Sec. 173.199 Diagnostic specimens and used health care products.

(a) Diagnostic specimens. Except as provided in this paragraph (a), diagnostic specimens are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section. Diagnostic specimens offered for transportation or transported by aircraft under the provisions of this section are subject to the incident reporting requirements in Sec. Sec. 171.15 and 171.16 of this subchapter. A diagnostic specimen meeting the definition of a hazard class other than Division 6.2 must be offered for transportation or transported in accordance with applicable requirements of this subchapter.

(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 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.

(4) The completed package must be capable of successfully passing the drop test in Sec. 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet). The outer packaging must be clearly and durably marked with the words `Diagnostic Specimen.'

(b) 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.

(4) 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).

(5) The outer packaging may not exceed 4 L (1 gallon) capacity.

(c) 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.

(d) Used health care products. A used health care product being returned to the manufacturer or the manufacturer's designee is excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this section. For purposes of this section, a health care product is used when it has been removed from its original inner packaging. Used health care products contaminated with or suspected of contamination with a Risk Group 4 infectious substance may not be transported under the provisions of this section.

(1) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(1).

(2) Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(1).

(3) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.
(e) Training. Each person who offers or transports a diagnostic specimen or used health care product under the provisions of this section must know about the requirements of this section.

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