STORE

# Guide to Shipping

# archival biological materials

## UN class 6.2 and class 7

Compiled by M Birschwilks

This manual is not intended to be an exhaustive or fully comprehensive reference,
rather a small guide to assist in the shipment of archival biological and any radioactive materials in compliance with existing regulations.

***This manual is to be used as a reference ONLY***.

## Preface

Certain biological materials fall within the description of dangerous goods for transport and both national and international legislation demand that stringent requirements are met if these goods are transported by any means.

This manual summarises the main requirements when transporting the most common types of biological research materials.

Every country issues own regulations about dangerous goods covering classification, packaging, labelling and documentation. These rules are based on UN Model Regulations on the Transport of Dangerous Goods.

The regulations on which this manual is based are those governing the transport of dangerous goods by road (ADR) and air (IATA) since these are likely to be the most common modes of transport used. The manual therefore covers the requirements of both.

! All persons undertaking any role in the transport chain should be properly trained to carry out their responsibilities to the required standards. They must appreciate the risks involved and have a detailed understanding of the relevant regulations.

## Purpose of shipping regulations

Shipping regulations have been published by international and national regulators in order to provide procedures for the shipper by which articles and substances with hazardous properties can be safely transported by air or surface.

“In the interest of global public health, human and animal specimens need to be transported safely, timely, efficiently and legally from the place where they are collected to the place where they will be analyzed. Regardless of the presumed infection status of the patient, specimens of human and animal origin should be packaged and transported in such a way as to protect those engaged in transportation from the risk of infection. Risks of infection of personnel involved in transport may not be fully eliminated. However, they can undoubtedly be kept to a minimum. In addition, damage to packaging also means that samples dispatched for urgent tasks like analyses are unlikely to arrive to destination on time.”

(World Health Organization; Transport of Infectious Substances: http://www.who.int/ihr/publications/who_hse_ihr_20100801/en/ ).

## Legal regulation

There are international agreements governing the transport of dangerous goods. The United Nations Committee of Experts issues UN Recommendations (http://www.unece.org) or Model Regulations on the Transport of Dangerous Goods. These are then adopted as the basis for international, national, regional and modal regulations.

The Regulations implement various European Council Directives that in turn apply the European agreements on the international carriage of dangerous goods by road and rail (known as ADR and RID respectively).

### *Transport by road and rail*

ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road; ADR applicable as from 1 January 2011 http://www.unece.org/trans/danger/publi/adr/adr2011/11contentse.html) [available at the time of the preparation] and RID (the Regulations concerning the International Carriage of Dangerous Goods by Rail). The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) is applicable for 46 countries. A number of non-EU countries have also adopted the ADR as the basis of their national legislation.

### *Transport by air*

The IATA Dangerous Goods Regulations is the global reference for shipping dangerous goods by air and the only reference recognized by the world's airlines (http://www.iata.org/ps/publications/dgr/Pages/index.aspx, DGR, 53rd edition applicable as from 1 January 2012; [currently available at the time of the preparation]) ensures the safe handling of dangerous goods in air transport, by providing help for classify, mark, pack, label and document dangerous shipments.

! In Europe the UN recommendations are embodied in the **ADR** regulations published by the United Nations Economic Commission for Europe (UNECE: http://www.unece.org/). The rules are **updated every two years**, and all EU member states are required to amend their domestic regulations to comply with the latest ADR rules.

## Dangerous goods in general

By definition dangerous goods are goods with certain hazardous properties. All hazardous materials which could potentially be transported are assigned to one of the nine main United Nations Classes.

### The classes of dangerous goods are:

| | |
|---|---|
| Class 1 | Explosive substances and articles |
| Class 2 | Gases |
| Class 3 | Flammable liquids |
| Class 4 | |
| 4.1 | Flammable solids, self-reactive substances and solid desensitized explosives |
| 4.2 | Substances liable to spontaneous combustion |
| 4.3 | Substances which, in contact with water, emit flammable gases |
| Class 5 | |
| 5.1 | Oxidizing substances |
| 5.2 | Organic peroxides |
| ***Class 6*** | |
| 6.1 | Toxic substances |
| ***6.2*** | ***Infectious substances*** |
| ***Class 7*** | ***Radioactive material*** |
| Class 8 | Corrosive substances |
| Class 9 | Miscellaneous dangerous substances and articles |

Each entry in the different classes has been assigned an UN Number. Dangerous goods to be transported have to be classified and assigned an UN number and proper shipping name. Both, the UN numbers and proper shipping names are standardised across the world and recognised internationally as a detailed description of the goods.

! Dangerous goods
Hazardous material — All the same.
HAZMAT

All given information here is described in detail (mostly) in the European Agreement concerning the international Carriage of Dangerous goods by Road ADR Volume I
http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeI.pdf
and Volume II
http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeII.pdf .

## Class 6.2 Infectious substances

The shipment of archival biological material is issued in this guide, therefore the focus will be on the following.

*CATEGORY A INFECTIOUS SUBSTANCE* – High containment, highly pathogenic deadly viruses and cultures of other highly infectious materials.

*CATEGORY B INFECTIOUS SUBSTANCE* – Infectious material not considered to be highly pathogenic and routine diagnostic specimens.

- ***EXEMPT human / animal patient SPECIMEN* – A human / animal patient specimen not likely to contain a pathogen.**

***Infectious substances*** mean materials known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN or 3373 as appropriate, and must be assigned to one of the following categories:

Infectious substances must be classified in Class 6.2 and assigned to UN2814, UN2900, UN 3291 or UN3373, as appropriate (UN numbers with the corresponding proper shipping names):

| | |
|---|---|
| UN 2814 | INFECTIOUS SUBSTANCE, AFFECTING HUMANS |
| UN 2900 | INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ***only*** |
| UN 3373 | BIOLOGICAL SUBSTANCE, CATEGORY B |

The UN description for Class 6.2 divides infectious substances into either Category A or Category B and this forms the basis for determining which of the above UN numbers should be assigned as follows:

### Category A: (ADR 2.2.62.1.4.1.)

Are Infectious substances that are carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to either humans or animals. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A Category A infectious substance must be assigned to identification number UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

### Category B: (ADR 2.2.62.1.4.2)

Are Infectious substances that do not meet the criteria for inclusion in Category A. That means an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals after exposure. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as “Biological substance, Category B” and assigned identification number UN 3373.

## Class 6.2-Exemptions (ADR 2.2.62.1.5)

- Following materials are not subject to the Regulations (ADR or IATA) unless they have other hazardous properties and therefore meet the criteria for inclusion in another hazard class for dangerous goods:

  - Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals
  - Substances containing micro-organisms which are non-pathogenic to humans or animals
  - Substances in a form that any present pathogens have been neutralised or inactivated such that they no longer pose a risk to health
  - Human or animal specimens for which there are minimal likelihood that pathogens are present is packed in a packaging which will prevent leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen” as appropriate. No hazard sign or UN number is required.

### Specimens in Fixatives

Specimens in formaldehyde, glutaraldehyde, or any other chemical fixative may be shipped as long as the amount of chemical is 30 ml or less in each individual container. Where the chemicals have hazardous properties it is likely that they will be subject to controls under the transport regulations. Ethanol and formaldehyde are classified as dangerous goods for transport, both being flammable, and formaldehyde (see formalin below) also being corrosive. Therefore, transport of samples containing surplus liquid of either chemical must meet the necessary transport requirements pertaining to the chemical.

#### Formalin

Formalin is a mixture of formaldehyde and methyl alcohol. IATA identifies formalin as formaldehyde solution:

- Full strength formalin is 37% formaldehyde; Formalin with >25% formaldehyde is classified as “formaldehyde solution, flammable, UN 1198, class 3”; Must be shipped as a dangerous good with shippers declaration!

- Formalin with >10% but <25% formaldehyde is classified as *UN 3334, class 9, aviation regulated liquid, n.o.s. (formaldehyde)* for transportation by air. **IF** shipped by road it does **NOT** require classification as a hazardous material.
- 10% formalin contains 3-4% formaldehyde. This is **NOT** regulated for transport by road or air.

## Packing / Labelling

The packaging requirements vary depending on the classification of the materials to be transported. The requirements are detailed in the applicable numbered Packing Instruction (PI), as referenced in the Dangerous Goods List against each UN number and proper shipping name. Many substances have already been classified and are in the "dangerous goods list", which is in part 3 of ADR. The lists are by UN Number (Table A) and alphabetical (Table B). Both lists are at the end of Volume 1 of ADR (http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeI.pdf). Apart from restrictions on the quantity of materials in packages for air transport, the packing requirements are essentially identical whether the goods are transported by road or by air. However, the road (ADR) and air (IATA) transport regulations use different numbers for the Packing Instructions that in some cases are unfortunately similar – for example ADR Packing Instruction 620 is analogous to IATA Packing Instructions 602.

### *Category A Infectious Substances*

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease to humans or animals after exposure. Category A infectious substances have two shipping names: *"Infectious substances, affecting humans"* (UN 2814) or *"Infectious substances, affecting animals"* (UN 2900).

#### Packaging

Category A infectious substances designated as UN 2814 or UN 2900 **must** be tripled packaged and **must** be transported in packaging that meets the United Nations class 6.2 specifications and complies with Packing Instruction **P620** (see ADR Vol. II, part 4, 4.1.4.) or **PI602** for the air mode (IATA). The maximum quantity of Category A infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum allowable quantity on passenger aircraft is 50 ml or 50 g.

## Labelling

The outer container of all Category A infectious substance packages must display the following on two opposite sides:

- Full name and address of the shipper (from).
- Full name and address of the consignee (to).
- Infectious substance label
- Proper shipping name, UN number, and net quantity of infectious substance

## *Category B Infectious Substances*

Category B infectious substances are infectious but do not meet the criteria for Category A. Category B infectious substances have the proper shipping name "Biological Substance, Category B" and the identification number UN 3373. Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR (ADR 4.1.4.1, P650).

## Packaging

Category B infectious substances must be tripled packaged and compliant with IATA Packing Instruction 650. The maximum quantity for a primary receptacle is 500 ml or 500g and outer packaging must not contain more than 4 L or 4 kg.

### Category B Packaging Requirements

- Primary container is leak proof
- Secondary container is leak proof
- Either the primary or the secondary container must be pressure tested at 95 kPa
- Either secondary or outer container is rigid (If the shipment is transported by air, the outer container must be rigid.)
- Drop tested from 1.2 m

## Labelling

The outer container of all Category B infectious substance packages must display the following on two opposite sides:

- Full name and address of the shipper (From).
- Full name and address of the consignee (To).
- The words ***"Biological Substance, Category B"***
- ***UN 3373 label***


BIOLOGICAL SUBSTANCE, CATEGORY B

### *Exempt packing instruction*

- Exempt Patient Specimens are specimens with low probability that pathogens are present. Exempt specimens are not regulated as Dangerous Goods. However, federal packaging, marking and labelling requirements do apply. There are two types of Exempt Patient Specimens, ***Exempt Human Specimen*** and ***Exempt Animal Specimen***.

#### Packaging

Exempt Patient Specimens must be tripled packaged. The packaging requirements are:

- Leak-proof primary container(s);
- Leak-proof secondary packaging;
- Fragile primary containers must be wrapped or separated to prevent contact and breakage;
- Sufficient absorbent material must be placed between the primary and secondary containers to absorb entire contents so that no liquid release will reach the outer packaging (no absorbent is needed if the sample is solid); and
- Rigid outer packaging of adequate strength for its capacity, weight and intended use with at least one side 100 X 100 mm or more.

#### Labelling

The outer package If packaging a patient specimen, the outer package must be marked with the following:

- Full name and address of the shipper (From).
- Full name and address of the consignee (To).
- The words "***Exempt human specimen***," or "***Exempt animal specimen***"
- the OUTER package does NOT need special labelling
- Inner containers containing blood and blood products must be labelled with a biohazard symbol

**A Shipper's Declaration for Dangerous Goods is not required.**

**Note** There is no limit for quantities shipped in the package.

| | | |
|---|---|---|
| EXEMPT HUMAN SPECIMEN | ***or*** | EXEMPT ANIMAL SPECIMEN |

### *P650 Packing instruction*

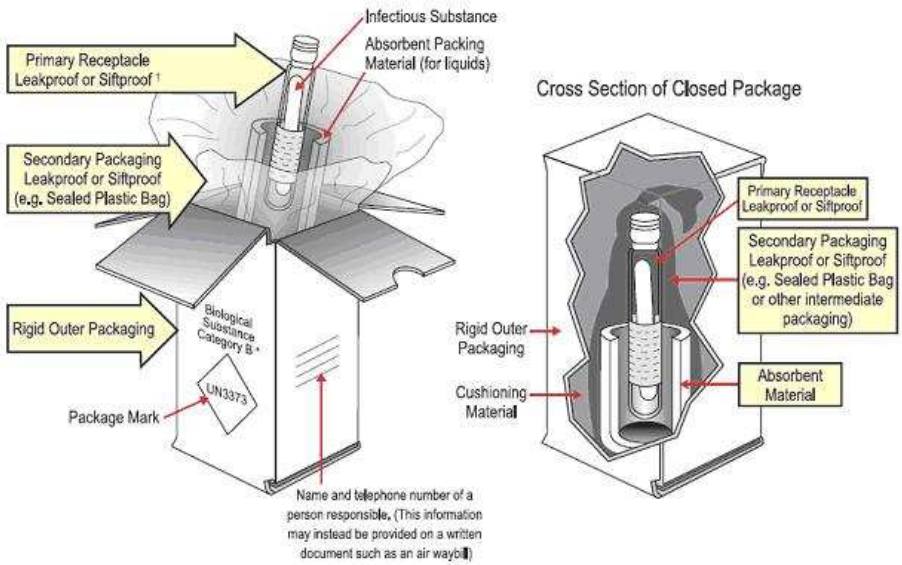
This packing instruction (PI) applies to UN No. 3373 (Biological Substance, Category B) and can be reviewed under: http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeII.pdf.

For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible.

The width of the line shall be at least 2mm; the letters and numbers shall be at least 6mm high


### *Triple Packaging*

- Triple Packaging **is required for all** Category A, Category B and Exempt Human or Animal Specimens. Triple packaging provides three layers of containment to protect the substances being shipped. These layers are primary, secondary, and outer containers (see exemplary figure below).



## Triple Packing Summary

| Category A (PI 602 / 620) | Category B (PI 650) | Exempt human or animal specimens |
|---|---|---|
| • Leak proof primary<br>• Leak proof secondary<br>• 95 kPa pressure test<br>• Rigid outer<br>• Minimum 100 mm x 100mm<br>• Absorbent material<br>• 9 meter drop test<br>• 7 kg penetration test<br>• UN marks and labels<br>• Full DG documentation<br>  | • Leak proof primary<br>• Leak proof secondary<br>• 95 kPa pressure test<br>• Rigid outer<br>• at least one surface :<br>min 100 mm x 100 mm<br>• Absorbent material<br>• 1.2 meter drop test<br>• 3373 mark<br>  | • Leak proof primary<br>• Leak proof secondary<br>• Adequate outer<br>• at least one surface:<br>min 100 mm x 100 mm<br>• Absorbent material |

### *Transport of glass slides*

- The main concern is to avoid breakage of the slides during transport. Most slides transported have been fixed thereby reducing the risk a biological hazard. However, the packaging should have the **"UN 3373"** label.

  Procedures as per specimen transportation apply.

  Slides should be put into plastic slide mailers which are placed in a sealed bag.

  The letter of explanation should be kept separate from the slides.

  All the material should then be placed in a rigid container surrounded with padding to protect against breakage.

  This container should be placed into a cardboard box and details added to ensure safe delivery of the sample. For postage it is more feasible to use a padded envelope instead of a box.

### *Brief overview*

| Shipment Type | Proper Shipping Name | UN Number | Hazard Class | Packing Instruction (PI) | Max for Passenger Aircraft | Max. for Cargo Aircraft |
|---|---|---|---|---|---|---|
| Category A infectious substance, affecting humans | Infectious substance, affecting humans | UN 2814 | 6.2 | 620 | 50 ml or 50 g | 4 L or 4 kg |
| Category A infectious substance, affecting animals | Infectious substance, affecting animals | UN 2900 | 6.2 | 620 | 50 ml or 50 g | 4 L or 4 kg |
| Category B infectious substance | Biological substance, category B | UN 3373 | 6.2 | 650 | 4 L or 4 kg | 4 L or 4 kg |
| Patient Specimens | "Exempt human specimens" Or "Exempt animal specimens" | – | – | Triple packaging | Primary receptacle (500ml or 500g) Outer packaging (4L or 4kg) | Primary receptacle (500ml or 500g) Outer packaging (4L or 4kg) |

## Documentation

Any carriage of goods subject to controls under the transport regulations must be accompanied by documentation as specified in those regulations. The information required must be clearly legible and exactly meet the specified format for air transport. The following includes requirements for paperwork included within the package and for paperwork accompanying the package for the carrier etc.

When transporting any biological material, paperwork must be included within the package between the secondary and the outer (attached to the secondary), giving the names and addresses of both the consignor (sender) and consignee (receiver), including emergency contact details (name and telephone number) and for dangerous goods, a description of the UN NUMBER and PROPER SHIPPING NAME

### *Documenting Category A*

Category A infectious substances **REQUIRE** a Declaration for Dangerous Goods for each shipment.

Category A infectious substances assigned to UN 2814 or UN 2900

- the proper shipping name must be supplemented with the technical name in parentheses on the Declaration for Dangerous Goods (the recognised biological/scientific/technical name of the microorganism).
- an itemised list of contents must be given, to include for each named item the number of tubes and their volume.

On the air waybill the **Additional Handling Information** box must read: *Dangerous Goods as per attached Shipper's Declaration*. For most carriers this is a box you would check on the side of the document.

If applicable, the **Nature and Quantity Of Dangerous Goods** box on the air waybill should read: *Infectious substance affecting humans* or *Infectious substance affecting animals*

### *Documenting Category B*

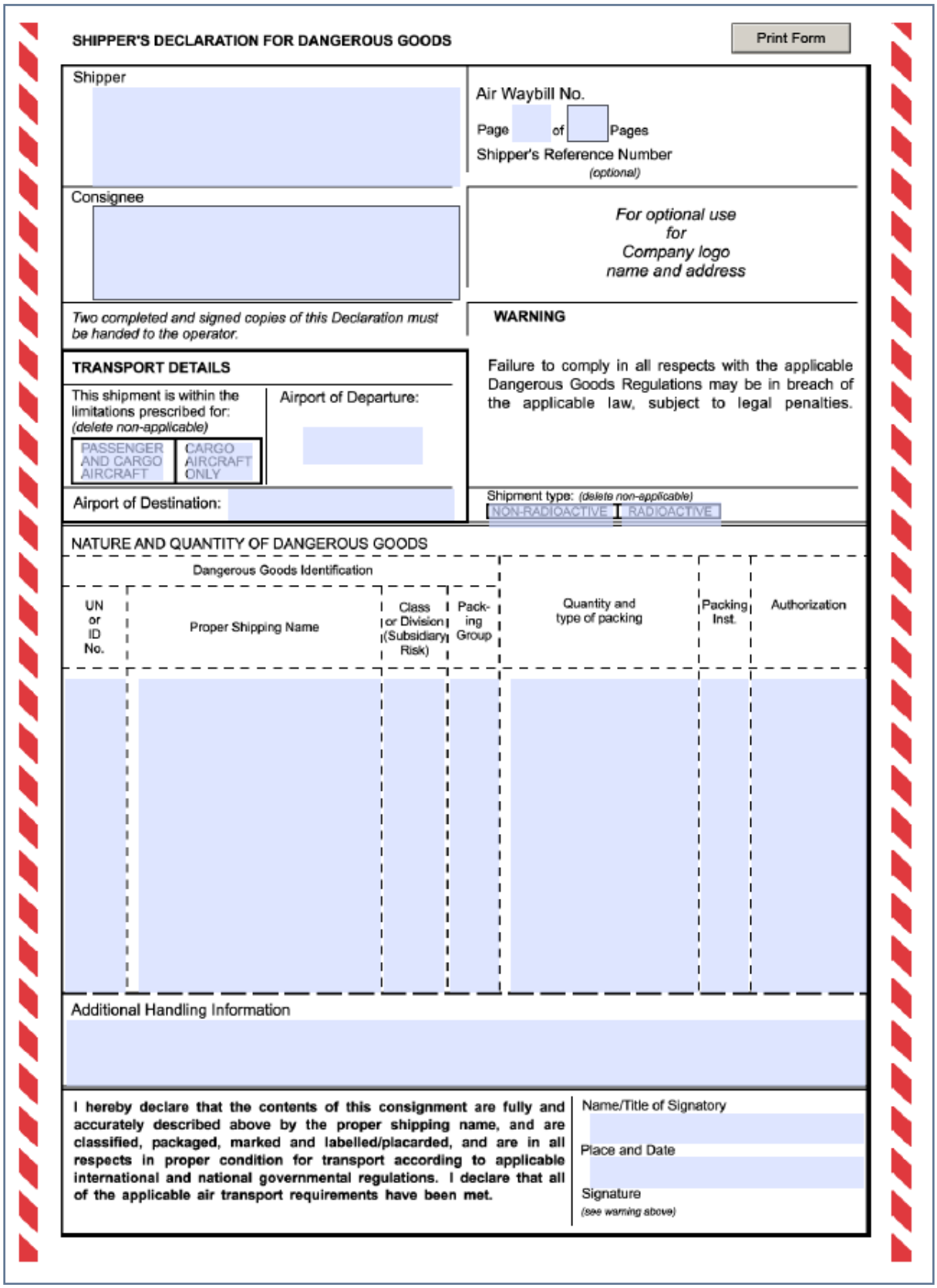
A Declaration for Dangerous Goods **NOT REQUIRED** for Category B substances. You will need to specify when filling out the shipment information that this is a dangerous goods shipment but no shipper's declaration is required.

If applicable, the "Nature and Quantity of Goods" section of the air waybill must be marked with "BIOLOGICAL SUBSTANCE, CATEGORY B" and "UN 3373".

### *Documenting Exempt Human and Animal Specimens*

- For exempt human or animal specimens, a shipper's declaration of dangerous goods is **NOT REQUIRED** as this classification is not considered a dangerous good. You will list the items on the air waybill by their technical name. For example: Human blood samples (non infectious).

- All shipper's declarations must be in English, typed, and printed in colour with red hatchings bordering the document. All shipper's declarations must conform to the following format:



**SHIPPER'S DECLARATION FOR DANGEROUS GOODS**

Print Form

Shipper

Air Waybill No.

Page ____ of ____ Pages

Shipper's Reference Number *(optional)*

Consignee

*For optional use for Company logo name and address*

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

**WARNING**

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

**TRANSPORT DETAILS**

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

PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

Airport of Departure:

Airport of Destination:

Shipment type: *(delete non-applicable)*

NON-RADIOACTIVE | RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

| Dangerous Goods Identification | | | | | | |
|---|---|---|---|---|---|---|
| UN or ID No. | Proper Shipping Name | Class or Division (Subsidiary Risk) | Pack-ing Group | Quantity and type of packing | Packing Inst. | Authorization |
| | | | | | | |

Additional Handling Information

**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/Title of Signatory

Place and Date

Signature *(see warning above)*

Source :

http://www.iata.org/whatwedo/cargo/dangerous_goods/Documents/DGD_ColumnFormat_F.pdf

## Class 7 – Radioactive material

Dangerous goods regulations define radioactive material as any material containing radionuclides where both the activity concentration and the total activity exceed the values specified in 2.2.7.2.2.1 to 2.2.7.2.2.6.

A radionuclide is an atom with an unstable nucleus and which consequently is subject to radioactive decay.

In table 2.2.7.2.2.1 the basic radionuclides values for individual radionuclides are given (http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeI.pdf).

The table was taken from Table 2 of IAEA Safety Standards Series TS-R-1; Subject Classification: 0606-Transport of radioactive material (2009; http://www-pub.iaea.org/books/IAEABooks/8005/Regulations-for-the-Safe-Transport-of-Radioactive-Material-2009-Edition-Safety-Requirements).

The IAEA TS-R-1 is the most important safety and administrative-related regulation for shipments of radioactive material.

*There are no subdivisions within Class 7, Radioactive Material.*

### *Reason for Regulation*

Whilst undergoing radioactive decay radionuclides emit ionizing radiation, which presents potentially severe risks to human health.

The IAEA Safety Standards Series TS-R-1 Regulations apply to the transport of *radioactive material* by all modes on land, water, or in the air, including transport which is incidental to the use of the *radioactive material*.

### *Basic Radionuclide Values*

The basic values for individual radionuclides are given in table 2 TS-R-1 (or you can use the ADR table 2.2.7.2.2.1)

- A1 and A2 in TBq;
- Activity concentration for exempt material in Bq/g; and
- Activity limits for exempt consignments in Bq.

### *Classification as excepted package*

Radioactive material shall be assigned to one of the UN number specified in Table 2.2.7.2.1.1 (http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2011/English/VolumeI.pdf)

Packages may be classified as excepted packages if they contain radioactive material in limited quantities as specified in table 2.2.7.2.4.1.2. (see table excerpt below).

A package containing radioactive material may be classified as an excepted package provided that the radiation level at any point on its external surface does **NOT exceed** 5µSv/h.

| Physical state of contents | Material package limits |
|---|---|
| solids | |
| special form | 1 E-03 A1 |
| other form | 1 E-03 A2 |

Radioactive material with activity not exceeding the limits specified in the table excerpt above may be classified under:

- UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGES – LIMITED QUANTITY OF MATERIAL

Prerequisite for this are:

- The package retains its radioactive content under routine conditions of carriage;
- The package bears marking "RADIOACTIVE" on an internal surface in such a manner that a warning of presence of radioactive material is visible on opening the package.

## US

The Department of Transportation (DOT) regulates the transport of "Hazardous Materials" in the United States. The Federal Regulations (49 CFR) also refer to the Technical Instructions from ICAO.

DOT uses the term "Hazardous Materials" instead of "Dangerous Goods". Hazardous Materials are defined as a substance or material the Secretary of Transportation has determined as capable of posing an unreasonable risk to health, safety, and property when transported by commerce.

The multimodal dangerous goods requirements are included in the Code of Federal Regulations, Title 49, Subtitle B, Chapter 1, parts 105 to 177. The titles 42-50 are revised as of October 1 annually. Each title is divided into chapters, which usually bear the name of the issuing agency. Each chapter is further subdivided into parts that cover specific regulatory areas. Large parts may be subdivided into subparts. All parts are organized in sections, and most citations to the CFR refer to material at the section level.
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR&searchPath=Title+49%2FSubtitle+B&oldPath=Title+49&isCollapsed=true&selectedYearFrom=2011&ycord=1679 (10–1–11 Edition).

- **Class 6** - Division 6.2 - Infectious Substances (49 CFR reference for definitions: 173.134)
- **Class 7** - Radioactive Materials (49 CFR reference for definitions: 173.403)

DOT and NRC (both regulate the transportation of radioactive material in the US) regulations based on IAEA TS-R-1 (formerly known as IAEA Safety Series No 6 (SS6)

The **NEW** exemption activity values **replace** the previous activity concentration threshold of 70Bq/g.

Radioactive material is any material containing radionuclides where both the ***activity concentration*** and the ***total activity in the consignment exceed the values specified*** in Table 2 of IAEA TS-R-1 (2009, can be reviewed under: http://www-pub.iaea.org/books/IAEABooks/8005/Regulations-for-the-Safe-Transport-of-Radioactive-Material-2009-Edition-Safety-Requirements ).

By contacting PHMSA's Office of Hazardous Materials Safety, information and answers to questions on compliance with the hazardous materials regulations (49 CFR parts 171 through 180) as well as interpretations of those regulations can be obtained (http://www.phmsa.dot.gov/hazmat).

## Russia

The documents regulating radiation safety rules are:

- Sanitary Rules and Norms 2.6.1.1.2523-09 “Norms of radiating safety” (“NRB-99/2009”)
- Sanitary Rules and Norms 2.6.1.799-99 “Basic sanitary rules of maintenance of radiating safety” (“OSPORB-99”)

In cooperation with the Southern Ural Biophysics Institute, the following regulations were compiled to **provide an orientational and supportiv**e basis for transportation actions.

*“Regulations for automobile transportation of dangerous goods”* (ratified by the order of the Transport Ministry of the Russian Federation, August 8, 1995 № 73) with amendments made June 11, October 14, 1999, as well as taking into consideration:

- Federal law № 257-FZ November 8, 2007 (about transportation of dangerous goods with automobile transport);
- The Transport Ministry of the Russian Federation order № 76 from October 13, 1999 (About the improvement measures of the government regulation of international automobile transportation of dangerous goods in the territory of the Russian Federation);
- Requirements of international conventions and agreements in which Russia is a party, in particular, European Agreement concerning the International Carriage of Dangerous Goods - ADR (tamognia.ru).

According to classification the following goods are considered dangerous:

- **Class 6.2** infectious substances, hazardous for humans and animals;
- **Class 7** Radioactive materials with specific activity over 70 kBq (70 Bq/g).

In compliance with clause 1.2 of *“Regulations for automobile transportation of dangerous goods”* the operation of regulation is not effective for “transportation of a limited amount of dangerous substances on one transportation device; such transportation is considered the transportation of nonhazardous goods”.

A limited amount of dangerous goods is defined in the regulations for safe transportation of a particular kind of a dangerous substance. To define it the use of European Agreement concerning the International Carriage of Dangerous Goods is possible.

The main sanitary regulations for radiation safety (OSPORB-99/2010). Sanitary regulations. – M.: Federal agency for control in the area of protection of consumers and human welfare. SP 2.6.1. – 89p:

- In compliance with Annex 3 of OSPORB-99/2010 the specific activities of induced radionuclides the specific activities of the induced radionuclides which allow the unlimited use of material, are
  - 100 Bq/g $^{3}H$
  - 1 Bq/g $^{237}Np$
  - 0.1 Bq/g $^{238}Pu$, $^{239}Pu$, $^{240}Pu$, $^{241}Am$
- According to Annex 4 of Radiation Safety Regulations-99/2009 the **minimal significant activity** of an open source of ionizing radiation is:

| Nuclide | minimal significant activity, Bq | minimal significant specific activity, Bq/g |
|---|---|---|
| $^{3}H$ | 1 E+09 | 1 E+06 |
| $^{238}Pu$<br>$^{239}Pu$<br>$^{241}Am$ | 1 E+04 | 1 E+00 |

In case the activity and the value of minimal specific activity of a source exceeds the above figures permission to use the source is required, which can be granted by an executive body authorized to perform state sanitary-epidemiological surveillance.

SUBI has documents which define the following:

- Temporary order of consideration of the documents, requesting permission to import and export biological material in the framework of research collaboration, submitted by organizations (institutions) to Ministry of Health of the Russian Federation, authorized by the first deputy Minister of Ministry of Health on October 12, 2000.

- Temporary order of consideration of the documents, requesting permission to import and export from the Russian Federation biological material in the framework of research collaboration, submitted by organizations (institutions) to Ministry of Health and Social Development of the Russian Federation, authorized by the first deputy Minister of Ministry of Health and Social Development in 2006.