (consignee) of the dangerous goods shall be included.

For infectious substances packages, the name and contact phone number for a 'responsible person', knowledgeable about the infectious substance, must also be provided (who may be the same or different to the shipper or receiver), and should be available for contact at all times throughout the shipment process. Fig. 8.1 gives an example of how such information can be displayed.



**Fig. 8.1. An example of emergency contact information to be provided on a DGTD**

*SOURCE: IATA Infectious Substances Shipping Guidelines*

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#### 8.1.2 DATE

The label should display the date on which the transport document (or an electronic copy of it) was prepared or given to the initial carrier.

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#### 8.1.3 DESCRIPTION OF THE DANGEROUS GOODS

A description of the dangerous goods should include the following information in the following order:

1. UN number (e.g. UN 2814, UN 2900).
2. Proper shipping name (e.g. Infectious substance, affecting humans). For Category A infectious substances, the technical name must follow the proper shipping name in brackets.
3. The primary hazard class and/or division (i.e. Class 6, Division 6.2).
4. The subsidiary hazard class – infectious substances do not have subsidiary classes, but this may be applicable to other dangerous goods that present multiple hazards; for example, methanol is Class 3, Subsidiary class 6.1.
5. If applicable, any packing group used for preparing the package – because the packing required for infectious substances is always a triple-layer package, a “packing group” is not assigned; however, packing groups may be applicable to other parts of the shipment (e.g. “PG II” should be used if a dry shipper is included).
6. Any other descriptive information required under other applicable national or international regulations.

**Example of a description of dangerous goods**

UN 2814, INFECTIOUS SUBSTANCE, AFFECTING HUMANS (Dengue virus), CLASS 6 DIVISION 6.2, PGII

A description of each dangerous good present in the package is required. Therefore, if a coolant such as dry ice is present, two entries will be required under this description.

#### 8.1.4 TYPE AND NET QUANTITY OF DANGEROUS GOODS FOR EACH PACKAGE

The number of packages, the type or material of outer packaging used (e.g. fibreboard box, plastic drum) and the net quantity of the dangerous good in each package must be provided. Quantity should be given by volume (e.g. mL, L) or mass (e.g. g, kg) as appropriate.

**Example of information on type and net quantity**

150 mL, packed in 3 solid plastic boxes (dry shippers, 4H2)

If more than one dangerous good is present (e.g. dry ice) then this information must be provided for each dangerous good. If a dry shipper or an overpack is used, this should also be indicated here, showing the type and quantity of the individual packages contained within.

**Net and gross**

Net refers to the total quantity of the dangerous good alone; for example, 40 mL net quantity of a bacterial culture.

Gross refers to the total mass of the package; for example, 50 g (0.05 kg) of culture, in 1 kg of dry ice wrapped in 1 kg of packaging materials = gross quantity of 2.05 kg.

#### 8.1.5 HANDLING REQUIREMENTS

Handling requirements are actions (if any) that are required to be taken by the carrier in the treatment of the package. Such requirements may be stipulated by the carrier or national or international authorities, but should at least include:

- supplementary requirements for handling (e.g. loading, stowing and unloading) – if none are required, a statement saying “No such requirements are necessary” should be provided;
- any restrictions that apply on the mode of transportation that can or must be used or any routing instructions; and
- emergency arrangements applicable to the package.



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### 8.1.6 EMERGENCY RESPONSE INFORMATION

All shipments of infectious substances in Category A must have the name and telephone number of a person responsible for the shipment marked on the package(s) and on the shipper's declaration (in the "Additional handling information" section). Infectious substances in Category B, UN 3373, must have the name, address and telephone number of a responsible person marked on either the package or on the air waybill.

In addition to emergency contact information, **appropriate information should be immediately available for carriers to use in emergency response to accidents or incidents involving infectious substances packages during transport.** This may include contact information for public health authorities, medical or first aid requirements (e.g. prophylaxis for exposed persons) or procedures for spill clean-up.

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### 8.1.7 CERTIFICATION (SHIPPER'S DECLARATION)

A statement should be given on the form from the shipper, acknowledging that the package has been prepared according to the applicable requirements. This statement must be signed and dated (see the example in Fig. 8.2).

**Example of a shipper's declaration**

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

The image shows a rectangular form with a white background and a thin black border. On the left and right sides, there are vertical red and white diagonal stripes. The form contains the following text:

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

Name of Signatory  
B. Smith

Date  
1 Jan 2019

Signature  
(See warning above) *B. Smith*

**Fig. 8.2 An example of a signed and dated shipper's declaration**

*SOURCE: IATA Infectious Substances Shipping Guidelines*

## 8.2 SPILL CLEAN-UP PROCEDURE

As part of the minimum information to be recorded on a DGTD, emergency response information should be available for relevant personnel, for use in the event that a breach of packaging occurs. The following spill clean-up procedure has been adapted from information presented in WHO's *Laboratory biosafety manual*,<sup>1</sup> and

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<sup>1</sup> Laboratory biosafety manual (3rd ed). Geneva: World Health Organization; 2004 (<https://apps.who.int/iris/handle/10665/42981>, accessed 7 July 2019).

represents an example of information that could be helpful for emergency response to an infectious substances spill.

The appropriate response in the event of exposure to any infectious substance is to wash or disinfect the affected area as soon as possible, regardless of the nature of the agent. Even if an infectious substance comes into contact with broken skin, washing of the affected area with soap and water or with an antiseptic solution can reduce the risk of infection. Medical advice should be obtained whenever there is a suspected exposure to infectious substances resulting from a damaged package.

The following procedure for clean-up can be used for spills of all infectious substances including blood. The person must be trained in such a procedure before performing these steps:

1. Wear gloves and protective clothing, including face and eye protection if indicated.
2. Cover the spill with a cloth or paper towels to contain it.
3. Pour an appropriate disinfectant over the cloth or paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).
4. Apply the disinfectant concentrically, beginning at the outer margin of the spill area, working towards the centre.
5. After about 30 minutes, clear away the materials. If there is broken glass or if other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.
6. Clean and disinfect the area of the spillage (if necessary, repeat steps 2–5).
7. Dispose of contaminated materials into a leakproof, puncture-resistant waste disposal container.
8. After successful disinfection, report the incident to the competent authority and inform them that the site has been decontaminated (see Incident reporting below).

#### Use of air waybills

Shipments of all goods by air are accompanied with an air waybill, even if they do not contain dangerous goods.

Even exempt human and exempt animal specimens, exempted from all other regulations, may be accompanied by an air waybill.

For these shipments, the phrase “exempt specimens” should be provided in the nature and quantity of goods box of the air waybill.

If shipped with coolant, the proper shipping name, UN number and new quantity of coolant in the package should also be provided.

Detailed information on disinfectants and their recommended use can be found in WHO’s *Laboratory biosafety manual*.<sup>2</sup>

### 8.3 AIR WAYBILL

An air waybill is a commonly requested shipping document that is part of the general condition of carriage for any goods via international air transport. Therefore, an air waybill must accompany all shipments of infectious

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<sup>2</sup> Laboratory biosafety manual (3rd ed). Geneva: World Health Organization; 2004 (<https://apps.who.int/iris/handle/10665/42981>, accessed 7 July 2019).

substance, even if a DGTD has already been filled out. It is common practice for the carrier to be the one to fill out the air waybill; however, in some circumstances the shipper will be asked to provide this.

The format of the air waybill will vary across carriers, operators and countries. Much like the DGTD, the air waybill will contain a number of general sections outlining information about the shipment, such as the shipper’s and receiver’s name and address, carrier information, and quantities and types of packages. However, there are two main sections pertaining to the nature of the hazard that must be carefully completed for infectious substances– the “Handling information” box and the “Nature and quantity of goods” box, as outlined below.

### 8.3.1 HANDLING INFORMATION BOX

- For Category A infectious substances – the statement “*Dangerous Goods as per Attached Shipper’s Declaration*” should be provided; if applicable (i.e. the volume of substance is >50 mL) the statement “*Cargo Aircraft Only*” or “*CAO*” should also be provided.
- For Category B infectious substances – contact information for a “responsible person”, knowledgeable about the shipment and available throughout the shipment process, should be provided.

### 8.3.2 NATURE AND QUANTITY OF GOODS BOX

- For Category A infectious substances – a general description of the substance can be provided, such as “laboratory samples”, “pathology samples”, or “infectious substance”.
- For Category B infectious substances – the UN number, proper shipping name and number of packages should be provided; if the substance is being shipped with dry ice, the UN number, proper shipping name and net quantity of dry ice should also be provided.

Fig. 8.3 shows an example of an air waybill that has been completed for a Category A infectious substance.

| Airport of Destination                                |              | Requested Flight/Date |                                  | Amount of Insurance | INSURANCE – If carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures in box marked “Amount of Insurance”. |       |   |
|---|--------------|-----------------------|----------------------------------|---------------------|---|-------|---|
| Handling Information                                  |              |                       |                                  |                     |   |       |   |
| Dangerous Goods as per attached Shipper's Declaration |              |                       |                                  |                     |   |       | SCI   |
| No. of Pieces RCP                                     | Gross Weight | kg<br>lb              | Rate Class<br>Commodity Item No. | Chargeable Weight   | Rate<br>/ Charge  | Total | Nature and Quantity of Goods (incl. Dimensions or Volume) |
|   |              |                       |                                  |                     |   |       | Pathology Samples   |

**Fig. 8.3. An example of a completed air waybill for a Category A infectious substance**

SOURCE: IATA Infectious Substances Shipping Guidelines

## ANNEX 1: WEBLINKS TO INTERNATIONAL REGULATIONS AND MODAL AGREEMENTS

Please note, all websites were current at 31 December 2018.

The United Nations (UN) dangerous goods website provides comprehensive detail concerning the UN recommendations on the transport of dangerous goods. It also provides links to the modal agencies:

<https://www.unece.org/trans/danger/danger.html>

The full text of the UN recommendations on the transport of dangerous goods, which can be downloaded in PDF format, can be found at:

[https://www.unece.org/trans/danger/publi/unrec/rev19/19files\\_e.html](https://www.unece.org/trans/danger/publi/unrec/rev19/19files_e.html)

The full text of the *European agreement concerning the international carriage of dangerous goods by road* (ADR) of 2017 can be found at:

<https://www.unece.org/trans/danger/publi/adr/adr2017/17contentse0.html>

The amendments and corrections to the ADR (which have been in force since 1 January 2017) can be found at:

[https://www.unece.org/trans/danger/publi/adr/adr2015\\_amend.html](https://www.unece.org/trans/danger/publi/adr/adr2015_amend.html)

Country-specific information and competent authorities for the enforcement of the ADR can be found at:

[https://www.unece.org/trans/danger/publi/adr/country-info\\_e.html](https://www.unece.org/trans/danger/publi/adr/country-info_e.html)

**Other modal agreements may be available for purchase by accessing the following websites.**

|             |   |
|-------------|---|
| <b>Air</b>  | <p>The <i>Technical instructions for the safe transport of dangerous goods by air</i> (International Civil Aviation Organization [ICAO] technical instructions) can be found at:</p> <p><a href="http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx">http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx</a></p> <p>Copies of state variations can be found at:</p> <p><a href="http://www.icao.int/safety/DangerousGoods/Pages/StateVariationPage.aspx">http://www.icao.int/safety/DangerousGoods/Pages/StateVariationPage.aspx</a></p> |
| <b>Rail</b> | <p>The international carriage of dangerous goods by rail (RID) regulations, created by the Intergovernmental Organisation for International Carriage by Rail (OTIF), can be found at:</p> <p><a href="http://otif.org/en/?page_id=174">http://otif.org/en/?page_id=174</a></p>  |

|             |  |
|-------------|--|
|             | <p>The RID regulations primarily apply to countries in Europe, the Middle East and North Africa. Several countries (mainly in Asia and Eastern Europe) apply RID through the Organization for Cooperation of Railways (OSJD). Details of OTIF membership can be found at:</p> <p><a href="http://otif.org/en/?page_id=51">http://otif.org/en/?page_id=51</a></p> |
| <b>Sea</b>  | <p>The <i>International Maritime Dangerous Goods Code (IMDG)</i> of the International Maritime Organization (IMO) can be found at:</p> <p><a href="http://www.imo.org/en/Publications/IMDGCode/Pages/Default.aspx">http://www.imo.org/en/Publications/IMDGCode/Pages/Default.aspx</a></p>  |
| <b>Post</b> | <p>The <i>letter post regulations final protocol</i> of the Universal Postal Union (UPU) may be found at:</p> <p><a href="http://www.upu.int/en/activities/letter-post/key-documents.html">http://www.upu.int/en/activities/letter-post/key-documents.html</a></p>   |

## ANNEX 2: SPECIAL PROVISIONS

“Special provisions” is a term used to describe certain circumstances or procedures that are not covered in standard regulations. These provisions supplement or modify the original regulations, indicating the dangerous good to which they apply can be shipped appropriately.

The following special provisions (written as found in the UN model regulations) may be applicable to some shipments of infectious substances. Numbers in parentheses ( ) indicate an equivalent special provision number for shipments being carried by air (as listed in the International Civil Aviation Organization [ICAO] technical instructions). Air-specific provisions are listed at the end:

- **144 (A58)** – An aqueous solution containing not more than 24% alcohol by volume is not subject to these Regulations.

**219 (A47)** – Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) packed and marked in accordance with packing instruction P904 [Packing Instruction 959 for A47] are not subject to any other requirements in these Regulations.

**223 (A3)** – If the chemical or physical properties of a substance covered by this description are such that when tested it does not meet the established defining criteria for the class or division listed in Column 3 of the Dangerous Goods List of Chapter 3.2, or any other class or division, it is not subject to these Regulations.

- **276 (A27)** – This includes any substance which is not covered by any of the other classes but which has narcotic, noxious or other properties such that, in the event of spillage or leakage on an aircraft, annoyance or discomfort could be caused to crew members so as to prevent the correct performance of assigned duties.

**279 (A113)** – The substance is assigned to this classification or packing group based on human experience rather than the strict application of classification criteria set out in these regulations.

- **318 (A140)** – For the purposes of documentation, the proper shipping name must be supplemented with the technical name (see 3.1.2.8). Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN2814 or UN2900, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the transport document, but not on the outer packagings.

Air transport specific special provisions applicable to some shipments of infectious substances may include the following (taken directly from the ICAO technical instructions, any references contained within these provisions should be sought from these Instructions):

- **A48** – Packaging tests are not considered necessary.
- **A81** – The quantity limits shown in columns 11 and 13 do not apply to body parts, organs or whole bodies.
- **A104** – A toxic subsidiary risk label, although not required by these Instructions, may be applied.

- **A117** –Wastes containing Category A infectious substances must be assigned to UN 2814 or UN 2900. Wastes transported under UN 3291 are wastes containing infectious substance in Category B or wastes that are reasonably believed to have a low probability of containing infectious substances. Decontaminated wastes which previously contained infectious substances may be considered as not subject to these Instructions unless the criteria of another class or division are met.
  
- **A151** – When dry ice is used as a refrigerant for other than dangerous goods loaded in a unit load device or other type of pallet, the quantity limits per package shown in columns 11 and 13 of Table 3-1 for dry ice do not apply. In such case, the unit load device must be identified to the operator and must allow the venting of the carbon dioxide gas to prevent a dangerous build-up of pressure.
  
- **A152** – Insulated packagings conforming to the requirements of Packing Instruction 202 containing refrigerated liquid nitrogen fully absorbed in a porous material are not subject to these Instructions provided the design of the insulated packaging would not allow the build-up of pressure within the container and would not permit the release of any refrigerated liquid nitrogen irrespective of the orientation of the insulated packaging and any outer packaging or overpack used is closed in a way that will not allow the build-up of pressure within that packaging or overpack. When used to contain substances not subject to these Instructions, the words “not restricted” and the special provision number A152 must be provided on the air waybill when an air waybill is issued.
  
- **A180** – Non-infectious specimens, such as specimens of mammals, birds, amphibians, reptiles, fish, insects and other invertebrates containing small quantities of UN 1170 (ethanol), UN 1198 (formaldehyde solution, flammable), UN 1987 (alcohols, n.o.s.) or UN 1219 (isopropanol), are not subject to these Instructions provided the following packing and marking requirements are met:
  - a. specimens are:
    - i. wrapped in paper towel and/or cheesecloth moistened with alcohol or an alcohol solution, and then placed in a plastic bag that is heat-sealed. Any free liquid in the bag must not exceed 30 mL; or
    - ii. placed in vials or other rigid containers with no more than 30 mL of alcohol or an alcohol solution;
  - b. the prepared specimens are then placed in a plastic bag that is then heat-sealed;
  - c. the bagged specimens are then placed inside another plastic bag with absorbent material then heat-sealed;
  - d. the finished bag is then placed in a strong outer packaging with suitable cushioning material;
  - e. the total quantity of flammable liquid per outer packaging must not exceed 1 L; and
  - f. the completed package is marked “scientific research specimens, not restricted. Special Provision A180 applies”.

The words “not restricted” and the special provision number A180 must be provided on the air waybill when an air waybill is issued.

ANNEX 3: INDICATIVE LIST OF BIOLOGICAL AGENTS SUBCLASSIFIED AS CATEGORY A

| Indicative examples of infectious substances included in Category A in any form unless otherwise indicated |  |
|--|--|
| UN number and proper shipping name   | Microorganism  |
| UN 2814<br><br>Infectious substance, affecting humans  | <i>Bacillus anthracis</i> (cultures only)  |
|  | <i>Brucella abortus</i> (cultures only)  |
|  | <i>Brucella melitensis</i> (cultures only)   |
|  | <i>Brucella suis</i> (cultures only)   |
|  | <i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only)  |
|  | <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only) |
|  | <i>Chlamydia psittaci</i> – avian strains (cultures only)                          |
|  | <i>Clostridium botulinum</i> (cultures only)                                       |
|  | <i>Coccidioides immitis</i> (cultures only)  |
|  | <i>Coxiella burnetii</i> (cultures only)   |
|  | Crimean-Congo haemorrhagic fever virus   |
|  | Dengue virus (cultures only)   |
|  | Eastern equine encephalitis virus (cultures only)                                  |
|  | <i>Escherichia coli</i> , verotoxigenic (cultures only)                            |
|  | Ebola virus  |
|  | Flexal virus   |
|  | <i>Francisella tularensis</i> (cultures only)                                      |
|  | Guanarito virus  |
|  | Hantaan virus  |
|  | Hantaviruses causing haemorrhagic fever with renal syndrome                        |



|  |
|--|
| Hendra virus   |
| Hepatitis B virus (cultures only)                        |
| Herpes B virus (cultures only)                           |
| Human immunodeficiency virus (cultures only)             |
| Highly pathogenic avian influenza virus (cultures only)  |
| Japanese Encephalitis virus (cultures only)              |
| Junin virus  |
| Kyasanur Forest disease virus                            |
| Lassa virus  |
| Machupo virus  |
| Marburg virus  |
| Monkeypox virus  |
| <i>Mycobacterium tuberculosis</i> (cultures only)        |
| Nipah virus  |
| Omsk haemorrhagic fever virus                            |
| Poliovirus (cultures only)                               |
| Rabies virus (cultures only)                             |
| <i>Rickettsia prowazekii</i> (cultures only)             |
| <i>Rickettsia rickettsii</i> (cultures only)             |
| Rift Valley fever virus (cultures only)                  |
| Russian spring-summer encephalitis virus (cultures only) |
| Sabia virus  |
| <i>Shigella dysenteriae type 1</i> (cultures only)       |
| Tick-borne encephalitis virus (cultures only)            |

|   |  |
|---|--|
|   | Variola virus  |
|   | Venezuelan equine encephalitis virus (cultures only)                           |
|   | West Nile virus (cultures only)  |
|   | Yellow fever virus (cultures only)   |
|   | <i>Yersinia pestis</i> (cultures only)   |
| <b>UN 2900</b>  | African swine fever virus (cultures only)                                      |
| <b>Infectious substance,<br/>affecting animals only</b> | Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only) |
|   | Classical swine fever virus (cultures only)                                    |
|   | Foot and mouth disease virus (cultures only)                                   |
|   | Lumpy skin disease virus (cultures only)                                       |
|   | <i>Mycoplasma mycoides</i> – Contagious bovine pleuropneumonia (cultures only) |
|   | Peste des petits ruminants virus (cultures only)                               |
|   | Rinderpest virus (cultures only)   |
|   | Sheep-pox virus (cultures only)  |
|   | Goatpox virus (cultures only)  |
|   | Swine vesicular disease virus (cultures only)                                  |
|   | Vesicular stomatitis virus (cultures only)                                     |

## ANNEX 4: PACKING INSTRUCTIONS

This annex provides the four packing instructions that may be relevant to the transport of infectious substances; that is, packing instruction P620, P650, P621 and P1954. [Sections A4.1–4.3](#) (P620, P650 and P621) are based on the United Nations (UN) model regulations. There may be additional requirements in equivalent packing instructions in modal agreements (e.g. PI620 and PI650 for air transport). [Section A4.4](#) is based on the International Civil Aviation Organization (ICAO) technical instructions. There is no equivalent for this packing instruction in the UN model regulations.

### A4.1 PACKING INSTRUCTION P620

**This instruction applies to UN 2814 and UN 2900, and the chapter and section numbers referenced in this instruction are from the UN model regulations.**

The following packagings are authorized, provided the special packing provisions described below are met.

Packagings meeting the requirements of Chapter 6.3 of the UN model regulations, and approved accordingly, and 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 fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them; and
- (b) a rigid outer packaging comprising:
  - drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1, 1H2, 1D, 1G);
  - boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2); or
  - jerricans (3A1, 3A2, 3B1, 3B2, 3H1, 3H2).

The smallest external dimension shall be not less than 100 mm (4 in).

### **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. Plastic primary receptacles capable of withstanding very low temperatures 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 consignment 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) Lyophilized substances may also be transported 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  $-40\text{ }^{\circ}\text{C}$  to  $+55\text{ }^{\circ}\text{C}$  ( $-104\text{ }^{\circ}\text{F}$  to  $+130\text{ }^{\circ}\text{F}$ ).
4. Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosive substances) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) 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 these regulations when packed in accordance with this packing instruction.
5. Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.

### **Special packing provisions**

1. Shippers 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

transport.

2. An itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A, the words “suspected category A infectious substance” shall be shown, in parentheses, following the proper shipping name on the document inside the outer packaging.
3. Before an empty packaging is returned to the shipper, or sent elsewhere, it must be disinfected or sterilized to nullify any hazard, and any label or mark indicating that it had contained an infectious substance must be removed or obliterated.

#### A4.2 PACKING INSTRUCTION P650

**This packing instruction applies to UN 3373, and the chapter and section numbers referenced in this instruction are from the UN model regulations.**

1. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between cargo transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.
2. The packaging shall consist of at least three components:
  - (a) a primary receptacle
  - (b) a secondary packaging, and
  - (c) an outer packagingof which either the secondary or the outer packaging shall be rigid.
3. Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings 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 transport, 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 each side having a length of at least 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.



5. At least one surface of the outer packaging must 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 of these regulations 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;
  - (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 a 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; and
  - (e) the primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).
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; and
  - (d) if there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport 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.
  - (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.
11. Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these regulations.
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 transport.
13. Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 mL or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosive substances) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these instructions need to be met.

**Additional requirement**

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.

**A4.3 PACKING INSTRUCTION P621**

**This packing instruction applies to UN 3291, and the chapter and section numbers referenced in this instruction are from the UN model regulations.**

The following packagings are authorized provided that the general provisions of 4.1.1 except 4.1.1.15 and 4.1.3 are met.

1. Provided that there is sufficient absorbent material to absorb the entire amount of liquid present and the packaging is capable of retaining liquids:
  - drums (1A2, 1B2, 1N2, 1H2, 1D, 1G);
  - boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2); and
  - jerricans (3A2, 3B2, 3H2).

Packagings shall conform to the packing group II performance level for solids.

2. For packages containing larger quantities of liquid:
  - drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1, 1H2, 1D, 1G);
  - jerricans (3A1, 3A2, 3B1, 3B2, 3H1, 3H2); and
  - composites (6HA1, 6HB2, 6HG1, 6HH1, 6HD1, 6HA2, 6HB2, 6HC, 6HD2, 6HG2, 6HH2, 6PA1, 6PB1, 6PG1, 6PD1, 6PH1, 6PH2, 6PA2, 6PB2, 6PC, 6PG2 or 6PD2).

Packagings shall conform to the packing group II performance level for liquids.

**Additional requirement**

Packagings intended to contain sharp objects such as broken glass and needles shall be resistant to puncture and retain liquids under the performance test conditions in Chapter 6.1.

**A4.4 PACKING INSTRUCTION PI 954**

**This packing instruction applies to passenger and cargo aircraft for UN 1845, and the chapter and section numbers referenced in this instruction are from the ICAO technical instructions.**

Part 4, Chapter 1 requirements must be met, including:

1. Compatibility requirements: substances must be compatible with their packagings as required by 4;1.1.3; and
2. Closure requirements: closures must meet the requirements of 4;1.1.4.

| <i>UN number and proper shipping name</i> | <i>Quantity – passenger</i> | <i>Quantity – cargo</i> |
|---|-----------------------------|-------------------------|
| UN 1845 Carbon dioxide, solid or dry ice  | 200 kg                      | 200 kg                  |

**Additional packing requirements**

1. In packages:

- (a) must be packed in accordance with the general packing requirements of 4;1 and be in packaging designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging;
- (b) the shipper must make arrangements with the operator(s) for each shipment, to ensure that ventilation safety procedures are followed;
- (c) the dangerous goods transport document requirements of 5;4 are not applicable provided alternative written documentation is provided describing the contents. The information on the document must be shown in the location provided for the description of the goods. Where an agreement exists with the operator, the shipper may provide the information by electronic data processing (EDP) or electronic data interchange (EDI) techniques. The information required is as follows and should be shown in the following order:
  - (i) UN 1845;
  - (ii) carbon dioxide, solid or dry ice;
  - (iii) the number of packages and the net quantity of dry ice in each package; and
- (d) the net mass of the carbon dioxide, solid or dry ice must be marked on the outside of the package.

2. Dry ice used for other than dangerous goods may be shipped in a unit load device or other type of pallet prepared by a single shipper provided that:

- (a) the shipper has made prior arrangements with the operator;
- (b) the unit load device, or other type of pallet, must allow the venting of the carbon dioxide gas to prevent a dangerous build-up of pressure (the marking requirements of 5;2 and the labelling requirements of 5;3 do not apply to the unit load device); and
- (c) the shipper must provide the operator with written documentation or, where agreed with the operator, information by EDP or EDI techniques, stating the total quantity of the dry ice contained in the unit load device or other type of pallet.