Annex A3 Shipping clinical specimens

Refer to current G*uidance on regulations for the Transport of Infectious Substances*

The 2017 update is available at:

http://apps.who.int/iris/bitstream/handle/10665/254788/WHO-WHE-CPI-2017.8-eng.pdf;jsessionid=971B46E26549C875C0C7A4B44F24752D?sequence=1

Definitions

Patient specimens

These are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, **blood and its components, tissue and tissue fluid swabs**, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Biological products

Biological products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

Because of the low hazard they present, the following substances of biological origin are **exempted from dangerous goods requirements and regulations**:

• Substances that do not contain infectious substances or will not cause disease in humans or animals

• Substances containing microorganisms that are not pathogenic to humans or animals

• Substances in a **form in which any pathogens present have been neutralized or inactivated** such that they no longer pose a health risk

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

• Blood and/or blood components collected and shipped for the purposes of transfusion and/or transplantation

• **Dried blood spots** and fecal occult blood screening tests

• Decontaminated medical or clinical wastes

Exempt Human/Animal Specimens: Human or animal specimens (patient specimens) for which there is minimal likelihood that pathogens are present are not subject to these Regulation if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate. The packaging should meet the following conditions:

(a) The packaging should consist of three components:

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

(ii) a leak-proof secondary packaging; and

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

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

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

Packaging, labelling and documentation requirements for infectious substances in Category B

Packaging

The triple packaging system continues to apply, including for local surface transport. Testing documents are not required, however. It may be possible to source packaging materials locally rather than finding an authorized supplier, provided that the packaging manufacturer and the shipper can comply fully with the requirements of P650. (See figure 9, below).

As for P620 (PI602 for the air mode), there is no comprehensive list of suppliers of packaging materials that comply with Packing Instruction P650. However, an Internet search using a suitable international or national search engine usually provides appropriate information, as well as access to national regulations. Search phrases such as "UN packaging" and "UN infectious substance packaging" produce extensive results. Carriers and forwarding agents should also be able to supply details of local suppliers or local companies that can provide such information.

To ensure correct preparation for transport, packaging manufacturers and subsequent distributors shall provide clear instructions to the consignor or persons preparing packages (e.g. patients) on how the packaging should be filled and closed.

For surface transport there is no maximum quantity per package. For air transport:

• No primary receptacle shall exceed 1 liter and the outer packaging must not contain more than 4 liters (for liquids)

• Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg (for solids)

These quantities exclude ice, dry ice or liquid nitrogen when used to keep specimens cold.

Figure 9. Example of the triple packaging system for the packing and labelling of Category B infectious substances (Figure kindly provided by IATA, Montreal, Canada)