

NCSLPH Shipping Guidelines

Diagnostic Specimens

Although Diagnostic Specimens transported by dedicated motor vehicles by private or contract carriers are exempted from most requirements of the Hazardous Materials Regulation (HMR), these Diagnostic Specimens would be required to meet new IATA, DOT, and USPS regulations if transported by air. Thus, for the safety of all personnel involved in packing, shipping and receiving diagnostic specimens, the following shipping and packaging guidelines are recommended:

Definition: Any human or animal material including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals.

UN Number Assignment: Diagnostic specimens must be assigned to UN 3373 unless the source patient or animal may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, *and for which effective treatment and preventative measures are usually not available*, in which case they must be assigned to UN 2814 (Infectious substance, affecting humans) or UN 2900 (Infectious substance, affecting animals).

Forbidden Organisms: Be aware that some bacterial pathogens and viruses of humans and animals are NEVER permitted to be shipped as Diagnostic Specimens in any form.

IATA Packing Instruction 650:

- A. Inner packaging comprising
 1. a water tight primary receptacle(s), maximum quantity 500 mL, with biohazard label
 2. a water tight secondary packaging, maximum quantity per outer packaging 4 Liters
 3. an absorbent material placed between primary receptacle and secondary packaging
 4. multiple primary receptacles must be wrapped individually
- B. Outer packaging of adequate strength for its capacity, weight and intended use
 1. each completed package must pass a drop test at a height of 1.2 meters
 2. primary receptacle or secondary packaging must withstand without leakage an internal pressure of 95 kPa (0.95 bar, 13.8 lb/sq. in.) in a range of -40°C to $+55^{\circ}\text{C}$
 3. packages must be at least 100 mm (4 inches) in the smallest external dimension
 4. an itemized list of contents must be placed between the secondary packaging and outer packaging
- C. Outer packaging has approved “Diagnostic or Clinical Specimen” label with biohazard symbol; UN designation is not required. In addition, the name, address and telephone number of shipper should be on outside of packaging.

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Infectious Substances

Definition: Substances known to contain, or reasonably expected to contain, pathogens. Pathogens are identified as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant micro-organisms (hybrid or mutant) that are known or reasonably expected to cause infectious disease in humans or animals. However, they are not subject to the provision of these Regulations for this division if they are unlikely to cause human or animal disease. *Infectious substances are subject to the Regulations for this division only if they are capable of spreading disease when exposure to them occurs.*

Division 6.2: (Infectious substance) means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph.

Risk Groups are categorized as RG1, RG2, RG3 and RG4; most will fall into RG2 or RG3

- Risk Group 1 (RG1) are not subject to regulations, as they pose no risk to humans or animals.
- Risk Group 2 (RG2) indicates pathogen is at lower risk of transmission from one infected person to another, the risk of the spread of infection is limited and effective treatments are available.
- Risk Group 3 (RG3) indicates pathogen is at slightly higher risk of transmission from one infected person to another relative to RG2, the risk of infection is limited and effective treatments are available.
- Risk Group 4 (RG4) indicates pathogen is at higher risk of transmission from one infected person to another relative to RG3, risk of infection is higher, therefore risk of transport is higher. Effective treatments may be limited or unavailable.

UN Number Assignment: Generally, material is usually classified as one of the following:

- UN 2814, Infectious substance, affecting humans
- UN 2900, Infectious substance, affecting animals

IATA Packaging Instructions 602

- A. Inner packaging must meet all of the following requirements:
- A water tight primary receptacle, with biohazard label

- Water tight secondary packing, with name, address and telephone number of shipper on outside of secondary packaging
- Primary receptacle or secondary packaging used for infectious substances must be capable of withstanding an internal pressure of 95 kPa and temperatures ranging from –40°C to 55°C
- When the primary receptacle contains liquids, an absorbent material must be placed between the primary receptacle and the secondary packaging.
- If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually to ensure that contact between them is prevented.
- The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.
- An itemized list of contents between the secondary packaging and outer packaging.

B. Outer packaging highlights include the following requirements:

- Must be of adequate strength for its capacity, mass and intended use.
- Each package must be capable of passing the tests specified in Sec 178.609 of CFR
- Liquid or solid substances must have primary receptacles that have leak proof seals, such as adhesive tape when screw caps are used
- Ice or dry ice must be placed outside the secondary packaging.
- Interior supports must be provided to secure the secondary packaging in the originals position after the ice or dry ice has dissipated.
- If ice is used, packaging must be leak proof.
- If dry ice is used, the outer packaging must permit the release of carbon dioxide gas.

C. Outer labeling requires approved “Infectious substance” label, and name of infectious substance given on dangerous goods bill must match exactly the name written on the outside of the packaging. In addition, the name, address and telephone number of shipper should be on outside of outer packaging.

Further information can be found at the following web sites:

www.saftpak.com, www.dot.gov, and www.iata.org