

Update: Shipping of Infectious Substances and Patient Specimens

If you ship infectious substances & patient specimens you should be aware of the International Air Transport Association (IATA) Dangerous Goods and U. S. Department of Transportation (DOT) regulations. IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For this reason, the University of Michigan's Department of Occupational Safety and Environmental Health (OSEH) trains all employees shipping infectious substances and patient specimens to IATA standards. This ensures employees will be in compliance with international as well as US laws. U.S. postal patrons can expect action by the government to align with the DOT and IATA regulation, however, no time line has been established for this. In the meantime, until such alignment is realized, the Postal Service will follow their current rules. For further information see the OSEH Guideline [“Training for the Safe Transportation of Biologics”](#).

Classification and Identification

Infectious substances are divided into 2 categories, Category A and Category B.

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 in otherwise healthy humans or animals. Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned UN 2814. Infectious substances which cause disease only in animals must be assigned UN 2900. Indicative examples of substances that meet these criteria are given in [Appendix A](#). Category A infectious substances will follow Packing Instruction 602 and must be packed in certified packaging systems. See [PI 602](#)

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

Marking and Labeling

When overpacks are used, the marking "**Overpack**" must be indicated on the outer box.

You do not need to include the technical name of the organism in the proper shipping name on the package. The **technical name still needs to appear on the Shipper's Declaration.**

Documentation

Any shipment that requires a shipper to complete a Shipper's Declaration for Dangerous Goods must have the statement **“I declare that all of the applicable air transport**

requirements have been met” on the declaration. The statement can be in the Additional Handling Information section or following the certification statement.

Category B

An infectious substance which does not meet the criteria for inclusion in Category A. This may include materials previously shipped as diagnostic specimens. Category B infectious substances are shipped with the proper shipping name “Biological Substance, Category B” and assigned to UN 3373.

Packaging, Marking and Labeling

Packaging of Category B infectious substances must comply with IATA Packing Instruction 650. Packing Instruction 650 include:

- A diamond marking inside which is UN 3373. The marking must be 2 inches by 2 inches minimum. The proper shipping name Biological Substance, Category B must be adjacent to the marking. The name, address and phone number of a responsible person must be on the air waybill **or** marked on the package. If an airway bill is used, the “Nature and Quantity of Goods” box must show the text “Biological Substance, Category B” and “UN 3373”. Outer packages must be rigid so as to retain its original shape and dimensions at all times under all conditions of transportation. The outer package must have one side with a minimum dimension of at least 100mm x 100mm (4 inches x 4 inches).

See [PI 650](#) for packaging requirements.

The following definitions are included in the IATA Dangerous Goods Regulations:

Cultures – are the result of a process by which pathogens are intentionally propagated. This definition *does not include patient specimens (i.e., throat swabs) intended for diagnostic purposes.*

Exceptions

The following are not subject to IATA or DOT regulations:

- **Materials that do not contain pathogens or only contains inactivated or neutralized pathogens (See Guidance Document for Shipping with Chemical Preservatives)**
- **Environmental samples that do not pose a significant threat of infection (i.e., food, water soil or dust samples)**
- **Dried blood spots, or fecal occult screening tests**
- **Blood or blood components collected for the purpose of transfusion**
- **Tissue or organs used for transplantation**
- **Patient Specimens**

Patient Specimens – are those collected directly from humans or animals, including, but not limited to , excreta, secretions, 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.

Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these regulations 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”. The packaging must meet the following conditions:

The packaging must consist of three components:

- A leak-proof primary receptacle
- A leak-proof secondary packaging
- 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 x 100 mm.

For liquids: absorbent material in sufficient quantity to absorb the entire contents must 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. When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

* **NOTE:** In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms of the source patient, or professional judgment concerning an individual circumstances of the source patient or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

Classification Guide for Infectious Substances and Biologic Substances

