DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Montreal, 18 to 22 April 2005

DRAFT GUIDANCE DOCUMENT (WHO)

Introduction

The following guidelines replace WHO/EMC/97.3. This document explains the changes that will apply in all modes of transport from 2005. It should be noted that the Risk Group concept that had formed the basis of the regulations up until 2004 is now replaced by a completely new system and is not related to Risk Groups Those readers wishing to understand the rationale behind the new system should study WHO/CDS/CSRL/LYO/2004.9 which can be downloaded from the WHO web site at:

http://www.who.int/csr/resources/publications/WHO_CDS_CSR_LYO_2004_9/en/

These guidelines are applicable to the transport of infectious substances and diagnostic specimens both nationally and internationally. They provide information for identifying and classifying the material to be transported and for its safe packaging and transport. The guidelines stress the importance of developing a working relationship between the groups involved - the sender, the carrier and the receiver - in order to provide for the safe and expeditious transport of this material.

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

There are no recorded cases of illness attributable to the release of specimens during transport, although there are reported incidents of damage to the outer packaging of properly packaged materials. The shipment of unmarked and unidentified infectious materials, improperly packaged, obviously increases the overall potential for exposure to all persons. Damage to packaging also means samples despatched for urgent analysis are unlikely to meet their destination.

The international regulations for the transport of infectious materials by any mode of transport are based upon the Recommendations of the United Nations Committee of Experts on the Transport of Dangerous Goods (UN). The Recommendations are reflected in international law through international modal agreements:

Air **The Technical Instructions For The Safe Transport Of Dangerous Goods By Air published by the International Civil Aviation Organisation (ICAO). The International Air Transport Association (IATA) in their Dangerous Goods Regulations also publishes the rules. The rules are applicable wherever there are international flights.**

Rail **Regulations Concerning The International Carriage Of Dangerous Goods By Rail (RID). These rules apply to Europe, the Middle East and North Africa.**

Road **The European Agreement Concerning the International Carriage of Dangerous Goods By Road (ADR). This convention applies to thirty nine countries. However versions of the convention are being used in South America and South East Asia**

Sea **The International Maritime Dangerous Goods Code (IMDG) this has been adopted by about 100 countries.**

Post **The Universal Postal Union (UPU) reflect the UN Recommendations using the ICAO text as a basis for shipments.**

Many countries adopt the UN recommendations for their national dangerous goods legislation.

The World Health Organization serves in an advisory capacity to these bodies. This document provides practical guidance to facilitate compliance with current international regulations. If, at a future date, any modification is made in the section of the UN Recommendations on the Transport of Dangerous Goods dealing with infectious substances and diagnostic specimens, these guidelines will be updated accordingly.

Note: This guide is based on the 13th revised edition of the UN Recommendations the text of which is reflected in the 2005 editions of the international modal regulations. Further changes were agreed for the 14th edition but they will not come into force until 2007. However some of the changes are regarded as editorial and do not affect safety or conflict with existing legal provisions and are likely to be optional until 2007, these are identified in this guide where appropriate.

Definitions

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

Infectious substances including diagnostic specimens

Infectious substances are defined as substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.The definition is applied to all specimens except those excluded (see below) Infectious substances are divided into two categories:

Category A An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Indicative examples of substances that meet these criteria are given in the table in Appendix A.

NOTE : An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

(a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

(b) Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373.

UN 3373 (Diagnostic Specimens) applies to human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

NOTE 1: The proper shipping name of UN 3373 is "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS."

NOTE 2: From 2007 the name Diagnostic specimen or clinical specimen is to be replaced with **"BIOLOGICAL SUBSTANCE, CATEGORY B".** However the air mode are willing to accept the use of the new name immediately and as will be seen the name is not used for the other modes there will be no conflict if this name is chosen.

Exemptions. It is recognised that some specimens are unlikely to present a risk during transport , Substances:

- which do not contain infectious substances or will not cause disease in humans or animals,
- containing microorganisms which are non pathogenic to humans or animals,
- in a form where the pathogens have been neutralised or inactivated such that they no longer pose a health risk
- containing environmental samples (including food and water samples) which are not considered to pose a significant risk of infection
- such as dried blood spots and blood components for the purposes of transfusion.

Genetically modified microorganisms which do not meet the definition of an infectious substance must be shipped as UN3245 Class 9 P904 (ICAO/IATA P913) - this is not addressed in this guide.

Preparing shipments for transport - Packaging, for Transport

Because of the distinction of risks between infectious substances (UN2814 and 2900) and diagnostic specimens (UN3373), there are variations to the packaging, labelling and documentation requirements. The packaging requirements are determined by the UN and are contained in the form of Packaging Instructions (PI) 620 (602 for ICAO/IATA regulations) and 650. The requirements are subject to change and upgrade by these organizations. The current packaging requirements are described below.

Basic triple packaging system

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

Each completed packaging is normally required to be marked, labelled and documented, the requirements for these aspects are described below.

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

Requirements for infectious substances of Category A

Packaging

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

Infectious substances Category A may only be transported in packaging which meets the UN class 6.2 specifications and complies with packing instruction (P) 620 (602) (See Appendix B). This ensures that strict performance tests which include a nine metre drop test and a puncture test have been met. The outer shipping package must bear the UN Packaging Specification Marking (Figure 2), the marking indicating that the package has passed a series of tests recognised by a competent authority. UN-approved packaging supplier listings may be obtained from carriers or from the appropriate national ministry or department, e.g. the Ministry of Transport, or a web search (see Appendix C).

Figure 1 INSERT DRAWING OF PACKAGING HERE

Figure 2

Package Specification Marking

For Category A infectious substances (UN2814 and UN2900)

4G/Class 6.2/04/GB/2470

- The UN packaging symbol
- The type of packaging (in this example a box(4) of fibreboard(G)
- Class 6.2 specially tested for infectious substances (Catgory A)
- Last two digits of year of manufacture
- Competent authority authorising the mark
- Identifier for the competent authority
- It is a requirement that the filler of such packagings have clear instructions on how the package should be prepared for transport.

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

The maximum net quantity of infectious substances of Category A which can be contained in an outer shipping package is unlimited for surface transport (road, rail and sea). For air transport the limits are as follows:

50 mL or 50 g by passenger aircraft

4 L - 4 Kg for cargo aircraft..

Primary receptacles exceeding 50 mL in combination packing must be oriented so the closures are upward, and labels (arrows) indicating the "UP" direction must be placed on two opposite sides of the package (see below).

Marking and Labelling

Marking

Each package shall have a label with the following information:

• the receiver's (consignee) name, address and telephone number

• the shipper's (sender, consignor) name, address and telephone number
• the UN Number followed by the proper shipping name (UN2814 Infectious Substances Affecting Humans or UN2900 Infectious Substances Affecting Animals as the case may be) followed by the scientific name of the substance.

E.g. UN 2814 Infectious Substances Affecting Humans (Monkeypox virus)

If that scientific name is not known but is suspected of meeting Category A the statement "suspected category A infectious substance" shall be used.

- temperature storage requirements (optional).

Labelling

For all dangerous goods to be shipped, specific hazard label(s) must be affixed to the outside of each package (unless exempted). The following hazard labels are of importance for substances of Category A

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

Figure 3

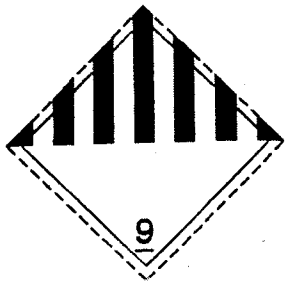


Name: Infectious Substance
Minimum dimensions: 100 x 100 mm
For small packages: 50 x 50 mm
No. per package 1
Colour: Black and white

The words "INFECTIOUS SUBSTANCE" should be shown. The phrase "In case of damage or leakage immediately notify a Public Health Authority" is optional

Hazard label for noninfectious genetically modified microorganisms (UN3245) and for carbon dioxide, solid (dry ice)(UN1845):

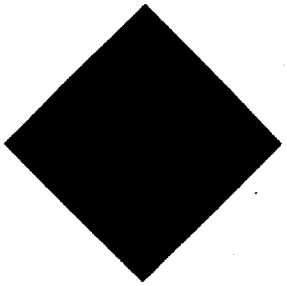
Figure 4



Name: Miscellaneous Substance
Minimum dimensions: 100 x 100 mm
For small packages: 50 x 50 mm
No. per package 1
Colour: Black and white

Hazard label for liquid nitrogen:

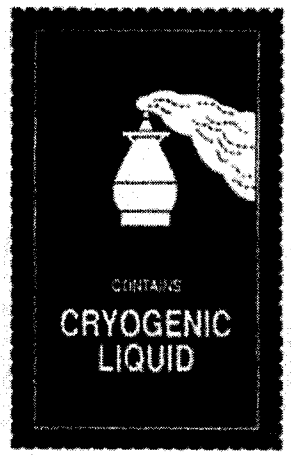
Figure 5



Name: Non- flammable, non- toxic gas
Minimum dimensions: 100 x 100 mm
For small packages: 50 x 50 mm
No. per package 1
Colour: Green and white or green and black

For any cryogenic liquid travelling by air the label belows must be shown in addition to the label above in dewars or flasks

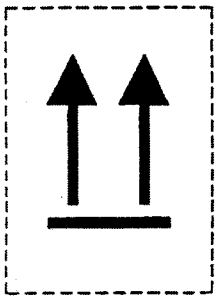
Figure 6



Name: Cryogenic liquid
Minimum dimensions: 75 x 105 mm
No. per package 1
Colour: Green and white

Packages containing liquid cultures of infectious organisms and genetically modified microorganisms must be packed so that the closure(s) of the inner packaging(s) are upward; the upright position of the packaging must be indicated by two "Package Orientation" labels (black or red arrows). The labels must be affixed on opposite sides of the packaging.

Figure 7



Name: Orientation Label
Minimum dimensions: 75 x 105 mm
No. per package 2 on opposite sides
Colour: Black and white or Red and white

The words "THIS SIDE UP" or "THIS END UP" may also be displayed on the top cover of the package:

In case shipments include only freeze-dried cultures the quantity should be given in g, not in mL. The "PACKAGE ORIENTATION" labels should be affixed to avoid any delay.
If the outer package is further packed in an overpack (with dry ice for instance) both outerpack and overpack must carry the above information, and the overpack must have a label stating "Overpack".

Documentation

Required shipping documents:
- to be prepared and signed by the shipper
- the shipper's Declaration of Dangerous Goods (Figure 4 is one example)
- a packing list/proforma invoice which includes the receiver's address, the number of packages, detail of contents, weight, value (note: please indicate a minimal value, for custom purposes, as the items are supplied free of charge)
- to be prepared by the carrier or his agent
- an air waybill if shipping by air or equivalent documents for road, rail and sea journeys.

An import and/or export permit and/or declaration if required.

Figure 8 EXAMPLE DANGEROUS GOODS NOTE TO GO HERE

Requirements for infectious substances of Category B

Packaging
The triple packaging system continues to apply the main difference is that there is no requirement to have a tested package. It may be possible to source such packagings locally rather than having to search for an authorised supplier provided that the packaging manufacturer and the medical instution can comply fully with the requirements of P650 (this is set out in Appendix D).

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

For surface transport there is no maximum quantity per package. For air transport:
- No primary receptacle shall exceed 1litre, and
- Not more than 4 litres per package.

There is also another important difference from P620(602) if all the requirements of P650 are met no other transport requirements have to be complied with for the consignment. P650 incorporates all the requirements needed to make a shipment.

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

Marking and Labelling

Figure 9



For surface transport – road, rail and sea no other mark is required. For air transport the mark must be shown but with the additional information below.
Minimum Dimension None (but air transport requires a side to be at least 50mm
No. per package: 1
Colour: None specified ensure that it is clearly visible

Air transport

The words " Diagnostic Specimen" or "Clinical Specimen" in letters at least 6mm high and must be adjacent to the mark above.
From 2007 the name will be "BIOLOGICAL SUBSTANCE, CATEGORY B" for all modes of transport but it can be used immediately without contravening the regulations.

Note: For air transport:

- Where dry ices (solid carbon dioxide) is used the label in figure 4 will have to be applied
- Where cryogenic gases are used Figure 6 (above) applies.

Documentation

No documentation is required for substances of Category B (Diagnostic specimens). However it is recommended that the following are complied with:

1. An address label with the following information:
   - the receiver's (consignee) name, address and telephone number
   - the shipper's (sender, consignor) name, address and telephone number

2. Required shipping documents:
- to be prepared and signed by the shipper
  - a packing list/proforma invoice which includes the receiver's address, the number of packages, detail of contents, weight, value (note: state that there is "no commercial value" as the items are supplied free of charge)
- to be prepared by the carrier or his agent
  - an air waybill if shipping by air.

Note 1: For international transport extra documents may be required, like an import and/or export permit and/or declaration (if required) .and/or a packing list/proforma invoice.

Note 2: The infectious substance label and the shipper's declaration of dangerous goods are not required for diagnostic specimens.

Overpacks

Wherever an overpack is used (often to consolidate several packages to the same desination) the marks and labels required must be repeated on the outer most layer of the overpack. This requirement applies to Category A and B substances.

Refrigerants For categories A and B

Ice or dry ice when used in a shipment must be placed outside the secondary receptacle. If wet ice is used it

should be in a leak-proof container and the outer package must also be leak-proof.

The secondary receptacle must be secured within the outer package to prevent damage after the refrigerant has melted or dissipated. Dry ice must not be placed inside the primary or secondary receptacle because of the risk of explosions. An overpack (a specially designed insulated outer package) may be used to contain dry ice. The outer package must permit the release of carbon dioxide gas if dry ice is used. ICAO(IATA) Packing Instruction 904 must be observed. Note there is no equivalent provision for surface transport.

If dry ice is used for infections substances, the details must appear on the shipper's Declaration for Dangerous Goods. In particular, the outer most packing must carry the "MISCELLANEOUS" hazard label for dry ice (see Figure 4).

If liquid nitrogen is used as a refrigerant, special arrangements must be made in advance with the carrier. Primary receptacles must be capable of withstanding extremely low temperatures and appropriate packaging requirement of the carrier must be observed. In particular, the outer most packing must carry the "NON-FLAMMABLE GAS" label for liquid nitrogen (see Figure 5) and if the shipment will travel by air then the cryogenic label (see figure 6) must be applied

Local Surface Transport

WHO BECAUSE THE UN SYSTEM IS UNIVERSAL WOULDN'T IT BE SIMPLER TO SAY USE P650 AS A BASIS AND DELETE THIS TEXT?

The text set out above will apply wherever the UN system has been adopted for national traffic the following notes are intended to aid medical professionals in those countries where the UN system has not been applied.

Examples include transport of specimens from a doctor's office/surgery to a laboratory, from a hospital to a diagnostic laboratory or from one laboratory to another. Such courier services may be operated by a hospital, a laboratory, a health service or other approved agency or organization.

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

The following practices should be observed:

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

Note: The practices 1 - 7 described above are not intended to supersede local or national requirements.

Transport Planning

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

The efficient transport and transfer of infectious materials requires good coordination between the sender, the carrier and the receiver (receiving laboratory), to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon well-established communication

and a partner relationship between the three parties.

The carriage of any goods whether dangerous or not is a commercial matter for a carrier. The dangerous goods rules set out in this guide are the governmental legal restrictions. If a carrier does not want to carry particular goods, he is under no legal obligation to do so. The concept of a "common carrier" required to take any goods ended 50 years ago.

As all carriers (airlines, hauliers and shipping lines) are "private carriers" they are allowed to refuse to carry goods or they can add additional requirements.

In recent years it has become clear that some carriers are indeed refusing to carry or are adding extra conditions. Provided such conditions do not conflict with the legal requirements this type of action is not illegal.

The airlines, through the IATA Dangerous Goods Regulations, list the main carrier restrictions in force. Some airlines will carry no dangerous goods at all whilst others will only carry a very limited range of goods. For some the other modes of transport carrier restrictions are not published centrally.

All have specific responsibilities to carry out in the transport effort.

The shipper (sender, consignor)

1. makes advance arrangements with the receiver of the specimens including investigating the need for an import permit;
2. makes advance arrangements with the carrier to ensure:
   - that the shipment will be accepted for appropriate transport
   - that the shipment (direct transport if possible) is undertaken by the most direct routing, avoiding arrival at weekends;
3. prepares necessary documentation including permits, dispatch and shipping documents;
4. notifies the receiver of transportation arrangements once these have been made, well in advance of expected arrival time.

The carrier

1. provides advice to the sender regarding the necessary shipping documents and instructions for their completion;
2. provides advice to the sender about correct packaging;
3. assists the sender in arranging the most direct routing and then confirms the routing;
4. maintains and archives the documentation for shipment and transport;
5. monitors required holding conditions of the shipment while in transit;
6. notifies the sender of any anticipated (or actual) delays in transit.

The receiver <u>(consignee)</u>

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

Shipments should not be dispatched until:

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

Requirements for Air Mail

Infectious substances and diagnostic specimens may be shipped by registered air mail. The basic triple packaging system is used with the same requirements as for other means of conveyance.
The address label must display the word "LETTRE" and the green Customs Declaration Label for Postal Mail is required for international mailing. Diagnostic specimens are to be identified with the violet UPU

"PERISHABLE BIOLOGICAL SUBSTANCES" label. Infectious substances are to be identified with the International Infectious Substance label (see Figure 3). Infectious substances must also be accompanied with a shipper's Declaration of Dangerous Goods form (see Figure 4 at the end of the document).
Because of local/international restrictions, prior contact should be made with the local post office to ascertain whether the packaged material will be accepted by the postal service.

Spill clean-up procedure

The appropriate response in the event of exposure to any infectious substance (including one of unknown nature) is to wash or disinfect the affected area as soon as possible, regardless of the agent. Even if an infectious substance comes in contact with non-intact skin, washing of the affected area with soap and water can reduce the risk of infection. Where access to soap and water is not readily available, antiseptic hand wipes, or antiseptic solutions can be used instead. The following procedure for clean-up can be used for spills of all infectious substances.

Procedure to be followed for cleaning up spillage of infectious substances or blood:

1. Wear gloves and protecting clothing, including face and eye protection
2. Cover the spill with cloth or paper towels to contain it
3. Pour an appropriate disinfectant over the paper towel and the immediately surrounding area (generally, 5% bleach solutions are appropriate but for spills on aircraft, quaternary ammonium disinfectants should be used)
4. After 30 minutes, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit it into a puncture-resistant container for disposal
5. Clean and disinfect the area of the spillage(repeat steps 2-4)
6. Dispose of contaminated materials into a waste bag

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

Incident reporting

No reports of infections resulting from transport-related exposures have been documented. However, there have been reports of the spread of respiratory infections (e.g., tuberculosis) associated with airline travel. Indeed, these were attributed to direct person-to-person contact and not to packaging problems or shipping incidents.

Statistical data collected by a group of central laboratories show that compliant packaging, P650 and P620, accomplishes the goal of assuring that infectious substances are transported without leakage and loss of materials: 106 broken vials from 4.92 million shipped primary containers per year (21.5 ppm) to any of the worldwide regional offices of the above mentioned central laboratories provides performance records for the efficacy of the recommended packing instructions. Moreover, the same statistical data show that leakages were all contained by the absorbent material, and no damage to secondary containers or outer packages were reported.

The various international modal regulations make it a duty to report incidents to the relevant transport competent authority in addition to any health authority. This particularly applies to Cattegory A infectious substances.

Appendix A

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
UN 2814 Infectious substances affecting humans	*Bacillus anthracis (cultures only)* *Brucella abortus (cultures only)* *Brucella melitensis (cultures only)* *Brucella suis (cultures only)* *Burkholderia mallei - Pseudomonas mallei* – Glanders *(cultures only)* *Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)* *Chlamydia psittaci* - avian strains (cultures only) *Clostridium botulinum (cultures only)* *Coccidioides immitis (cultures only)* *Coxiella burnetii (cultures only)* Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) *Escherichia coli*, verotoxigenic (cultures only) Ebola virus Flexal virus *Francisella tularensis (cultures only)* Guanarito virus Hantaan virus Hantaviruse causing hemorragic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus *Mycobacterium tuberculosis (cultures only)* Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) *Rickettsia prowazekii (cultures only)* *Rickettsia rickettsii* (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus *Shigella dysenteriae type 1 (cultures only)* Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) *Yersinia pestis* (cultures only)

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	**Micro-organism**
UN 2900 Infectious substances affecting animals only	African swine fever virus (cultures only) Avian paramyxovirus Type 1 –Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease viru (cultures only) *Mycoplasma mycoides* - Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

Appendix C Suitable Infectious packaging

There is no comprehensive list of suppliers of either 620(602) or 650 packagings however a search on web sites using search engines such as Google.com, MSN.com, Yahoo.com and Lycos.com or their local equivalents usually produces substantial list of suppliers along with access to national regulations.

Search phrases such as:

- "infectious packaging",
- "UN packaging" and
- "UN infectious packaging"

produce extensive results.

It is possible that many carriers and forwarding agents can supply details of local companies who may be able to provided details of local suppliers

Other useful web sites

The UN dangerous goods website provides comprehensive detail concerning their Recommendations on the Transport of dangerous Goods. It provides links to the other modal agencies

http://www.unece.org/trans/danger/danger.htm

The site below provides the full text of the UN Recommendations that can be downloaded in PDF format. Readers wishing to see the full text should download Part 2, Part4 and Part 5 of the Recommendations

http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html

The site below provides the full text of ADR that can be downloaded in PDF format. Readers wishing to study this text should download Part 2.2(2.2.52 to 2.2.7), Part 4 Chapter 4.1 and Part 5

http://www.unece.org/trans/danger/publi/adr/adr2003/ContentsE.html

P620	**PACKING INSTRUCTION**	**P620**

This instruction applies to UN Nos. 2814 and 2900.

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

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

(a) Inner packagings comprising:

(i) leakproof primary receptacle(s);

(ii) a leakproof secondary packaging;

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

(b) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension shall be not less than 100 mm.

Additional requirements:

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

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

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

   (b) Substances consigned refrigerated or frozen: Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;

   (c) Substances consigned in liquid nitrogen: Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the 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) Lyophilised substances may also be carried in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

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

Additional requirements for air transport

Special packing provisions

1) Shippers of infectious substances must 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 must 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 and assignment to UN 2814 or UN 2900, the words "suspected Category A infectious substance" must be shown in parentheses following the proper shipping name on the itemized list of contents inside the outer packaging.

Appendix D P650 use UN but add air variations and 2004 text below

The text below is the UN packing instruction used by all surface modes of transport and the text on the right hand side are the air transport variations which must be taken into account when a shipment will travel by air.

Text in bold on the right hand column indicates changes that will be adopted by the other modes of transport from 2007 and could be used now without contravening current regulations.

P650	PACKING INSTRUCTION	P650
This packing instruction applies to UN 3373.		
	AIR Variations	
(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings 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 three components: (a) a primary receptacle, (b) a secondary packaging, and (c) an outer packaging	The outer packaging must 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 width of the line shall be at least 2 mm; the letters and numbers shall be at least 6 mm high.	4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. **The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm,** the width of the line must be at least 2 mm, and the letters and numbers must be at least 6 mm high. The proper shipping name "Diagnostic specimen" or "Clinical specimen" in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark. **Note: From 2007 the terms "Diagnostic specimen" or "Clinical specimen" will be replaced by "BIOLOGICAL SUBSTANCE, CATEGORY B" and this name will have to appear on all packages for all modes of transport. ICAO being the only organisation requiring names on these packages has agreed this new name can be used immediately as an alternative.**	
	5) At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm.	



(5) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.3 and 6.3.2.4 of these Regulations except that the height of the drop shall not be less than 1.2 m.

(6) For liquid substances

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

And must not contain more than 1 litre

(b) The secondary packaging shall be leakproof;

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

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

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

f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(7) For solid substances

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

And must not exceed the outer packaging mass limit

(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.

d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;

e) 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, must be used.

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

(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry 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 after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice".

(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.

(9) 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.

10) When packages are placed in an overpack, the package markings required by this packing instruction must 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 Instructions except for the following:

a) the proper shipping name, UN number and the name, address and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package;

b) classification must be in accordance with 2;6.3.2;

c) the incident reporting requirements in 7;4.4 must be met; and

d) the inspection for damage or leakage requirements in 7;3.1.3 and 7;3.1.4;

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

(10) 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 must not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. 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 be met.

This packing instruction applies to UN 2814 and UN 2900.

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

Packagings meeting the requirements of Part 6, Chapter 6 and approved accordingly consisting of:

a) inner packagings comprising:

i) watertight primary receptacle(s);

ii) a watertight 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;

b) a rigid outer packaging of adequate strength for its capacity, mass and intended use. The smallest external dimension must be not less than 100 mm.

Additional requirements:

1. Inner packagings containing infectious substances must not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of Part 1;3.1 and 5;1.1 j). 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 must apply:

a) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles must be of glass, metal or plastics. Positive means of ensuring a leakproof seal must be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they must 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 must be placed around the secondary packaging(s) or, alternatively, in an overpack with one or more complete packages marked in accordance with 6;2.2.2. Interior supports must 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 must be leakproof. If dry ice is used, the outer packaging or overpack must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used;

c) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature must be used. The secondary packaging must 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 must also be fulfilled. The primary receptacle and the secondary packaging must 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 must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range –40°C to +55°C.

Special packing provisions

1) Shippers of infectious substances must 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) The definition in Part 1, Chapter 3, and the general packing provision of Part 4, Chapter 1, apply to infectious substances packages.

3) An itemized list of contents must 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 and assignment to UN 2814 or UN 2900, the words "suspected Category A infectious substance" must be shown in parentheses following the proper shipping name on the itemized list of contents inside the outer packaging.

This packing instruction applies to UN 3373.

1) The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including transhipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed 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 must consist of three components:

   a) a primary receptacle;

   b) a secondary packaging; and

   c) a rigid outer packaging.

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

4) For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm, the width of the line must be at least 2 mm, and the letters and numbers must be at least 6 mm high. The proper shipping name "Diagnostic specimen" or "Clinical specimen" in letters at least 6 mm high must be marked on the outer package adjacent to the diamond-shaped mark.

5) At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm.

6) The completed package must be capable of successfully passing the drop test in 6;6.2 as specified in 6;6.1.5 of the Instructions except that the height of the drop must not be less than 1.2 m.

7) For liquid substances:

   a) The primary receptacle(s) must be leakproof and must not contain more than 1 litre;

   b) The secondary packaging must be leakproof;

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

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

   e) The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar);

   f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

8) For solid substances:

   a) The primary receptacle(s) must be siftproof and must not exceed the outer packaging mass limit;

   b) The secondary packaging must be siftproof;

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

   d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;

   e) 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, must be used.

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

   a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Instructions must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If carbon dioxide, solid (dry

ice) is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings;

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

10) When packages are placed in an overpack, the package markings required by this packing instruction must 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 Instructions except for the following:

a) the proper shipping name, UN number and the name, address and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package;

b) classification must be in accordance with 2;6.3.2;

c) the incident reporting requirements in 7;4.4 must be met; and

d) the inspection for damage or leakage requirements in 7;3.1.3 and 7;3.1.4;

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

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

13) Other dangerous goods must not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. 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 be met.