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Part III

Department of Transportation

**Research and Special Programs
Administration**

**49 CFR Part 171 et. al.
Hazardous Materials: Revision to
Standards for Infectious Substances; Final
Rule**



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11. In § 172.502, paragraph (b)(2) is revised to read as follows:

§ 172.502 Prohibited and permissive placarding.

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(b) * * *

(2) The restrictions of paragraph (a) of this section do not apply to the display of a BIOHAZARD marking, a “HOT” marking, or an identification number on a white square-on-point configuration in accordance with §§ 172.323(c), 172.325(c), or 172.336(b) of this part, respectively.

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PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

12. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5127, 44701; 49 CFR 1.45, 1.53.

13. In § 173.6, paragraph (a)(4) is redesignated as paragraph (a)(5), and a new paragraph (a)(4) is added to read as follows:

§ 173.6 Materials of trade exceptions.

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(a) * * *

(4) A Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product, or regulated medical waste. The material must be contained in a combination packaging. For liquids, the inner packaging must be leak tight, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging must be constructed of a rigid material resistant to punctures and

leaks. For all Division 6.2 materials, the outer packaging must be a strong, tight packaging securely closed and secured against movement.

(i) For a diagnostic specimen or biological product, combination packagings must conform to the following capacity limitations:

(A) One or more inner packagings where the gross mass or capacity of each inner packaging does not exceed 0.5 kg (1.1 pound), or 0.5 L (17 ounces), and an outer packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon); or

(B) A single inner packaging with a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons) in a single outer packaging.

(ii) For a regulated medical waste, a combination packaging must consist of one or more inner packagings having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon), and an

outer packaging having a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons).

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14. Section 173.28 is amended by adding paragraph (f) to read as follows:

§ 173.28 Reuse, reconditioning and remanufacture of packagings.

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(f) A Division 6.2 packaging to be reused must be disinfected prior to reuse by any means effective for neutralizing the infectious substance the packaging previously contained. A secondary packaging or outer packaging conforming to the requirements of § 173.196 or § 173.199 need not be disinfected prior to reuse if no leakage from the primary receptacle has occurred.

15. Section 173.134 is revised to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions and exceptions.

(a) *Definitions and classification criteria.* For purposes of this subchapter, the following definitions and classification criteria apply:

(1) *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph (a). Assignment to a risk group is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning

individual circumstances of the source patient or animal. Infectious substances are subject to applicable requirements in 42 CFR Part 72—Interstate Shipment of Etiologic Agents.

(2) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. A *biological product* includes a material manufactured and distributed in accordance with one of the following provisions: 9 CFR part 102 (Licenses for Biological Products); 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR part 104 (Permits for Biological Products); 21 CFR part 312 (Investigational New Drug Application); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR parts 600 to 680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). A *biological product* known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material prepared and maintained for growth and storage and containing a Risk Group 2, 3 or 4 infectious substance.

(4) *Diagnostic specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A *diagnostic specimen* is not assigned a

UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(5) *Regulated medical waste* means a waste or reusable material known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment or immunization of human beings or animals; or the production or testing of biological products. *Regulated medical waste* containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(6) *Risk group* means a ranking of a micro-organism's ability to cause injury through disease. A *risk group* is defined by criteria developed by the World Health Organization (WHO) based on the severity of the disease caused by the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a *risk group* and a packing group. The criteria for each *risk group* according to the level of risk are as follows:

RISK GROUP TABLE

Risk group	Pathogen	Risk to individuals	Risk to the community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	High	High.
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	High	Low.
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	Moderate	Low.
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	None or very low	None or very low.

(7) *Sharps* means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. *Sharps* includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

(8) *Toxin* means a Division 6.1 material from a plant, animal, or bacterial source. A *toxin* containing an infectious substance or a *toxin* contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(9) *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

(b) *Exceptions*. The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(1) A biological product known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen.

(2) A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs.

(3) A biological product, including an experimental product or component of a product, subject to Federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.

(4) Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

(5) Blood collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as

part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped in accordance with § 173.199.

(6) A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. If a diagnostic specimen or biological product meets the definition of regulated medical waste in paragraph (a)(5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(7) Laundry or medical equipment conforming to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment being transported for disposal.

(8) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(9) A living person.

(10) Any waste or recyclable material, other than regulated medical waste, including—

(i) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(ii) Sanitary waste or sewage;

(iii) Sewage sludge or compost;

(iv) Animal waste generated in animal husbandry or food production; or

(v) Medical waste generated from households and transported in accordance with applicable state, local, or tribal requirements.

(11) Corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory.

(12) Forensic material transported on behalf of a U.S. Government, state, local

or Indian tribal government agency, except that—

(i) Forensic material known or suspected to contain a Risk Group 2 or 3 infectious substance must be shipped in a packaging conforming to the provisions of § 173.24.

(ii) Forensic material known or suspected to contain a Risk Group 4 infectious substance listed as a select agent in 42 CFR Part 72 must be transported in packaging capable of meeting the test standards in § 178.609 of this subchapter. The secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(13) Environmental microbiological samples, such as a sample of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

(14) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act.

(c) *Exceptions for regulated medical waste*. The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste transported by a private or contract carrier is excepted from—

(i) The requirement for an “INFECTIOUS SUBSTANCE” label if the outer packaging is marked with a “BIOHAZARD” marking in accordance with 29 CFR 1910.1030; and

(ii) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of this section if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030.

(2) A waste culture or stock of a Risk Group 2 or 3 infectious substance may be offered for transportation and transported as a regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier using a vehicle dedicated to the transportation of regulated medical waste. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.

16. Section 173.196 is revised to read as follows:

§ 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.

17. Section 173.197 is revised to read as follows:

§ 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 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.

(c) *Large Packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements of the UN Recommendations 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 intermediate bulk containers 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 cultures and stocks of infectious substances containing Risk Group 4 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 stocks and cultures of infectious substances containing Risk Group 2 or 3 pathogenic organisms; 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 § 178.603 (drop test), as specified for solids 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 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.

18. A new § 173.199 is added to read as follows:

§ 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 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.

PART 177—CARRIAGE BY PUBLIC HIGHWAY

19. The authority citation for part 177 continues to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

20. In § 177.834, paragraphs (a) and (g) are revised to read as follows:

§ 177.834 General requirements.

(a) *Packages secured in a vehicle.* Any tank, barrel, drum, cylinder, or other packaging not permanently attached to a motor vehicle and containing any Class 2 (gases), Class 3 (flammable liquid), Division 6.1 (poisonous), Division 6.2 (infectious substance), Class 7 (radioactive), or Class 8 (corrosive) material must be secured against movement within the vehicle on which it is being transported, under conditions normally incident to transportation.

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(g) *Prevent relative motion between containers.* Containers of Class 1 (explosive), Class 2 (gases), Class 3 (flammable liquid), Class 4 (flammable solid), Class 5 (oxidizing), Division 6.1 (poisonous), Division 6.2 (infectious substance), or Class 8 (corrosive) materials must be so braced as to prevent motion thereof relative to the vehicle while in transit. Containers having valves or other fittings must be loaded to minimize the likelihood of damage thereto during transportation.

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21. In § 177.843, paragraph (d) is added to read as follows:

§ 177.843 Contamination of vehicles.

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(d) Each transport vehicle used to transport Division 6.2 materials must be