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

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

NOV 12 2002

DOT-E 12452
(SECOND REVISION)

EXPIRATION DATE: December 31, 2003

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: California Department of Health Services
Berkeley, CA

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the transportation in commerce of certain infectious substances in special packagings, transported by a contract carrier. 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; and § 173.196 in that an alternative package is not authorized, except as specified herein.

5. BASIS: This exemption is based on the application of the California Department of Health Services (DHS), dated October 1, 2002, submitted in accordance with § 107.109.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Proper Shipping Name/ Hazardous Materials Description	Hazard Class/ Division	Identi-fication Number	Packing Group
Infectious substances, affecting humans, *(Risk Group 2 and 3 materials as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Tenth revised edition)**	6.2	UN2814	N/A
Infectious substances, affecting animals *only, (Risk Group 2 and 3 materials as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Tenth revised edition)**	6.2	UN2900	N/A

* No Risk Group 4 materials are authorized for transportation under this exemption.

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Freezers: Infectious substances in paragraph 6 that are transported in freezers must conform with the following provisions:

(1) Primary receptacles must be water-tight cryovials, tightly secured, and packed with multi-layered polypropylene sheets within the freezer to prevent the contents from shifting.

(2) Freezers must be filled with sufficient liquid nitrogen and/or dry ice prior to movement to keep the primary receptacles frozen at all times, and sufficient absorbent material to absorb the entire contents of all primary receptacles and any liquid nitrogen in case of an incident.

(3) Each freezer must be of metal construction and doors or closures must be securely closed with straps. Each freezer must be secured against movement in the transport vehicle.

b. PACKAGING - Movable Shelving Units:

(1) Infectious substances in paragraph 6 that are stored in walk-in freezers and cold rooms and packaged in movable shelving units must be packaged as follows:

(i) infectious substances must be in watertight cryovials that serve as primary receptacles;

(ii) cryovials must be boxed or in racks and placed on super-absorbent lined movable shelving units.

(iii) the shelving units must be wrapped with absorbent materials and over-wrapped with 800 gauge polypropylene stretch-wrap as a secondary packaging encasing the moveable metal shelving unit(s); and

(iv) sufficient absorbent material must be used to absorb the entire contents of all primary receptacles.

(2) The moveable metal shelving units must be transported in refrigerated trucks. The contents must remain refrigerated at all times. Shelving units must be secured against movement in the transport vehicles.

c. OPERATIONAL CONTROLS -

(1) This exemption only authorizes the transport of packages containing infectious substances from DHS's old facilities in Berkeley, California to their new facility in Richmond, California in two (2) phases. In the initial phase, DHS will move approximately 28 liquid nitrogen freezers, 27 mechanical freezers, and two (2) refrigerated (4 °C) trucks carrying the contents of -20 °C walk-in freezers with an estimated volume of 11.2 m^3 (397 ft^3) and the contents of walk-in cold rooms with an estimated volume of 10 m^3 (343 ft^3). In the second phase, the numbers of the freezers and the refrigerated trucks may not exceed those authorized for the initial phase.

(2) Packages must be prepared, transported, and unpacked by contract carrier under DHS supervision, as outlined in the application for exemption. Except for infectious substances from cold rooms, all infectious substances must remain frozen at all times. Emergency refrigeration procedures must be in place and operational in the event of loss of refrigeration.

(3) The materials in all freezers must be delivered to the Richmond location within one (1) hour of departure from the Berkeley location.

(4) An itemized list of contents for each freezer or shelving unit must be securely attached to the outside of each unit.

(5) Each freezer or movable shelving units must be labeled with infectious substance labels.

(6) Emergency responders and back-up equipment necessary to mitigate a spill must accompany each transport vehicle.

8. SPECIAL PROVISIONS: A copy of the packing lists outlined in paragraph 7c.(4) for each freezer and movable shelving unit on a vehicle must be carried in the cab compartment of that transport vehicle.

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:

- 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.:

Ann Mazzullo

Robert McGuire
Associate Administrator for
Hazardous Materials Safety

NOV 12 2002
(DATE)

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.

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: SHwang/alb