



U.S. Department  
of Transportation

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

**Research and  
Special Programs  
Administration**

February 23, 2004

DOT-E 13358  
(FIRST REVISION)

EXPIRATION DATE: April 30, 2004

1. GRANTEE: Pacific Bio-Material Management, Inc.  
Fresno, CA
2. PURPOSE AND LIMITATION:
  - a. This emergency exemption authorizes the one-time, one-way transportation in commerce of certain infectious substances in special packagings transported by Pacific Bio-Material Management, Inc. 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.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR Subpart C of Part 172 in that the shipping paper requirements are waived; § 172.301(a), (b) and (c) in that the marking requirements are waived; § 173.196 (a) and (b) in that an alternative package is not authorized, except as specified herein; and § 178.609 in that testing requirements for packagings are waived.
5. BASIS: This emergency exemption is based on the application of Pacific Bio-Material Management, Inc. dated December 23, 2003, submitted in accordance with § 107.117 and a determination that it is necessary to prevent significant injury to persons or property, and additional information dated February 18, 2004.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

| <b>Hazardous Materials Description</b>                 |                               |                              |                      |
|--|-------------------------------|------------------------------|----------------------|
| <b>Proper shipping name</b>                            | <b>Hazard Class/ Division</b> | <b>Identification Number</b> | <b>Packing Group</b> |
| Infectious substances, affecting humans*               | 6.2                           | UN2814                       | n/a                  |
| Infectious substances, affecting animals <i>only</i> * | 6.2                           | UN2900                       | n/a                  |

\* Limited to Risk Group 1, 2 or 3 only, as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Twelfth revised edition, 2001. Risk Group 4 materials are not authorized for transport under this exemption.

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Infectious substances, as listed in Paragraph 6, that are transported in freezers must conform to the following provisions:

(1) The infectious substances must be contained in sealed cryo-bags (primary receptacles) capable of withstanding immersion in liquid nitrogen. Each cryo-bag must be packaged in individual metal cassettes and then in a metal frame. The volume of infectious substances in each cryo-bag must not exceed 100 ml. Not more than four (4) cryo-bags must be packed in a metal frame. Not more than 120 frames (Model 1520HE) or 60 frames (Model XLC 1211) must be packed in a liquid nitrogen freezer. Sufficient absorbent material must be placed in each freezer to absorb the entire contents of all primary receptacles in case of bag breakage or leakage. The freezer serves as the outer packaging.

(2) The freezers must be constructed of double-walled stainless steel with vacuum insulation between the walls.

(3) Bags, metal cassettes, and metal frames must be secured within the freezer to prevent the contents from shifting.

(4) Each freezer lid must be securely closed to prevent opening during transportation.

(5) The infectious substances in the freezers must be kept frozen at all times within the operating temperature range of -130 °C to -195 °C using liquid nitrogen. A back-up freezer system and liquid nitrogen sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time must be carried on the transport vehicle.

(6) Each freezer must be labeled with an INFECTIOUS SUBSTANCE label (see § 172.432) and be marked with orientation arrows in accordance with § 172.312(a).

(7) All freezers must be secured against movement in the transport vehicle.

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages containing infectious substances from the University of Texas Anderson Cancer Center on Holcombe Blvd. to Cryogene on Kirby Dr. both in Houston, Texas using a specialized, dedicated transport vehicle. Packages must be prepared, transported, and unpacked by Pacific Bio-Material Management, Inc. The frozen materials must be delivered to the Kirby Dr. facility within 30 minutes of their departure from the Holcombe Blvd. facility. Transportation of the infectious substances under this exemption may only occur between the hours of 7:00 pm and 5:00 am.

(2) Only one transport vehicle may be operated at any time.

(3) Only two freezers and one back-up freezer may be in a transport vehicle during any single trip.

(4) Not more than a total of five (5) filled nitrogen freezers are authorized to be transported under this emergency exemption.

(5) An itemized list of contents must be securely attached to the outside of each freezer.

(6) An emergency response team and equipment necessary to mitigate a spill must accompany each transport vehicle.

(7) All other conditions specified in the application must be met.

8. SPECIAL PROVISIONS:

- a. The emergency response team and transport vehicle operator must have a copy of packing lists for each freezer.
- b. A current copy of this exemption must be maintained at each facility where the package is offered for transportation.
- c. The shipping paper requirements in 49 CFR Subpart C of Part 172 and the marking requirements in § 172.301 (a), (b) and (c) are waived.

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.

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.:



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for Robert A. McGuire  
Associate Administrator for  
Hazardous Materials Safety

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: Steve Hwang:dl