

November 3, 2006



U.S. Department  
of Transportation

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

**Pipeline and Hazardous  
Materials Safety Administration**

DOT-SP 11799  
(ELEVENTH REVISION)

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: (See individual authorization letter)
2. PURPOSE AND LIMITATION:
  - a. This special permit authorizes the transportation in commerce of certain infectious substances in special packagings. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
  - b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce.
  - c. Unless otherwise stated herein, this special permit consists of the special permit authorization letter issued to the grantee together with this document.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196(b) for testing and § 173.196(e)(2)(iii) in that direct cooling with liquid nitrogen must be used instead of exchangers.
5. BASIS: This special permit is based on the application of Cryonix Inc. dated December 20, 2004 and supplemental information dated February 14, 2005 submitted in accordance with § 107.105 and additional information dated April 8, 2005.

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 only*	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, Eleventh revised edition, 1999. 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 vials (primary receptacles), must be secured in individual cells of a box. The volume of culture material in each vial must not exceed 1.0 ml. Not more than one hundred (100) vials must be packed in a box. Not more than sixteen (16) filled and closed boxes must be packed in a plastic bag (secondary packaging) which must be heat sealed. Sufficient absorbent material must be placed between the primary and secondary packagings to absorb the entire contents of all primary receptacles in case of vial breakage or leakage. No more than fifteen (15) plastic bags may be packed in a freezer with capacity not more than 0.85 cubic meters (30 cubic feet). The freezer serves as the outer packaging. Testing required in § 173.196(b) is waived.

(2) Voids in the storage space of the freezer must be filled with bubble wrap to prevent the contents from shifting.

(3) All freezer doors must be secured with safety latches and straps to prevent opening during transportation.

(4) The infectious substances in the freezers must be kept frozen at all times within the operating temperature range of -20 °C to -140 °C by using liquid nitrogen heat exchangers or dry ice. The amounts of liquid nitrogen or dry ice carried on the transport vehicle must be sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time.

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

(6) The freezers are constructed of double-walled steel with insulation material between the walls.

b. OPERATIONAL CONTROLS -

(1) This special permit authorizes the transport of packages containing infectious substances using a specialized dedicated transport vehicle. The freezer on the dedicated transport vehicle must be precooled using liquid nitrogen coils, brought as closely as possible to the secondary packages, and wheeled back to the vehicle. Packages must be prepared, transported, and unpacked by the contract carrier.

(2) Not more than two transport vehicles may be operated at all times.

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

(4) Emergency refrigeration and spill response procedures must be in place and operational to address loss of refrigeration, delay in transportation or release of an infectious substance.

8. SPECIAL PROVISIONS: None.
9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each 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 Robert A. McGuire  
Associate Administrator  
for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials 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](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: SHwang/KFW/sln