Shipping of Infectious Substances and Patient Specimens

If you ship infectious substances or 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. For further information see the OSEH Guideline “Training for the Safe Transportation of Biologies”.

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 620 (previously PI 602) and must be packed in certified packaging systems. See PI 620

*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.
*Note- Changes to Federal Express Air Shipping Regulations for Category A shipments:

Federal Express has implemented many changes to the manner in which you must ship Dangerous goods with them. The change with the biggest impact is that FedEx Express will require all Shipper's Declarations for Dangerous Goods (DDG) to be prepared using one of the following methods:

- FedEx-approved vendor software applications
- Preapproved shipper-proprietary software
- FedEx Express automated shipping solutions that have dangerous goods edit checks.

Note: FedEx Ship Manager® Software and FedEx Ship Manager® Server both have Dangerous Goods edit checks. The interactive templates previously available on Fedex.com are no longer offered. So those of you can no longer use the FedEx DDG PDF document for generating your DDG for shipment on FedEx.

FedEx has also changed how you can ship lithium batteries. If you have any questions or would like additional information please contact FedEx directly at the FedEx Dangerous Goods/Hazardous Materials Hotline at 1.800.GoFedEx/1.800.463.3339 (say "dangerous goods" when prompted).

**Category B**

An infectious substance which does not meet the criteria for inclusion in Category A. 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, 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.

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.

**Training for Shipping Infectious Substances (Category A, Biological Substance, Category B) and Exempt Patient Specimens**

Training is available on the OSEH website.

- The course **BLS209W Regulations for Shipping Biologics – Infectious Substances, Category B** is an on-line course intended to train individuals who prepare exempt patient specimens or Biological Substance, Category B (UN3373) materials. Dry ice is also included in this training course.

- The course **BLS208W Regulations for Shipping Biologics – Infectious Substances Category A** is an on-line course intended to train individuals who prepare exempt patient specimens or Category A Infectious Substances (UN2814, UN2900). Dry ice is also included in this training course.

**Note - Training must be documented and repeated every two years.**

Registration for these courses is available on the OSEH website Safety Training Tab. Please contact OSEH at 763-6973 if you need assistance with classifying your shipment.

To receive credit for these courses you must:

- Register on the OSEH website Safety Training Tab
- Review the course material
- Complete exam at the end of the course
Does the substance contain pathogens?

Yes

Was the substance collected for the purpose of transfusion or transplantation?

Yes

No

Is it a dried blood spot or fecal occult screening test?

Yes

No

Are you shipping a Patient Specimen unlikely to contain pathogens?

Yes

Ship as Patient Specimen

No

May it contain an infectious substance that when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals.

Yes

Infectious Substance, Category A: UN 2814, Use PI 620

No

Infectious Substance, Category B: UN 3373. Use PI 650

Your shipment is not subject to DOT/IATA Shipping Regulations