

§ 173.198

§ 178.601 of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria:

(i) The sharps container is specifically approved and certified by the U.S. Food and Drug Administration as a medical device for reuse.

(ii) The sharps container must be permanently marked for reuse.

(iii) The sharps container must be disinfected prior to reuse by any means effective for the infectious substance the container previously contained.

(iv) The sharps container must have a capacity greater than 7.57 L (2 gallons) and not greater than 151.42 L (40 gallons) in volume.

[67 FR 53140, Aug. 14, 2002, as amended at 68 FR 57632, Oct. 6, 2003; 68 FR 75744, Dec. 31, 2003]

§ 173.198 Nickel carbonyl.

(a) Nickel carbonyl must be packed in specification steel or nickel cylinders as prescribed for any compressed gas except acetylene. A cylinder used exclusively for nickel carbonyl may be given a complete external visual inspection instead of the pressure test required by § 180.205 of this subchapter. Visual inspection must be in accordance with CGA Pamphlet C-6 (IBR, see § 171.7 of this subchapter).

(b) Packagings for nickel carbonyl must conform to § 173.40.

[Amdt. 173-224, 55 FR 52643, Dec 21, 1990, as amended at 67 FR 51643, Aug. 8, 2002; 68 FR 75742, Dec. 31, 2003]

§ 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 §§ 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.

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(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 packagings must be secured in outer packagings 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 § 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: