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TITLE 49--TRANSPORTATION

CHAPTER I--RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION, DEPARTMENT OF
TRANSPORTATION

PART 173_SHIPPERS_GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS--
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and Class 7

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**.

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(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)(i).

(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)(i).

(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**.

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(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.

[67 FR 53142, Aug. 14, 2002]