U.S. Department
of Transportation
**Research and
Special Programs
Administration**

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

MAR 2 3 2001

DOT-E 11631
(SIXTH REVISION)

EXPIRATION DATE: January 31, 2003

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Health Care Incinerators
Fargo, North Dakota

(See Appendix A to this document for a list of additional grantees)

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the transportation in commerce of certain non-DOT specification bulk bins containing regulated medical waste. 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, including loading and unloading.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 172.101 Col 8(c) and § 173.197 in that bulk packagings are not authorized for regulated medical waste except as specified herein.

5. BASIS: This exemption is based on the application of Health Care Incinerators dated March 16, 2001, submitted in accordance with § 107.109.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous materials description -- proper shipping name	Hazard Class/ Division	Identi-fication Number	Packing Group
Regulated medical waste	6.2	UN3291	II

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7. PACKAGING AND SAFETY CONTROL MEASURES:

a. PACKAGING - The authorized packaging is a triple packaging consisting of an outer packaging, an intermediate plastic film bag packaging, and an inner plastic film bag packaging as follows:

(1) The outer packaging is a Rubbermaid tilt truck Model 1314, 1315, 1316, 1025 or 1026, not to exceed 303 gallons capacity, constructed of seamless high density polyethylene. The inner surface must be smooth and non-porous.

(2) The intermediate packaging must be a plastic film bag, closed to be liquid-tight. Only one intermediate bag may be used for each outer packaging.

(3) The inner packaging must be one of the following:

(i) A plastic film bag not greater than 40 gallon capacity, or

(ii) A sharps container, impervious to puncture and rigid in construction, or

(iii) A container for liquids.

(4) Multiple inner packagings may be contained in one intermediate bag.

(5) Any plastic film bag used under this exemption, as either an intermediate or inner packaging, must be certified by its manufacturer as being capable of passing the tests 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 Test. Each plastic film 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.

b. TESTING - The outer packaging must be capable of meeting the requirements of § 178.603 (drop test), as specified for solids at the Packing Group II performance level.

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c. OPERATIONAL CONTROLS -

(1) The outer packaging may be reused provided it has an interior surface that is smooth, non-porous and free of cracks or other defects that could obstruct decontamination operations. The exterior surface must be non-porous and easy to decontaminate.

(2) Prior to being reused, the outer packaging must be decontaminated.

(3) The outer packagings are authorized for the transportation of regulated medical waste only if such packagings are dedicated exclusively to the transportation of waste materials.

(4) All regulated medical waste must be contained in intermediate packagings that are securely closed and leak resistant. Intermediate and inner film bag packagings may not be reused.

(5) Puncture-resistant sharps containers may not be greater than 38 L (10 gallons) in volume.

(6) Inner packagings for liquids may not exceed 19 L (5 gallons) capacity and must meet the non-bulk packaging standards for Packing Group I for liquids.

(7) Waste materials containing small amounts of liquid may be packaged as a solid provided the inner container has sufficient absorbent materials to absorb and retain all liquid during transportation.

(8) Outer packagings that contain regulated medical waste are authorized for transportation only on vehicles dedicated exclusively for transporting waste materials.

(9) Outer packagings must be closed with lids held in place by ratchet straps. Outer packagings may not be stacked in transportation.

(10) During transportation, outer packagings must be secured in place by hold-down bars as described in the petitioners application on file with the Office of Hazardous Materials Exemptions and Approvals.

(11) Prior to transporting a package containing regulated medical waste, the carrier must perform an external visual inspection of each outer packaging to determine that it is properly closed and free of leakage.

(12) The holder of this exemption is responsible for informing the persons responsible for placing waste materials in inner packagings of the limitation on liquids in packagings for solids.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modifications or changes are made to the packages and it is reoffered for transportation in conformance with this exemption and the HMR.

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

c. MARKING - The outside of each outer packaging must be plainly and durably marked "DOT-E 11631".

9. MODE 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:

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

No person may use or apply this exemption, including display of its number, when the 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.:

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Robert A. McGuire
For Associate Administrator
for Hazardous Materials Safety

(DATE)

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

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

Copies of exemptions may be obtained from the AAHMS, U.S. Department of Transportation, 400 7th Street, S.W., Washington, DC 20590-0001, Attention: Records Center, 202-366-5046.

PO: PTO/sln

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The following are hereby granted party status to this exemption based on their application(s) submitted in accordance with § 107.107 or § 107.109, as appropriate:

Company Name City & State	Application Date	Issue Date	Expiration Date
BayCare Services Clearwater, FL	1/26/2001	2/8/2001	1/31/2003
Bayfront Medical Center St. Petersburg, FL	3/26/1999	4/12/99	3/31/2001
MDS of Tennessee LLC Franklin, TN	2/22/2001	2/27/2001	1/31/2003
Medico Environmental Services, Inc. Clearwater, FL	3/26/01	MAR 27 2001	1/31/2003
Elliot 1 Day Surgery Center Manchester, NH	8/16/1999	12/14/99	3/31/2001
Catholic Medical Center Manchester, NH	8/16/1999	12/14/99	3/31/2001

for Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety