

November 8, 2010



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue, Southeast
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 11185
(TENTH REVISION)

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: (See individual authorization letter)
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of solid regulated medical waste, as defined in paragraph 7.a. below, in a non-DOT specification packaging consisting of a bulk outer packaging and non-bulk inner packagings conforming to the provisions of this special permit. This special permit provides no relief from any Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce, including loading and unloading.
 - c. Unless otherwise stated herein, this special permit consists of the special permit authorization letter issued to the grantee together with this document.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180. All sections referenced in this special permit are found in these Parts.
4. REGULATIONS FROM WHICH EXEMPTED: The 49 CFR § 172.101 entry in Columns (8)(b) and (8)(c) for Regulated medical waste, and § 173.197 in that a non-DOT specification packaging is defined and authorized herein.
5. BASIS: This special permit is based on the Pipeline and Hazardous Materials Safety Administration's (PHMSA) editorial review under § 107.121 initiated on December 4, 2008.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Regulated medical waste	6.2	UN3291	II

7. SAFETY CONTROL MEASURES:a. LIMITATIONS ON REGULATED MEDICAL WASTE:

(1) This special permit authorizes the transportation of regulated medical waste, as defined in § 173.134(a)(4), in a packaging system which consists of a bulk outer packaging - caster cart (Cart) used exclusively for medical waste, and non-bulk inner packagings. The inner packaging may be a plastic film bag conforming to paragraph 7.b.(2) of this special permit or a rigid packaging conforming to the requirements of § 173.197.

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

(3) Only solid regulated medical waste may be transported in the plastic film bags described in paragraph 7.b.(2) below. No free liquids are authorized. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent materials to absorb and retain all liquid during transportation.

(4) Division 6.1 toxic waste and Class 7 radioactive waste, with the exception of those materials that are chemotherapeutic waste, may not be transported under this special permit. Division 6.1 and Class 7 chemotherapeutic waste may be transported under this special permit in accordance with paragraph 8.b.

(5) Untreated cultures and stocks of infectious substances at Biosafety Level 4, as defined in HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, May 1993, Section II, may not be transported under this special permit.

(6) Sharps containers may be transported under this special permit in accordance with paragraph 8.b.

b. PACKAGING: The authorized packaging consists of triple packaging of which the outer packaging is the Meese Model 72F Poly-Trux Cart and the intermediate and inner packagings are plastic film bags.

(1) The cart must be a solid, one piece body made up of a molded polyethylene base with a hinged front lid and lockable top. The nominal volume of the cart cannot exceed 1,378 L (364 gallons). The cart must be mounted on roller wheels. Its body may have a low cut front with plastic flap closure. The exterior surface, except for the fasteners of the plastic closure and pull handle, must be smooth, non-porous and easy to decontaminate.

(2) The outer packaging must be lined with one intermediate packaging that is a plastic bag that has been certified by its manufacturer as being capable of passing the test prescribed for tear-resistance in ASTM D 1922-94A, titled Propagation Tear Resistance of Plastic Film, and for impact resistance in ASTM D 1709-97, titled Test Method for Impact Resistance by the Free Falling Dart Method. Each intermediate plastic lining must have 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. The intermediate plastic lining must be closed to a leakproof condition prior to the transportation of regulated medical waste. The intermediate plastic lining must be durably marked or tagged with the name city and state of the offeror. An intermediate plastic film bag may contain more than one inner packaging.

(3) All regulated medical waste, except sharps containers, must be contained in inner packagings that are plastic film bags. Each inner plastic film bag must be closed securely to a leakproof condition prior to being placed in the intermediate plastic film bag. Plastic film bag inner packagings must be certified by the manufacturer as being capable of passing the test prescribed for tear-resistance in ASTM D 1922-94A, titled Propagation Tear Resistance of Plastic Film, and for impact resistance in ASTM D 1709-97, titled Test Method for Impact Resistance by the Free Falling Dart Method. Each bag must have 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. Marking of inner packagings is not required.

c. RESPONSIBILITIES OF SPECIAL PERMIT HOLDER (CARRIER):

(1) The carrier must provide a copy of this special permit to each person from whom the carrier intends to accept regulated medical waste for transportation under this special permit, and the carrier must obtain and retain from each such offeror of regulated medical waste a written certification that the offeror understands and accepts the responsibilities of an offeror as specified in paragraph 7.d.

(2) The carrier must provide a Cart that meets the requirements of paragraph 7.b.(1). The Cart must be used exclusively for transporting medical waste.

(3) Prior to providing a Cart for reuse, the carrier must decontaminate the Cart with a disinfectant that is registered with the U.S. Environmental Protection Agency (EPA) for use as a disinfectant. A list of registered disinfectants may be obtained from EPA by calling 1-800-447-6349.

(4) Prior to transporting regulated medical waste, the carrier must perform an external visual inspection of the transport vehicle to determine that it is closed and free of leakage.

(5) The carrier must transport a vehicle loaded with one or more Carts containing regulated medical waste to a final destination that is authorized by applicable laws for storage, treatment or disposal of such wastes, without unnecessary delay from the time the carrier's motor vehicle leaves the offeror's premises.

(6) The carrier must have a written spill response plan that includes provisions for the decontamination of spilled materials and for personal protective equipment to be carried on the vehicle and used to protect its employees from contact with infectious materials in any form.

(7) The carrier must respond to any release from a Cart that occurs during its transportation, including its unloading from the vehicle. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the Cart involved.

(8) As required by paragraph 12 of this special permit, the carrier must report any release of any material from the Cart during its transportation (including the unloading of the Cart off of the carrier's motor vehicle). The unloading or emptying of the contents of the Cart at a storage, treatment or disposal facility does not constitute a release under this paragraph.

d. RESPONSIBILITIES OF OFFERORS:

(1) A person who offers a regulated medical waste (e.g., a hospital or clinic that generates regulated medical waste) must comply with all applicable requirements of the HMR except as provided by this special permit.

(2) The offeror must provide the carrier (holder of this special permit) a signed certification that the offeror has received a copy of the special permit and understands and accepts the responsibilities of an offeror as stated in this special permit.

(3) The offeror must maintain a current copy of this special permit at each location where the regulated medical waste is offered for transportation (disposal).

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(4) The offeror's signature on the certification required on a shipping paper serves as affirmation of compliance with terms of this special permit. The requirements for a shipping paper are contained in §§ 172.200 - 172.204.

(5) No package containing materials prohibited by paragraph 7.a. of this special permit may be offered for transportation under this special permit.

(6) When filled, a plastic film bag may not weigh more than 10 kg (22 lbs).

(7) Plastic film bags must be closed with a minimum of entrapped air and sealed by twisting the bag at the top and taping or tying the twist to prevent the release of any material from the bag when it is inverted.

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

(9) During all times that a Cart is at the offeror's premises, and not under the carrier's direct control, the Cart is the responsibility of the offeror. The hinged lid on the Cart must be closed except when regulated medical waste is being loaded into the Cart.

(10) During all times that a truck or trailer is parked at the offeror's premises, and not under the carrier's direct control, the truck or trailer is the responsibility of the offeror. The doors on the vehicle must be closed except when regulated medical waste is being loaded into the vehicle.

(11) Before loading the Cart into a transport vehicle, the offeror must assure that the Cart is closed and sealed to prevent the release of any material during transportation.

(12) The offeror must load each Cart containing regulated medical waste into the transport vehicle in accordance with the carrier's instructions.

(13) The offeror must have a written spill response plan that provides for the decontamination of spilled materials and for personal protective equipment to be used to protect its employees from contact with infectious materials in any form.

(14) The offeror must respond to any release from a Cart that occurs during its loading into the carrier's transport vehicle. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the Cart involved.

e. TESTING - The Cart must be capable of meeting the requirements of §§ 178.603 (drop test) and 178.606 (stacking test), as specified for solids at the Packing Group II performance level.

8. SPECIAL PROVISIONS:

a. MARKING: The carrier must plainly and durably mark the outside of each Cart with "DOT-SP 11185" and with identification numbers in the manner specified for a bulk packaging in §§ 172.302(b), (c) and 172.331. Carts previously marked "DOT-SP 11185" are authorized for use under this special permit.

b. Chemotherapeutic waste, untreated stocks and cultures of infectious substances at Biosafety Level 1, 2 and 3, unabsorbed liquids, and sharps (e.g., glass, needles, or other sharp objects) may be transported in a Cart only if packaged in rigid non-bulk packagings as prescribed in the HMR (See §§ 173.134, 173.196 and 173.197).

c. Carts containing regulated medical waste as authorized by this special permit must be transported by a private or contract carrier in a transport vehicle dedicated to the service of hauling waste materials only. Each transport vehicle must be decontaminated after each delivery of regulated medical waste, prior to any loading of decontaminated carts for reuse.

d. Transport vehicles may deliver decontaminated Carts for reuse. If a transport vehicle is used to deliver and pick up Carts at multiple locations on a single trip, the carrier must have a loading plan that keeps empty Carts for reuse segregated from Carts containing regulated medical waste.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS: The carrier must keep a current copy of this special permit aboard each motor vehicle used to transport packages covered by this special permit. The exception in § 173.134(b) (3) (ii) does not apply to waste transported under the authority of this special permit.

11. COMPLIANCE:
 - a. Failure by a person to comply with the terms and conditions prescribed in this special permit and the HMR may result in modification, suspension or termination of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq.

 - b. Each [Hazmat employee], as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

 - c. No person may use or apply this special permit, including display of its number, when the special permit has expired or is otherwise no longer in effect.

 - d. The offering and transportation of regulated medical waste in a packaging authorized by this special permit is not subject to the registration and fee requirements of Subpart G of 49 CFR Part 107.
Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous

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materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: PTolson/sln