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requirements, depending on the physical state and other characteristics of the material.

(1) *Infectious substances shipped at ambient temperatures or higher*. Primary receptacles must be made of glass, metal, or plastic. Positive means of ensuring a leakproof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape, paraffin sealing tape, or manufactured locking closure. Lyophilized substances may also be transported in primary receptacles that are flame-sealed with glass ampoules or rubber-stoppered glass vials fitted with metal seals.

(2) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice)*. Ice, dry ice, or other refrigerant must be placed around the secondary packagings or in an overpack with one or more complete packages marked in accordance with §178.503 of this subchapter. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack must be leakproof. If dry ice is used, the outer packaging or overpack must permit the release of carbon dioxide gas and otherwise meet the provisions in §173.217. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost.

(3) *Infectious substances shipped in liquid nitrogen*. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of transport by aircraft to which they could be subjected if refrigeration were lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in §172.312(a) of this subchapter must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal containing or contaminated with an infectious substance must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging meeting the requirements of §173.197.

[67 FR 53140, Aug. 14, 2002, as amended at 71 FR 32260, June 2, 2006; 74 FR 2259, Jan. 14, 2009]

§173.197 Regulated medical waste.

(a) *General provisions*. Non-bulk packagings, Large Packagings, and non-specification bulk outer packagings used for the transportation of regulated medical waste or clinical waste or (bio) medical waste must be rigid containers meeting the provisions of subpart B of this part.

(b) *Non-bulk packagings*. Except as provided in §173.134(c) of this subpart, non-bulk packagings for regulated medical waste or clinical waste or (bio) medical waste must be UN standard packagings conforming to the requirements of Part 178 of this subchapter at the Packing Group II performance level. A non-bulk packaging used as a sharps container must be puncture-resistant for sharps and sharps with residual fluid as demonstrated by conducting the performance tests in Part 178, subpart M, of this subchapter on packagings containing materials representative of the sharps and fluids (such as sterile sharps) intended to be transported in the packagings. Sharps containers must be securely closed to

prevent leaks or punctures in conformance with the instructions provided by the packaging manufacturer in accordance with §178.2(c) of this subchapter.

(c) *Large Packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements specified in subparts P and Q of part 178 of this subchapter and conforming to other requirements of this paragraph (c) may be used for the transportation of regulated medical waste, provided the waste is contained in inner packagings conforming to the requirements of paragraph (e) of this section. * * * Each Large Packaging design must be capable of meeting the vibration test specified in §178.819 of this subchapter. Each Large Packaging is subject to the periodic design requalification requirements for IBCs in §178.801(e) of this subchapter, and to the proof of compliance requirements of §178.801(j) and record retention requirements of §178.801(l) of this subchapter. Inner packagings used for liquids must be rigid.

(1) *Authorized packagings.* Only the following Large Packagings are authorized for the transportation of liquid or solid regulated medical waste:

(i) Metal: 50A, 50B, or 50N.

(ii) Rigid plastic: 50H.

(2) *Additional requirements.* Each Large Packaging used to transport liquid regulated medical waste must contain absorbent material in sufficient quantity and appropriate location to absorb the entire amount of liquid present in the event of an unintentional release of contents. Each Large Packaging design intended for the transportation of sharps containers must be puncture resistant and capable of retaining liquids. The design must also be tested and certified as meeting the performance tests specified for intermediate bulk containers intended for the transportation of liquids in subpart O of part 178 of this subchapter.

(d) *Non-specification bulk packaging.* A wheeled cart (Cart) or bulk outer packaging (BOP) is authorized as an outer packaging for the transportation of regulated medical waste in accordance with the provisions of this paragraph (d).

(1) *General requirements.* The following requirements apply to the transportation of regulated medical waste in Carts or BOPs:

(i) Regulated medical waste in each Cart or BOP must be contained in non-bulk inner packagings conforming to paragraph (e) of this section.

(ii) Each Cart or BOP must have smooth, non-porous interior surfaces free of cracks, crevices, and other defects that could damage plastic film inner packagings or impede disinfection operations.

(iii) Except as otherwise provided in this paragraph (d), each Cart or BOP must be used exclusively for the transportation of regulated medical waste. Prior to reuse, each Cart or BOP must be disinfected by any means effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated concentrated stock cultures of infectious substances containing Category A materials may not be transported in a Cart or BOP.

(v) Division 6.1 toxic waste or Class 7 radioactive waste, with the exception of chemotherapeutic waste, may not be transported in a Cart or BOP.

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated concentrated stock cultures of infectious substances containing Category B infectious substances; unabsorbed liquids; and sharps containers may be transported in a Cart or BOP only if packaged in rigid non-bulk packagings conforming to paragraph (a) of this section.

(2) *Wheeled cart (Cart).* A Cart is authorized as an outer packaging for the transportation of regulated medical waste if it conforms to the following requirements:

(i) Each Cart must consist of a solid, one-piece body with a nominal volume not exceeding 1,655 L (437 gallons).

(ii) Each Cart must be constructed of metal, rigid plastic, or fiberglass fitted with a lid to prevent leakage during transport.

(iii) Each Cart must be capable of meeting the requirements of §178.810 (drop test) at the Packing Group II performance level.

(iv) Inner packagings must be placed into a Cart and restrained in such a manner as to minimize the risk of breakage.

(3) *Bulk outer packaging (BOP).* A BOP is authorized as an outer packaging for regulated medical waste if it conforms to the following requirements:

(i) Each BOP must be constructed of metal or fiberglass and have a capacity of at least 3.5 cubic meters (123.6 cubic feet) and not more than 45 cubic meters (1,590 cubic feet).

(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 concentrated stock cultures of infectious substances containing Category B infectious substances, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as required in 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 1922, ''Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method'' (IBR, §171.7 of this subchapter) and for impact resistance in ASTM D 1709, ''Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method'' (IBR, §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 or clinical waste or (bio) medical waste transported in a Large Packaging, Cart, or BOP must be packaged in a rigid inner packaging conforming to the provisions of subpart B of this part. conforming to the provisions of subpart B of this part. 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 must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in Part 178, subpart M, 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; 71 FR 32261, June 2, 2006; 71 FR 78632, Dec. 29, 2006; 75 FR 60339, Sept. 30, 2010]

§ 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 Category B infectious substances.

(a) *Category B infectious substances.* Except as provided in this paragraph (a), Category B infectious substances are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section. Category B infectious substances offered for transportation or transported under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter and to the requirements in § 175.75(b) of this subchapter concerning cargo location. Except as provided in paragraph (a)(9) of this section, a Category B infectious substance 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) A Category B infectious substance must be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid 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 rigid 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 designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation. The packaging must be capable of successfully passing the drop tests in §§ 178.609(d) and (h) of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

(5) The following mark must be displayed on the outer packaging on a background of contrasting color. The width of the line must be at least 2 mm (0.08 inches) and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length. The