

New DOT Regulations for shipping of Medical Diagnostic Specimens

A new Federal Department of Transportation (DOT) Regulation, HM226 was implemented on February 14, 2003 that will significantly impact shipping and packaging requirements for medical diagnostic specimens. Although TVMDL has no enforcement or regulatory role in the implementation of these new regulations, we feel an obligation to assist our clients by providing the attached brief summary of these changes. An excellent summary of key points in the regulation was also written by Chris Copeland, Legal Counsel for TVMA, and it is available in the March 2003 TVMA, FYI publication. Currently there is an effort underway in the DOT, the U.S. Postal Service, and the International Aviation Transport Association Agency to align their regulations and to eliminate conflicting requirements. However, that alignment process has not been completed and you are encouraged to consult with individual carriers if you have specific questions on their shipping requirements. The complete regulation can be found on the Department of Transportation web site at <http://hazmat.dot.gov/67fr-53118.pdf>.

§ 173.199 Diagnostic specimens and used health care products.

- (1) Diagnostic specimens must be packaged in a **triple packaging**, consisting of a primary receptacle, a secondary packaging, and an outer packaging.
- (2) **Primary receptacles** (i.e. Blood tube, specimen jar, etc.) must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging.
- (3) **Secondary packaging** must be secured in outer packaging with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging. An orange and black "**Biohazard Symbol**" must be fixed to the outer surface of the secondary container.
- (4) The completed package must be capable of successfully passing the **drop test** in § 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet).
- (5) The **outer packaging** must be clearly and durably marked with the words "**Diagnostic Specimen.**"

(a) **Liquid diagnostic specimens:** Liquid diagnostic specimens must be packaged in conformance with the following provisions:

- (1) The primary receptacle must be leakproof with a volumetric capacity of not more than 500 ml (16.9 ounces).
- (2) Absorbent material must be placed between the primary receptacle and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles.
- (3) The secondary packaging must be leakproof.

(b) **Solid diagnostic specimens:** Solid diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, secondary packaging, and outer packaging, conforming to the following provisions:

- (1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds).
- (2) If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them.
- (3) The secondary packaging must be leakproof.
- (4) The outer packaging may not exceed 4 kg (8.8 pounds) capacity.

(c) **For shipments by aircraft,** the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

- (1) The outer packaging may not exceed 4 L (1 gallon) capacity.
- (2) This volume limitation does not apply to parcels containing "animal body parts, whole organs, or whole bodies."

(d) **Fines and penalties:** According to 49 CFR Sec. 171.1 (c) "Any person who knowingly violates a requirement of the federal hazardous material transportation law.... Is liable for a civil penalty of not more than ...\$27,500... and not less than \$250 for each violation ...and shall be fined under Title 18, United States code, or imprisoned for not more than 5 years, or both."