

July 1, 2009



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 13556
(SEVENTH 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 certain regulated medical wastes, designated as sharps, in non-DOT specification containers fitted into custom designed wheeled racks for transport by motor vehicle. This special permit provides no relief from the 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. The safety analyses did not consider the hazards and risks associated with consumer use or other uses not associated with transportation in commerce.
 - 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.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.301(c) in that the special permit number is not required on packagings; § 173.197(d) in that the rigid plastic packagings in custom designed wheeled racks are not required to meet the non-bulk performance oriented packaging standards; and § 173.24(f)(1)(ii) in that the wheeled racks do not have to be leakproof.

5. BASIS: This special permit is based on the application of Stericycle, dated May 12, 2009, submitted in accordance with § 107.105 and the public proceeding thereon.
6. HAZARDOUS MATERIALS (49 CFR § 172.101):

| Hazardous Materials Description | | | |
|--|-------------------------------|------------------------------|----------------------|
| Proper Shipping Name | Hazard Class/ Division | Identification Number | Packing Group |
| Regulated medical waste, n.o.s. | 6.2 | UN3291 | II |

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed are non-DOT specification sharps containers which are fitted into a custom designed wheeled rack for transportation. The sharps containers are made of rigid plastic, ranging in size from 1 gallon to 18 gallons capacity, and marked with a biohazard symbol. The sharps containers and wheeled racks must conform to the photographs and descriptions in the special permit applications of Bio Systems, Inc. or Medical Systems, Inc. on file with the Office of Hazardous Materials Special Permits and Approvals (OHMSPA).

(1) Sharps containers must be registered under the Medical Device Regulations of FDA. The containers must be made of puncture resistant plastic that meets ASTM Standard F2132-01, Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps.

(2) Sharps containers must be securely fitted into wheeled racks that hold them in an upright position.

(3) The wheeled racks must contain full rows of sharps containers secured in place by a moveable bar.

(4) The wheeled racks must be securely held in place on the motor vehicle by straps or load bars during transportation.

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(5) Only regulated medical waste designated as sharps may be transported in the sharps containers authorized by this special permit.

(6) No shelf in any wheeled rack may exceed the manufacturer's recommended load capacity.

b. OPERATIONAL CONTROLS - Transportation of medical waste sharps containers in wheeled racks must be by private carrier in a motor vehicle dedicated to regulated medical waste service. Other packages of regulated medical wastes and other wastes being transported to facilities designated by local authorities and designed for the disposal of medical waste may be carried on the same vehicle.

8. SPECIAL PROVISIONS:

a. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

b. The marking requirements of § 172.301(c) are waived.

c. The wheeled racks and plastic sharps containers must be decontaminated before each reuse. Wheeled racks may be used to transport both reusable and non-reusable sharps containers.

d. Packages permanently marked "Regulated medical waste" on or before January 1, 2007 may continue to be used for the life of the packaging.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit

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

o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

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.

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

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 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 Theodore L. Willke
Associate Administrator for Hazardous Materials Safety

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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: sln/MooreBe