

liquid per 0.45 kg (1 pound) water capacity of cylinder. Each filled cylinder must be tested for leakage before being offered for transportation or transported and must show absolutely no leakage; this test must consist of passing a piece of Guignard's sodium picrate paper over the closure of the cylinder, without the protection cap attached, to detect any escape of hydrogen cyanide from the cylinder. Other equally efficient test methods may be used in place of sodium picrate paper.

(c) Packagings for hydrogen cyanide must conform to § 173.40.

[Amdt. 173–224, 55 FR 52643, Dec. 21, 1990, as amended at 56 FR 66271, Dec. 20, 1991]

§ 173.196 Infectious substances.

(a) *Division 6.2 packaging.* A Division 6.2 packaging must meet the test standards of § 178.609 of this subchapter and must be marked in conformance with § 178.503(f) of this subchapter. Division 6.2 packaging is a triple packaging consisting of the following components:

(1) A watertight primary receptacle.

(2) A watertight secondary packaging. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be wrapped individually to prevent contact between them.

(3) An outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure at least 100 mm (3.9 inches) at its smallest overall external dimension.

(4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.

(5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.

(6) The primary receptacle or secondary packaging used for infectious substances 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).

(7) The primary receptacle or secondary packaging used for infectious

substances must be capable of withstanding without leakage temperatures in the range of -40°C to $+55^{\circ}\text{C}$ (-40°F to $+131^{\circ}\text{F}$).

(b) *Additional requirements for packaging infectious substances.* Infectious substances must be packaged according to the following requirements depending on the physical state and other characteristics of the material:

(1) *Infectious lyophilized (freeze-dried) substances.* Primary receptacles must be flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.

(2) *Liquid or solid infectious substances—*

(i) *Infectious substances shipped at ambient temperatures or higher.* Authorized primary receptacles are those 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.

(ii) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside 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 outside packaging must be leakproof. If dry ice is used, the outside packaging 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 air transport to which they could be subjected if refrigeration were lost.

(iii) *Infectious substances shipped in liquid nitrogen.* Primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. 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 air transport to which they could be subjected if refrigeration were to be lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks (also called “dry shippers”) 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]

§ 173.197 Regulated medical waste.

(a) *General provisions.* Non-bulk packagings, large packagings, and bulk outer packagings used for the transportation of regulated medical waste must be rigid containers meeting the provisions of subpart B of this part.

(b) *Non-bulk packagings.* Except as otherwise provided in §173.134 of this subpart, non-bulk packagings for regulated medical waste must be DOT specification packagings conforming to the requirements of Part 178 of this subchapter at the Packing Group II performance level. A non-bulk packaging must be puncture-resistant for sharps and sharps with residual fluid as dem-

onstrated 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.

(c) *Large Packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements of the UN Recommendations (IBR, see §171.7 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