§ 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.

(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).

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

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

(2) 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
§ 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.

[Amendment to be published]

§ 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...