

January 8, 2015



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 16137

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| EXPIRATION DATE: September 30, 2016 |
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(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Diversified Laboratory Repair
Gaithersburg, MD
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of certain infectious substances in special packagings (freezers) transported by Diversified Laboratory Repair, Inc. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
 - 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 (b) (2) and 178.609(d) in that alternative packaging is authorized.
5. BASIS: This special permit is based on the application of Diversified Laboratory Repair dated April 4, 2014 and updated on October 10, 2014 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 | Identification Number | Packing Group |
| Biological substance, Category B | 6.2 | UN3373 | N/A |

* Only category B infectious substances, as defined in § 173.134 are authorized for transport by this special permit.

7. SAFETY CONTROL MEASURES:a. PACKAGING -

(1) Watertight vials (primary receptacles) not exceeding 5 mL in size must be secured in individual cells of stainless steel boxes. Not more than eighty one (81) vials may be packed in a box. Not more than sixteen (16) filled and closed boxes containing 1.0 mL vials or eight (8) containing 5 mL vials must be packed in a plastic heat-sealed bag (secondary packaging). Multiple primary receptacles placed in a single secondary packaging must be either wrapped individually or separated to prevent contact between them. Sufficient absorbent material must be placed between the primary and secondary packaging to absorb the entire contents of all primary receptacles in case of vial breakage or leakage. Not more than thirty (30) plastic bags must be packed in a freezer with a capacity not more than 0.8 cubic meters (28 cubic feet). The freezer serves as the outer packaging.

(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 -85 °C by a compressor driven freezer system. A back-up freezer system and

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liquid nitrogen or dry ice 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.

(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 (freezers) containing infectious substances using a specialized transport vehicle from the National Institutes of Health campus in Bethesda, MD to the Food and Drug Administration campus in White Oak, MD. The freezer on the dedicated transport vehicle must be precooled, brought as closely as possible to the secondary packages, and wheeled back to the vehicle. Packages must be prepared, transported, and unpacked by Diversified Laboratory Repair personnel.

(2) Not more than one transport vehicle will be operated using this special permit at a time.

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

(4) All freezers must be temperature monitored during the transit.

(5) Emergency refrigeration (such as stand-by freezers, dry ice and/or liquid nitrogen) and spill response procedures must be in place and operational to address loss of refrigeration, delay in transportation or release of an infectious substance.

(6) Complete training records must be maintained on every employee.

(7) An itemized list of contents must be enclosed between the secondary and outer packagings.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package and it is reoffered for transportation in conformance with this special permit and the HMR.

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

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 Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

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