June 13, 2006



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

Pipeline and Hazardous Materials Safety Administration

> DOT-SP 13321 (THIRD REVISION)

EXPIRATION DATE: May 31, 2010

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. <u>GRANTEE</u>: Quest Diagnostics, Inc Collegeville, PA

2. PURPOSE AND LIMITATION:

a. This special permit authorizes the transportation in commerce of certain infectious substances in specially designed, reusable textile bags. 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. The safety analyses did not consider the hazards and risks associated with consumer use, use as a component of a transport vehicle or other device, or other uses not associated with transportation in commerce.

c. Party status will not be granted to this special permit.

- 3. <u>REGULATORY SYSTEM AFFECTED</u>: 49 CFR Parts 106, 107 and 171-180.
- 4. <u>REGULATIONS FROM WHICH EXEMPTED</u>: 49 CFR § 173.28(b)(3) in that textile bags are not authorized for reuse except as specified herein.

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- 5. <u>BASIS</u>: This special permit is based on the application of Quest Diagnostics, Inc., dated May 26, 2006, submitted in accordance with § 107.109.
- 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Diagnostic specimen	6.2	N/A	N/A
Infectious substances, affecting animals only	6.2	UN2900	N/A
Infectious substances, affecting humans	6.2	UN2814	N/A

7. SAFETY CONTROL MEASURES:

a. <u>PACKAGING</u> - The prescribed packaging is a specially designed UN5L3 textile bag, meeting the description and performance of TEN-E Packaging Services, Inc. Test Report Number: 02-2338 on file with the Office of Hazardous Materials Special Permits and Approvals (OHMSPA). The construction of the textile bag is as follows:

(1) An outer bag fabricated from polyester fabric with a PVC backing. The bag is closed with a plastic zipper.

(2) The bag has a removable inner liner coated with PVC and attached to the outer bag with hook and loop (e.g., Velcro®) fasteners.

(3) The outer bag has two vents to permit carbon dioxide to escape from the packaging when dry ice is used as a refrigerating material.

(4) The outer bag has 4 side handles and 1 carrying strap.

(5) The approximate dimensions of the outer bag are: $18-3/4'' \ge 9-7/8'' \ge 16-3/8''$.

b. OPERATIONAL CONTROLS -

(1) Prior to reuse the outer packaging, including the removable inner liner, must be inspected by the grantee to ensure it is acceptable for continued use, is capable of meeting the design test requirements for an infectious substance packaging and meets the requirements for the initial design type. Each bag must be inspected to ensure that:

(i) All handles are securely fastened to the bag in accordance with the design type; and

(ii) Seams are free from defects in stitching, heat sealing or gluing which would render the packaging unsafe for transporting infectious substances; and

(iii) Fabric used to construct the package is free from cuts, tears and punctures. Additionally, fabric must be free from scoring which may render the package unsafe for transport; and

(iv) Vents are unobstructed and capable of venting carbon dioxide gas, if dry ice is to be used as a refrigerating material.

(2) The liner and textile bag may not be reused if the inner packagings are compromised and release the infectious substances within the packaging.

(3) The zippers on the outer textile bag must be secured with a tamper evident seal after the infectious substances are loaded into the packaging.

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 or its contents and it is reoffered for transportation in conformance with this special permit and the HMR. Continuation of DOT-SP 13321 (3rd Rev.)

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

c. Quest Diagnostics, Inc. must have a copy of TEN-E Packaging Services, Inc. Test Report Number: 02-2338 and the latest periodic retest report required by § 178.601(e) on file. Test reports must be made available to a DOT representative upon request.

d. Packagings permanently marked 'DOT-E 13321', prior to October 1, 2007 may continue to be used under this special permit for the remaining service life of the packaging or until the special permit is no longer valid. Packagings marked on or after October 1, 2007 must be marked 'DOT-SP 13321'.

e. Shipping papers displaying 'DOT-E 13321' may continue to be used until October 1, 2007, provided the special permit remains valid.

- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, passenger aircraft and cargo aircraft only.
- 10. <u>MODAL REQUIREMENTS</u>: A current copy of this special permit must be carried aboard each aircraft or motor vehicle used to transport packages covered by this special permit. The shipper must furnish a current copy of this special permit to the air carrier before or at the time the shipment is tendered.
- 11. <u>COMPLIANCE</u>: 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 <u>et</u> seq:
 - All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
 - 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.

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o Registration required by § 107.601 <u>et seq</u>., 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. <u>REPORTING REQUIREMENTS</u>: 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.:

R. Ryan Port

for Robert A. McGuire Associate Administrator for Hazardous Materials Safety

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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 Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: DB/AM