An overview

- Dangerous goods and the international regulatory framework
- ICAO and the UN Recommendations
- Infectious substances
- Radioactive material
  - Denial of shipments
What are dangerous goods?
Annex 18 Definition

- Articles or substances which are capable of posing a **risk to health, safety, property** or the **environment** and which are classified in the list of dangerous goods in the Technical Instructions or which are classified according to those Instructions.
International Regulatory Framework
United Nations and Dangerous Goods

- United Nations Economic and Social Council
- Sub-Committee of Experts on the Transport of Dangerous Goods
- IAEA Safety Standards Series Requirement TS-R-1 (ST-1 Revised)

UN Recommendations on the Transport of Dangerous Goods — Model Regulations
Multimodal harmonization
The basics

• 9 classes or divisions
  – Indicates type of hazard
• Of these, 5 have packing groups assigned
  – Indicates degree of hazard
• 4 digit identifier (preceded by “UN”)
• Official UN transport name
  – Proper shipping name (PSN)
• 3000 substances or articles in list
Classification

- Class 1: Explosives
- Class 2: Gases
  - Division 2.1: Flammable gas
  - Division 2.2: Non-flammable, non-toxic gas
  - Division 2.3: Toxic gas
- Class 3: Flammable liquids
- Class 4
  - Division 4.1: Flammable solids
  - Division 4.2: Substances liable to spontaneous combustion
  - Division 4.3: Substances, which on contact with water, emit flammable gases
- Class 5
  - Division 5.1: Oxidizer
  - Division 5.2: Organic Peroxides
- Class 6
  - Division 6.1: Toxic substances
  - Division 6.2: Infectious substances
- Class 7: Radioactive material
- Class 8: Corrosives
- Class 9: Miscellaneous dangerous goods
ICAO and dangerous goods transport
Annex 18

• *The Safe Transport of Dangerous Goods by Air*

• “The Standards and Recommended Practices of this Annex shall be applicable to all international operations of civil aircraft.”
Technical Instructions

- Issued every two years to reflect UN cycle
- “Each Contracting State shall take the necessary measures to achieve compliance with the detailed provisions contained in the Technical Instructions.” (*Annex 18, 2.2.1*)
Safety in the transport chain

• Shipper
  – Classify, pack, mark, label and document

• Operator
  – Inspect, accept, store, load, provide information

• Consignee
Classification

- **Class 1: Explosives**
- **Class 2: Gases**
  - Division 2.1: Flammable gas
  - Division 2.2: Non-flammable, non-toxic gas
  - Division 2.3: Toxic gas
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- **Class 6**
  - Division 6.1: Toxic substances
  - **Division 6.2: Infectious substances**
- **Class 7: Radioactive material**
- **Class 8: Corrosives**
- **Class 9: Miscellaneous dangerous goods**
Div 6.2 Infectious substances

• Includes:
  – Infectious substances
  – Patient specimens
  – Cultures
  – Biological products
  – Medical or clinical waste
Classification of infectious substances

• Risk assessment
• Category A or B

• Previously, laboratory risk groups were used as basis for transport
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 in otherwise healthy humans or animals.

Mycobacterium tuberculosis
<table>
<thead>
<tr>
<th>UN Number and Proper Shipping Name</th>
<th>Micro-organism</th>
</tr>
</thead>
</table>
| **UN 2814** Infectious substances affecting humans | Venezuelan equine encephalitis virus (cultures only)  
West Nile virus (cultures only)  
Yellow fever virus (cultures only)  
*Yersinia pestis* (cultures only) |
| **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 virus (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) |
Classification

- Infectious substances assigned to Category A and which cause disease in humans or both in humans and animals must be assigned to UN 2814
  
  • **UN 2814**: Infectious substances, affecting humans

- Infectious substances assigned to Category A and which cause disease only in animals must be assigned to UN 2900
  
  • **UN 2900**: Infectious substances, affecting animals only
Assignment to UN 2814 or UN 2900

- Known medical history of the source human or animal
- Endemic local conditions
- Symptoms of patient or animal
- Professional judgement concerning individual circumstances of 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 must be assigned to **UN 3373**

- The proper shipping name of **UN 3373** is **Biological substance – Category B**
Exceptions

- 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 which have been treated so that the pathogens have been neutralised or inactivated so that they no longer pose a health risk

- Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection

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

- Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Instructions if specimen is transported in a packaging that:
  • will prevent any leakage and
  • is marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate
Professional judgement to be used....

- Blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA);
- Those required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring;
- Those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol;
- Pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals.
Classification of biological products

- (a) Those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. *Substances in this group are not subject to these Instructions.* E.g. Vaccines approved for use

- (b) Those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. *Substances in this group must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.*
Classification of medical/clinical wastes

- Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substance must also be assigned to:

  **UN 3291**  Clinical Waste, unspecified, n.o.s
  
  *(or)*

  *(Bio)* Medical Waste, n.o.s
  
  *(or)*

  Regulated medical waste, n.o.s

*Decontaminated* medical or clinical wastes which previously contained infectious substances are not subject to these instructions unless they meet the criteria for inclusion in another class.
Packaging for Category A

• A leak-proof primary receptacle(s) containing the specimen;
• A leak-proof secondary packaging; and
• An outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100mm x 100mm
Absorbent material

• Absorbent material must be placed between the primary receptacle and secondary packaging. The absorbing material must be sufficient to absorb the entire contents of all primary receptacles.
If refrigerated or frozen....

- Most frequently used refrigerants are ‘Dry Ice’ and ‘Liquid Nitrogen’
- For ‘Dry Ice’, the outer packaging must allow the release of carbon dioxide gas
- For ‘Liquid Nitrogen’, the shippers must use plastic primary receptacles, which can withstand very low temperatures
Marking and labelling

- Primary Hazard
- Subsidiary Risk Label when required
- Orientation labels on opposite sides on combination packages containing more than 50 mL of liquid in the package
- “Cargo Aircraft Only” label if applicable
Packagings for Category B

- UN 3373 Biological substance – Category B are similar to those for Category A infectious substances, except that they have not been officially tested and no “Package Specification Markings” are required.
Category B

- At least one surface of the package must have minimum dimensions of 100mm x 100mm
- Liquid Substances
  - Primary receptacle: leakproof and not more than 1L
  - Secondary receptacle: leakproof
  - Primary or secondary packaging must withstand internal pressure of 95 kPa
  - Rigid outer packaging: max 4 L
- Solid Substances
  - Primary receptacle: sifproof and must not exceed outer packaging mass limit
  - Secondary receptacle: sifproof
  - Rigid outer packaging: max 4 kg
Marking

• Each package must be “marked” UN 3373 (‘diamond-shaped’)
  – Dimensions
    • Each side at least 50mm
    • Width of the line at least 2mm
    • Letters and numbers at least 6mm

• PSN: Biological Substance – Category B
  – Dimensions: letters at least 6mm high
Overpack
Marking / Labelling / Documentation requirements for Category A substances

Proper Shipping Name, UN number and net quantity

Hazard Labels

Name & Phone of responsible person

Package Specification Number

Name and Address of Shipper and Consignee are required

Infectious substances, affecting humans, UN 2814, 50 mL
Dry Ice UN 1845, 5 kg

Shipper:
KVS & Partners bvba
Nederokkerzeelstraat 6
B-1910 Berg, Belgium

Dr. Smith
+1-145885962

GB/2530

Consignee
IMCOCHEM
14 RUE ST.JOSEPH
MONTREAL, QC 8500 CANADA
Marking/Labelling/Documentation requirements for Category B substances

Proper Shipping Name, UN number

Hazard Labels

Name & Phone of responsible person (or indicated on AWB)

Name and Address of Shipper and Consignee

KVS & Partners bvba
Nederokkerzeelstraat 6
B-1910 Berg, Belgium

Dr. Smith
+1-145885962

IMCOCHEM
14 RUE ST.JOSEPH
MONTREAL, QC 8500 CANADA

UN 3373
Biological substance, category B

UN 1845, Dry Ice, 5 kg
Marking/Labelling/Documentation requirements for a shipment of medical waste

Proper Shipping Name, UN number and Net Quantity

UN 3291 Medical waste, n.o.s
5 kg

Shipper
Consumal Analytic
5 Road Liverleeze
54WL8 London5, UK

Consignee
Indaver n.v.
Haven 1944, Molenweg 4
B-9130 Kallo, Belgium

Hazard Labels

Name and Address of Shipper and Consignee are required

Package Specification Number

1H2/Y12/S/09
B/Rigid 000040
IAEA regulations establish safety standards which provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of radioactive material.
Objective

- The objective is to protect persons, property and the environment from the effects of radiation during the transport of radioactive material.
- This protection is achieved by requiring:
  - a) containment of the radioactive contents
  - b) control of external radiation level
  - c) prevention of criticality
  - d) prevention of damage caused by heat
The two primary risks from radioactive materials are:

- Contamination: through direct contact with radioactive material
- Radiation: through exposure to Alpha, Beta and Gamma radiation being emitted by radioactive material

It is the ultimate goal of the regulations to limit during the transport of radioactive materials the absorbed dose for staff crew and passengers.

- ALARA = As Low as Reasonable Achievable
Effective barriers

- $\alpha$ – radiation
- $\beta$ – radiation
- $\gamma$ – radiation

Layers:
- Paper / carton
- Aluminium / Plastic
- Lead
Radiation protection programme

• The nature and extent of the measures to be taken must be related to the magnitude and likelihood of radiation exposures

• At least following elements must be included:
  – compliance with the ALARA-principle
  – emergency response procedures
  – training
  – if applicable, individual or work place monitoring records: where it is assessed that the effective dose
    • is likely to be between 1 and 6 mSv/year: a dose assessment program via workplace monitoring or individual monitoring must be conducted; and
    • is likely to exceed 6 mSv/year: individual monitoring must be conducted.
Some definitions

- **ACTIVITY** of a radioactive material is a measure of the quantity of radioactivity and is used to determine the amount of radioactive material which may be transported in various types of packagings. As each radioactive atom decays, the remaining activity declines.

- “Activity” = the average number of atomic transformations (disintegrations) occurring per second.

  - SI Unit: **Becquerel** = Bq & Bq = 1 disintegration/sec

  - Multiples of Becquerel:
    - 1 kBq = 1000 Bq
    - 1 GBq = 1000 MBq
    - 1 MBq = 1000 kBq
    - 1 TBq = 1000 GBq

  - Old Unit: **Curie** = Ci
    - 1 Ci = 37 GBq
Dose Equivalent

- Effect of ionising radiation on tissue depends on the type of radiation, its energy and amount of radiation absorbed.
- “Dose equivalent” = absorbed dose multiplied with a quality factor depending on the type of radiation
  - SI Unit: **Sievert** = Sv
  - Old Unit: rem (1 Sv = 100 rem)
  - Multiples:
    - 1 mSv = 0.1 rem
    - 1 µSv = 0.1 mrem

- Legally the maximum effective dose for the normal population is 1 mSv/year and for radiation workers 20 mSv/year
Half-life

- Radioactive material decays at a rate determined by nature; half-life is the time it takes for the activity to be reduced by half.

- Half-life of various radioactive isotope:
  - Iodine-125 (I-125) 59.4 days
  - Iodine-131 (I-131) 8.02 days
  - Iridium-192 (Ir-192) 73.83 days
  - Cobalt-60 (Co-60) 5.26 years
  - Fluorine-18 (F-18) 109.71 minutes
  - Molybdenum-99 (Mo-99) 66 hours
Transport Index

- A single number assigned to a package, overpack or freight container to provide control over radiation exposure.

- Maximum radiation level measured at a distance of 1m at any point on the external surface of the package.

\[
\begin{align*}
10 \ \mu\text{Sv/h} & = 0.01 \ \text{mSv/h} \\
\text{TI} &= 1
\end{align*}
\]
Contamination

- The presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm² for Beta and Gamma emitters and low toxicity Alpha emitters, or 0.04 Bq/cm² for all other Alpha emitters

This is either:

- non-fixed contamination: contamination that can be removed from a surface during normal handling
- fixed contamination: contamination other than non-fixed contamination
Radioactive Material definition

- Radioactive material is defined as any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in the Instructions.
The following basic values for individual radionuclides are given:

- $A_1$ (special form) and $A_2$ (other form) in TBq
- Activity concentration for exempt material in Bq/g
- Activity limit for exempt consignments in Bq
Classification

- **Special form** radioactive material is either an indispersible solid radioactive material or a sealed capsule containing radioactive material.
- Special form radioactive material must meet the requirements of the Instructions including testing.
- The design for special form requires unilateral approval.

- **Other form** - Radioactive material that does not meet the definition of special form.
Classification of packages

• Packaging for the transport of radioactive material must provide for:
  – Containment
  – Protection from radiation
  – Prevention from criticality
  – Prevention of damage caused by heat

• The quantity of radioactive material in a package must not exceed the limits specified in the Instructions
The following types of packages are used for radioactive material:

- Excepted packages
- Industrial package Type 1 (Types IP-1 package)
- Industrial package Type 2 (Types IP-2 package)
- Industrial package Type 3 (Types IP-3 package)
- Type A packages
- Type B(U) package
- Type B(M) package
- Type C packages
Exepted package

- Packages may be classified as excepted packages if:
  - they contain radioactive material in limited quantities;
  - they contain instruments of articles in limited quantities;
  - they contain articles manufactured of natural uranium, depleted uranium or natural thorium; or
  - they are empty packages having contained radioactive material

- A package containing radioactive material must be classified as an excepted package provided that the radiation level at any point on its external surface does not exceed 5 µSv/h
Industrial packages

- Industrial packagings Type 1 (Type IP-1) are normal strong packaging that must meet the general packing requirements for radioactive materials.

- Industrial packagings Type 2 (Type IP-2) must meet the requirements of a Type IP-1 and are in addition subject to drop and stacking tests.

- Industrial packagings Type 3 (Type IP-3) must comply with the requirements for Type A packages and must be tested as for Type A packages containing solids.
Type A packages

- Type A packaging are used when the activity and/or the radiation limits for excepted materials have been exceeded.
- Type A packages must not contain activities greater than the following:
  - for special from radioactive material – $A_1$
  - or
  - for all other radioactive material – $A_2$
Fluorodeoxyglucose (FDG)

[Type A]
Ir-192 needles [Type A]
Ir-192 needles [Type A]
Am-241 [Type A]
Mo-99 [Type A]
Mo-99 generator
Requirements for Type A packages

- A type A package must comply with the General Packing Requirements and the requirements for Type A packages as described in the Instructions
  - the smallest overall external dimension of the package must not be less than 10 cm
  - the outside of every package must incorporate a feature, such as a seal, which is not readily breakable and which, while intact, will be evidence that the package has not been opened
- Type A packages must be tested to demonstrate ability to withstand normal conditions of transport
Type A packages

- Type A packages are intended to provide a safe, economical means for transporting relatively small quantities of radioactive material.
  - These are expected to retain their integrity under conditions that may occur during transport.
  - It is assumed, however, that type A packages may be damaged in a severe accident and that a fraction of the contents may be released.
  - In the event of a release, the risks of external radiation or contamination are low.
  - For larger amounts of radioactive material, a Type B package is required.
Type B packages

- A Type B Package is a packaging containing an activity that may be in excess of $A_1$ or in excess of $A_2$
- Type B packages are not only tested to demonstrate ability to withstand normal conditions of transport, but also to demonstrate ability to withstand accident conditions in transport
Type B(U)
Type B(U)
Ir-192 disk [Type B(U)]
Ir-192 disk [Type B(U)]
Requirements for Type B packages

- Type B(U) and Type B(M) packages, if transported by air must not contain activities greater than the following:
  - For low dispersible radioactive material – as authorized for the package design as specified in the certificate of approval
  - For special form radioactive material – 3,000 $A_1$ or 100,000 $A_2$ whichever is the lower; or
  - For all other radioactive material – 3,000 $A_2$
Requirements for Type C packages (theoretical!)

- Type C package must not contain:
  - Activities greater than those authorized for the package design
  - Radionuclides different from those authorized for the package design, or
  - Contents in a form, a physical or chemical state different from those authorized for the package design
### Transport conditions to be considered in package design

<table>
<thead>
<tr>
<th></th>
<th>Excepted package</th>
<th>IP-1</th>
<th>IP-2</th>
<th>IP-3</th>
<th>Type A package</th>
<th>Type B package</th>
<th>Type C package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine (incident free)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Normal (minor mishaps)</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Accident (severe accidents)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
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</tr>
</tbody>
</table>

### Package test requirements for normal conditions of transport

<table>
<thead>
<tr>
<th></th>
<th>Excepted package</th>
<th>IP-1</th>
<th>IP-2</th>
<th>IP-3</th>
<th>Type A package</th>
<th>Type B package</th>
<th>Type C package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop test 0.3-1.2 m</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Stacking</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Water spray</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penetration 1.0 m</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penetration 1.7 m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Package test requirements for accident conditions of transport

<table>
<thead>
<tr>
<th>Test Condition</th>
<th>Exception Package</th>
<th>IP-1</th>
<th>IP-2</th>
<th>IP-3</th>
<th>Type A Package</th>
<th>Type B Package</th>
<th>Type C Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop test 9 m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Liquid</td>
<td>HDD</td>
<td>X</td>
</tr>
<tr>
<td>Penetration 1 m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Crush test 9m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LDD</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Thermal test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Water immersion 15m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Water immersion 200 m</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contents &gt; 10^5 A_2</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Puncture / tearing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Enhanced thermal test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Impact test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
Excepted Packages

- Handling label for Excepted Packages of Radioactive Materials
Glove-Box GANUK GmbH

Zulassungs-Nr.: D 2086 B(U)-85
Behältertyp: B(U)
Fassinhalt / Jahr: 34 2000
Gesamtgewicht: 250 kg
Datum nächste WKP: 12/2003

USA 0532 B(U)-85

Gewährleistung: 2003

RADIOACTIVE

No. 03 02 02 65 DE
Mallinckrodt Medical B.V.
Westerduinweg
Petten/Holland
Storage

- Radioactive Material must be segregated sufficiently from workers and members of the public. The following values must be taken into account:
  a) for workers in regularly occupied working areas, a dose of 5 mSv/year
  b) for members of the public, in areas where the public has regular access, a dose of 1 mSv/year

- Additional requirements for fissile material
Loading – Separation Distances

Minimum distance: 1.15 m

Minimum distance: 1 m

Total TI = 6
Denial of shipments

• Many radiopharmaceuticals must be transported by air but sometimes delayed beyond useful life
  – negative perception
  – concern about cost/extent of training
  – lack of awareness about need to use and transport
• IAEA – International Steering Committee
  – To be a negligible problem by 2014........
Limitations

- For air transport, some dangerous goods are too dangerous to be carried by aircraft, others may be carried on “Cargo Aircraft Only” (CAO) and some are acceptable on both cargo and passenger aircraft.
- Both Cat B infectious substances and radioactive material in excepted packages may be transported by mail.
- Dangerous goods must not be transported in passenger baggage (with some exceptions)......
http://legacy.icao.int/anb/FLS/DangerousGoods/
krooney@icao.int