

July 30, 2007



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 14517

EXPIRATION DATE: March 31, 2008

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: The Children's Hospital
Denver, CO
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the one-time, one-way transportation in commerce of certain infectious substances other than Risk Group 4 in specially designed packaging (freezers). This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196(a) and (b) in that packaging requirements are waived; Part 172, Subpart C in that shipping paper requirements are waived; and 49 CFR § 178.609 in that testing requirements for packagings are waived.
5. BASIS: This special permit is based on the application of The Children's Hospital dated May 15, 2007 submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Infectious substances, affecting humans*	6.2	UN2814	N/A

* Limited to Risk Groups 1, 2 or 3 only as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Fourteenth revised edition, 2005. Risk Group 4 materials are not authorized for transport by this special permit.

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 396 boxes may be placed on racks in a -70°C ultracold 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 -70°C ultracold freezer. The materials packaged for liquid nitrogen storage must be contained in Cryocyte Bags and placed in aluminum canisters which will be slotted into aluminum inventory racks and placed in a -196°C liquid nitrogen 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. Each freezer serves as an outer packaging.

(2) All freezers are constructed of steel or stainless steel and 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 (ultracold freezer) and -196°C (liquid nitrogen 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 special permit authorizes one-time, one-way transportation from the research and clinical laboratories located at 1056 E. 19th Avenue, Denver, CO to the new Children's Hospital at 13123 E. 16th Avenue, Aurora CO. Packages must be prepared and unpacked by the Children's Hospital staff. The frozen materials must be delivered to the hospital within one (1) hour of its departure from the research and clinical laboratories.

(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 Children's Hospital institutional Biosafety committee must be available during the move in conjunction with the Denver and Aurora fire department Hazardous Materials teams in the event of an accidental spill or leak.

8. SPECIAL PROVISIONS:

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

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

9. MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each cargo vessel or motor vehicle used to transport packages covered by this special permit.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit 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 special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this special permit 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 special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)- 'The Hazardous Materials Safety and Security Reauthorization Act of 2005' (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term 'exemption' to 'special permit' and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Theodore L. Willke
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: PHH-31.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: LAVALLE