

the drop test in 49 CFR 178.603 at a drop height of at least 1.2 meters (3.9 feet). The address side of the outer shipping container must be clearly and durably marked "Diagnostic Specimen." A shipping paper is not required.

b. Solid (or Dried) Diagnostic Specimens.

(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 container, they must be individually wrapped or separated with sufficient cushioning material to prevent contact between them. The secondary container must be siftproof to contain the contents should the primary receptacle(s) leak. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(3) The outer shipping container may not exceed 4 kg (8.8 pounds) capacity. The outer shipping container must be clearly and durably marked "Diagnostic Specimen." A shipping paper is not required.

8.7 Sharps Waste and Other Mailable Regulated Medical Waste

Regulated medical waste and sharps waste known to contain or suspected of containing an infectious substance in Risk Group 4 are nonmailable. Regulated medical waste and sharps waste as defined in 8.2e and 8.2g, respectively, and classified in Risk Group 1, 2, or 3 are permitted for mailing only using merchandise return service (see S923) with First-Class Mail or Priority Mail, subject to the following requirements:

a. Authorization. Each distributor or manufacturer of a complete regulated medical waste or sharps waste mailing container system (including all component parts required to safely mail such waste to a storage or disposal facility) must obtain authorization from the USPS prior to mailing. Before applying for authorization, each type of mailing container system must be tested and certified under the standards in 8.7d by an independent testing facility. The manufacturer or distributor in whose name the authorization is being sought must submit a written request to the manager, Mailing Standards, USPS Headquarters (see G043 for address). The request for authorization must contain the following:

(1) An irrevocable \$50,000 surety bond or letter of credit as proof of sufficient financial responsibility to cover disposal costs if the manufacturer (or distributor) ceases doing business before all its waste container systems

are disposed of or to cover cleanup costs if spills occur while the containers are in USPS possession. The surety bond or letter of credit must be issued in the name of the manufacturer or distributor seeking the authorization and must name the USPS as the beneficiary or obligee, as appropriate.

(2) Address of the headquarters or general business office of the distributor or manufacturer seeking the authorization.

(3) Address of each disposal and storage site.

(4) List of all types of mailing container systems to be covered by the request, a complete sample of each mailing container system, and proof of package testing certifications performed by the independent testing facility that subjected the packaging materials to the testing requirements in 8.7d.

(5) Copy of the proposed waste manifest (*i.e.*, shipping paper) to be used with each mailing container system.

(6) 24-hour toll free telephone number for emergencies.

(7) List of the types of waste to be mailed for disposal in each mailing container system.

(8) Copy of the merchandise return service label to be used with each mailing container system.

b. Packaging. Regulated medical waste and sharps waste in Risk Group 4 are nonmailable. A waste material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4, must be packaged under 8.10. The packaging for regulated medical waste and sharps waste in Risk Group 1, 2, or 3 is subject to these standards:

(1) Regulated medical waste and sharps waste meeting the definitions in 8.2e and 8.2g, respectively, must be collected in a rigid, securely sealed, and leakproof primary receptacle. For sharps waste, the primary receptacle must also be puncture-resistant and may not have a maximum capacity that exceeds 3 gallons in volume. For regulated medical waste, the primary receptacle may not have a maximum capacity that exceeds 5 gallons in volume. Each primary receptacle may not contain more than 50 ml (1.66 ounces) of residual waste liquid. Each primary receptacle must display the international biohazard symbol shown in Exhibit 8.7c(2). Each primary receptacle must maintain its integrity when exposed to temperatures between 0° and 120°F.

(2) The primary receptacle must be packaged within a watertight secondary container or containment system. The

secondary container may consist of more than one component. If one of the components is a plastic bag, it must be at least 3 mil in thickness and be used in conjunction with a strong fiberboard box. A plastic bag by itself does not meet the requirement for a secondary container. Several primary receptacles may be enclosed in a secondary container. The primary receptacle(s) must fit securely and snugly within the secondary container to prevent breakage during ordinary processing.

(3) The secondary container must be enclosed in a strong outer shipping container constructed of 200-pound grade corrugated fiberboard. The joints and flaps of the outer shipping container must be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant. Fiberboard boxes with interlock bottom flaps (*i.e.*, easy-fold) are not permitted as outer shipping containers unless reinforced with water-resistant tape. The secondary container must fit securely and snugly within the outer shipping container to prevent breakage during ordinary processing.

(4) There must be enough material within a watertight barrier to absorb and retain three times the total liquid allowed within the primary receptacle (150 ml per primary receptacle) in case of leakage.

(5) Each mailpiece must not weigh more than 25 pounds.

(6) In each mailing container system, the authorized manufacturer or distributor must include a step-by-step instruction sheet that clearly details the proper sequence and method of container system assembly prior to mailing to prevent package failure during transport due to improper assembly. The instruction sheet must also include a customer service telephone number, or provide specific information on where such a telephone number is located elsewhere on the container system, for third-party end users to contact if they have assembly questions or find a component part is missing.

c. Mailpiece Labeling, Marking, and Documentation. Regulated medical waste and sharps waste must meet the following requirements:

(1) Each primary receptacle and outer shipping container must bear a label, which cannot be detached intact, showing: (a) The company name of the manufacturer or the distributor to which the mailing authorization is issued; (b) the USPS Authorization Number, and; (c) the container ID number (or unique model number) signifying that the