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

OCT 1 1 2000

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

DOT-E 12224
(FIRST REVISION)

EXPIRATION DATE: **January 31, 2001**

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: BioCor, Incorporated
Jacksonville, FL

2. PURPOSE AND LIMITATION:

a. This exemption 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 exemption. This exemption provides no relief from any 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. All sections referenced in this exemption 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 exemption is based on the application of BioCor Inc. dated February 26, 1999 submitted in accordance with § 107.109.

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 exemption 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 (BOP) 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 exemption or a rigid packaging conforming to the requirements of § 173.197.

(2) Inner packagings must be placed into the BOP in such a manner as to minimize the risk of breakage. Rigid inner packages, otherwise conforming to the HMR, may not be placed in the same BOP with plastic bags unless separated from the plastic bags by the barrier described in paragraph 7.b.(1)(v). Rigid inner packagings must be secured to prevent movement during transportation.

(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 allowed. 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 exemption. Division 6.1 and Class 7 chemotherapeutic waste may be transported under this exemption 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 exemption.

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

b. PACKAGING: The following packaging system is authorized:

(1) Bulk Outer Packaging (Metal or Fiberglass)(BOP):

(i) The BOP must be of metal or fiberglass construction and have a capacity of at least 3.5 cubic meters (124 cubic feet) and not more than 45 cubic meters (1590 cubic feet) in volume. It must be leakproof and have interior surfaces that are smooth, non-porous and free of cracks, crevices and other defects which could damage inner packages or obstruct decontamination operations.

(ii) The BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top that prevents the intrusion of water (e.g., rain or snow).

(iii) Each opening in the BOP must be fitted with a closure that will prevent the intrusion of water and release of any liquid during all loading and transportation operations.

(iv) In the upright position, the BOP must be liquid-tight at the bottom and able to contain a liquid quantity of at least 300 liters (80 gallons) with closures open.

(v) The BOP may be equipped with a rigid mechanical barrier to separate plastic film bags from rigid inner packagings. The barrier must have smooth surfaces. The barrier must be constructed to physically divide the inside of the BOP into at least two separate compartments. The barrier must be capable of maintaining the required separation under conditions normally incident to transportation.

(2) Inner Packaging:

(i) A plastic film bag used under this exemption 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.

(ii) Inner packagings must be durably marked or tagged with the name, city and state location of the offeror.

c. RESPONSIBILITIES OF EXEMPTION HOLDER (CARRIER):

(1) The carrier must provide a copy of this exemption to each person from whom the carrier intends to accept regulated medical waste for transportation under this exemption, 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 BOP that meets the requirements of paragraph 7.b.(1). The BOP must be loaded on the vehicle by the carrier and used exclusively for transporting medical waste.

(3) Prior to providing a BOP for reuse, the carrier must decontaminate the BOP 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) Before loading the BOP onto a motor vehicle, the carrier must assure that each closure of the BOP is secured and sealed to prevent the release of any liquid during loading or transportation.

(5) Prior to transporting regulated medical waste, the carrier must perform an external visual inspection of each BOP to determine that it is securely

attached to the vehicle, closed, and free of leakage.

(6) The carrier must transport a BOP 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 loads the BOP onto the carrier's motor vehicle at the offeror's premises.

(7) 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.

(8) The carrier must respond to any release from the BOP that occurs during its transportation, including its loading and 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 BOP involved.

(9) As required by paragraph 12 of this exemption, the carrier must report any release of any material from the BOP during its transportation (including the loading and unloading of the BOP onto or off of the carrier's motor vehicle). The unloading or emptying of the contents of the BOP 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 exemption.

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

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

(4) The offerer's signature on the certification required on a shipping paper serves as affirmation of compliance with terms of this exemption. 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 exemption may be offered for transportation under this exemption.

(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 tieing the twist to prevent the release of any material from the bag when it is inverted.

(8) Inner packagings must be placed into the BOP in such a manner as to minimize the risk of breakage. Rigid inner packages, otherwise conforming to the HMR, may not be placed in the same BOP with plastic bags unless separated from the plastic bags by the barrier described in paragraph 7.b.(1)(v). Rigid inner packagings must be secured to prevent movement during transportation.

(9) During all times that a BOP is at the offeror's premises, and not under the carrier's direct control, the BOP is the responsibility of the offeror. All openings on the BOP (including top, side and rear doors) must be securely closed except when regulated medical waste is being loaded into the BOP.

8. SPECIAL PROVISIONS:

a. MARKING: The carrier must plainly and durably mark the outside of each BOP with "DOT-E 12224" and with identification numbers in the manner specified for a bulk packaging in §§ 172.302(b), (c) and 172.331.

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 BOP only if packaged in rigid non-bulk packagings as prescribed in the HMR (See §§ 173.134, 173.196 and 173.197) and if separated and secured as provided by paragraph 7.d.(8).

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

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

11. COMPLIANCE:

a. Failure by a person to comply with the terms and conditions prescribed in this exemption and the HMR may result in modification, suspension or termination of this exemption 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 exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

c. 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.

d. The offering and transportation of regulated medical waste in a packaging authorized by this exemption is not subject to the registration and fee requirements of Subpart G of 49 CFR Part 107.

12. REPORTING REQUIREMENTS: The grantee of this exemption is required to report each incident involving loss of packaging contents, or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable.

Issued at Washington, D.C.:

OCT 1 1 2000
(DATE)

Robert A. McGuire
for Associate Administrator for
Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590-0001. 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, SW, Washington, DC 20590-0001, Attention: Records Center, 202-366-5046.

PO: PTOlson/AM