



U.S. Department
of Transportation

400 Seventh Street, S.W.
Washington, D.C. 20590

**Research and
Special Programs
Administration**

OCT - 4 2004

DOT-E 13556
(SECOND REVISION)

EXPIRATION DATE: August 31, 2006

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Bio Systems, Inc.
Lake Forest, IL
2. PURPOSE AND LIMITATION:
 - a. This exemption 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 exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in development of this exemption 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.
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 exemption number is not required on packagings; and § 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.
5. BASIS: This exemption is based on the application of Bio Systems, Inc. dated July 22, 2004, submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

OCT - 4 2004

Hazardous Materials Description			
Proper shipping name	Hazard Class/ Division	Identi- fication Number	Packing Group
Regulated medical waste	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 exemption application of Bio Systems, Inc. on file with the Office of Hazardous Materials Exemptions and Approvals.

(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.

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

OCT - 4 2004

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 may be carried on the same vehicle, but no other lading is authorized on the vehicle.

8. SPECIAL PROVISIONS:

a. A current copy of this exemption 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.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

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

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption 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 exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this exemption 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 exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

OCT - 4 2004

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

- 12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (Sections 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued in Washington, D.C.:

Robert A. McGuire
 Robert A. McGuire
 Associate Administrator for
 Hazardous Materials Safety

OCT - 4 2004

Date

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, D.C. 20590. Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at <http://hazmat.dot.gov/exemptions> Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: PTolson/dl