

(ii) Each BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top to prevent the intrusion of water (*e.g.*, rain or snow).

(iii) Each opening in a BOP must be fitted with a closure to prevent the intrusion of water or the release of any liquid during all loading, unloading, and transportation operations.

(iv) In the upright position, each BOP must be leakproof and able to contain a liquid quantity of at least 300 liters (79.2 gallons) with closures open.

(v) Inner packagings must be placed in a BOP in such a manner as to minimize the risk of breakage. Rigid inner packagings may not be placed in the same BOP with plastic film bag inner packagings unless separated from each other by rigid barriers or dividers to prevent damage to the packagings caused by load shifting during normal conditions of transportation.

(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated cultures and stocks of infectious substances containing Risk Group 2 or 3 pathogenic organisms, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as provided by paragraph (d)(3)(v) of this section.

(e) *Inner packagings authorized for Large Packagings, Carts, and BOPs.* After September 30, 2003, inner packagings must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, Cart, or BOP originates at a single location and is delivered to a single location.

(1) *Solids.* A plastic film bag is authorized as an inner packaging for solid regulated medical waste transported in a Cart, Large Packaging, or BOP. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent material to absorb and retain all liquid during transportation.

(i) The film bag may not exceed a volume of 175 L (46 gallons). The film bag must be marked and certified by its manufacturer as having passed the tests prescribed for tear resistance in ASTM D 1709-01, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method* (see §171.7 of this subchapter), and for impact resistance in ASTM D 1922-00a, *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method* (see §171.7 of this subchapter). The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.

(ii) The plastic film bag must be closed with a minimum of entrapped air to prevent leakage in transportation. The bag must be capable of being held in an inverted position

with the closed end at the bottom for a period of 5 minutes without leakage.

(iii) When used as an inner packaging for Carts or BOPs, a plastic film bag may not weigh more than 10 kg (22 lbs.) when filled.

(2) *Liquids.* Liquid regulated medical waste transported in a Large Packaging, Cart, or BOP must be packaged in a rigid inner packaging conforming to the requirements of paragraph (a) of this section. Liquid materials are not authorized for transportation in inner packagings having a capacity greater than 19 L (5 gallons).

(3) *Sharps.* Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in §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.

§ 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 (incorporated by reference; 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]

§ 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.

(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:

(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

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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.

(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 53240, Aug. 14, 2002]

EFFECTIVE DATE NOTE: At 67 FR 53140, Aug. 14, 2002, §173.199 was added, effective Oct. 1, 2002. At 67 FR 54967, Aug. 27, 2002, the effective date was corrected to Feb. 14, 2003.

§ 173.201 Non-bulk packagings for liquid hazardous materials in Packing Group I.

(a) When §172.101 of this subchapter specifies that a liquid hazardous material be packaged under this section, only non-bulk packagings prescribed in this section may be used for its transportation. Each packaging must conform to the general packaging requirements of subpart B of part 173, to the requirements of part 178 of this subchapter at the Packing Group I performance level, and to the requirements of the special provisions of column 7 of the §172.101 table.

(b) The following combination packagings are authorized:

Outer packagings:

- Steel drum: 1A1 or 1A2
Aluminum drum: 1B1 or 1B2
Metal drum other than steel or aluminum: 1N1 or 1N2
Plywood drum: 1D
Fiber drum: 1G
Plastic drum: 1H1 or 1H2
Steel jerrican: 3A1 or 3A2
Plastic jerrican: 3H1 or 3H2
Aluminum jerrican: 3B1 or 3B2
Steel box: 4A
Aluminum box: 4B
Natural wood box: 4C1 or 4C2

- Plywood box: 4D
Reconstituted wood box: 4F
Fiberboard box: 4G
Expanded plastic box: 4H1
Solid plastic box: 4H2

Inner packagings:

- Glass or earthenware receptacles
Plastic receptacles
Metal receptacles
Glass ampoules

(c) Except for transportation by passenger aircraft, the following single packagings are authorized:

- Steel drum: 1A1 or 1A2
Aluminum drum: 1B1 or 1B2
Metal drum other than steel, or aluminum: 1N1 or 1N2
Plastic drum: 1H1 or 1H2
Steel jerrican: 3A1 or 3A2
Plastic jerrican: 3H1 or 3H2
Aluminum jerrican: 3B1 or 3B2
Plastic receptacle in steel, aluminum, fiber or plastic drum: 6HA1, 6HB1, 6HG1, 6HH1
Plastic receptacle in steel, aluminum, wooden, plywood or fiberboard box: 6HA2, 6HB2, 6HC, 6HD2 or 6HG2
Glass, porcelain or stoneware in steel, aluminum or fiber drum: 6PA1, 6PB1 or 6PG1
Glass, porcelain or stoneware in steel, aluminum, wooden or fiberboard box: 6PA2, 6PB2, 6PC or 6PG2
Glass, porcelain or stoneware in solid or expanded plastic packaging: 6PH1 or 6PH2
Cylinders, specification, as prescribed for any compressed gas, except for Specifications 8 and 3HT

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended by Amdt. 173–241, 59 FR 67518, Dec. 29, 1994; Amdt. 173–261, 62 FR 24734, May 6, 1997]

§ 173.202 Non-bulk packagings for liquid hazardous materials in Packing Group II.

(a) When §172.101 of this subchapter specifies that a liquid hazardous material be packaged under this section, only non-bulk packagings prescribed in this section may be used for its transportation. Each packaging must conform to the general packaging requirements of subpart B of part 173, to the requirements of part 178 of this subchapter at the Packing Group I or II performance level (unless otherwise excepted), and to the particular requirements of the special provisions of column 7 of the §172.101 table.

(b) The following combination packagings are authorized:

Outer packagings: