U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

JUN 4 2004

DOT-E 13487

EXPIRATION DATE: June 30, 2005

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: University of Colorado Health Services Center
Denver, CO

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the one-time, one-way transportation in commerce of certain infectious materials 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; § 173.196(a)&(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 exemption is based on the application of University of Colorado Health Services Center dated February 13, 2004 and supplemental information dated April 13, April 23, April 26, May 4, and May 7, 2004, submitted in accordance with § 107.105 and the public proceeding thereon.

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6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	**Hazard Class/ Division**	**Identi-fication Number**	**Packing Group**
Infectious substances, affecting humans*	6.2	UN2814	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 by this exemption.

7. SAFETY CONTROL MEASURES:

a. PACKAGING -

(1) Infectious substances, as listed in Paragraph 6, must be packed as follows: The substances, contained in sealed cryo-vials (primary receptacles), must be packaged in individual fiberboard boxes. The volume of the substance in each vial must not exceed 1 ml. Not more than 100 vials may be packed in a fiberboard box. Not more than 400 boxes (ultracold upright freezer) or 396 boxes (ultracold chest freezer) may be placed on racks in a freezer. Leak-proofed test tubes (primary receptacles), placed on tube racks, must be wrapped in a plastic bag prior to placing the tube racks on racks in a -20 °C freezer. Sufficient absorbent material must be placed in each freezer to absorb the entire contents of all primary receptacles in case of breakage or leakage and to prevent the contents from shifting during transport. The freezer serves as the outer packaging.

(2) All freezers are constructed of steel and the ultracold freezers (-70 °C to -120 °C) are double-walled.

(3) Boxes and racks must be tightly secured within the freezer to prevent the contents from shifting.

(4) All freezer doors and lids must be securely closed and wrapped 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 -70 °C to -120 °C (ultracold freezer) and -20 °C (-20 °C freezer) using dry ice. Dry ice sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time must be used in the freezers on the transport vehicle.

(6) 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 Colorado research laboratories at 4200 E. 9th Avenue, Denver, Colorado to new buildings at 12800 E. 19th Avenue and 12801 E. 17th Avenue, Aurora, Colorado using a contract transport vehicle. Packages must be prepared and unpacked by the University of Colorado staff. The frozen materials must be delivered to the Aurora facility within 1 hour of its departure from the Denver campus facility.

(2) Not more than one transport vehicle may be operated at any time.

(3) Not more than eight freezers may be in a transport vehicle.

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

(5) Emergency equipment necessary to mitigate a spill must accompany each transport vehicle.

(6) The University of Colorado Health Sciences Center emergency response team must be on duty during transport.

8. SPECIAL PROVISIONS:

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

b. The shipping paper requirements of 49 CFR Part 172 Subpart C and the marking requirements of 49 CFR 172.301(a), (b) and (c) are waived.

c. Emergency responders and escorts must have a copy of packing lists for the freezer being transported.

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.
- 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.
- 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.:

JUN 4 2004

Date

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, Department of Transportation, 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: STHWANG