

U.S. Department of Transportation Approves Special Permit for the Safe Transport of Ebola Infected Medical Waste for Disposal

WASHINGTON—This afternoon, the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) in coordination with the Centers for Disease Control and Prevention (CDC) announced that it has issued an emergency special permit allowing a Lake Forest, Ill.-based company to transport large quantities of Ebola-contaminated waste from Texas Health Presbyterian Hospital Dallas for disposal.

The special permit will cover all of Texas, not just waste originating at Texas Health Presbyterian Hospital Dallas, which is beneficial should another diagnosed case present itself in the state. The special permit also extends to the removal of household hazardous material, including the patient's home. Special permits are issued to individual companies to ensure that each holder is fit to conduct the activity authorized. PHMSA has been in proactive discussions with CDC to prepare guidance to address emerging issues elsewhere in the United States should they develop.

The special permit issued today offers Stericycle, Inc. two alternative options for packaging the waste material prior to transport. Both options require a series of inner and outer packaging and the application of a CDC-authorized disinfectant to the inner packaging. The special permit also provides instructions for operation controls during transport, and requires the carrier to maintain a written spill response plan with guidelines for protecting employees and decontaminating any released material in the event of an accident. For more information about the special permit, please click <u>here</u>.

The Hazardous Materials Regulations authorizes the issuance of special permits that allow a company or individual to package or ship hazardous materials in a manner that varies from existing regulations but maintains an equivalent level of safety. Solid materials contaminated with the Ebola virus are classified as <u>Category A infectious substances</u> according to the Hazardous Materials Regulations. Current safety regulations governing the transport of Category A infectious substances require packaging that may not be always suited for the transport of larger quantities of contaminated waste. The treatment of Ebola patients creates a relatively large quantity of contaminated medical waste.

While the U.S. Department of Transportation's PHMSA approves the special permit to Stericycle, the contract for services is between the company and Texas Health Presbyterian Hospital

Dallas. All questions related to the terms of the contract and operational logistics such as the costs, the times of pick up, disposal locations, the volume of materials, etc. should be answered by the state of Texas health officials or the hospital.

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DOT 94-14

Friday, October 3, 2014

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Pipeline and Hazardous Materials Safety Administration

DOT-SP 16266 Second Revision

EXPIRATION DATE: November 30, 2014

 GRANTEE: Stericycle, Inc. Lake Forest, IL

2. PURPOSE AND LIMITATION:

- a. This emergency special permit authorizes the transportation in commerce of certain Ebola contaminated medical waste for autoclaving or incineration. 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 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. No party status will be granted to this special permit.
- REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196(a) in that alternative packaging is authorized.
- 5. BASIS: This emergency special permit is based on the application of Stericycle, Inc. dated October 1, 2014, submitted in accordance with § 107.117 and a PHMSA determination that the special permit is in the public

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interest and that it is necessary to prevent significant injury to persons or property and additional information provided on October 2, 2014.

HAZARDOUS MATERIALS (49 CFR § 172.101):

N/A	UN2814	6.2	Infectious substances, affecting humans
Packing Group	Identi- fication Number	Hazard Class/ Division	Proper shipping name
	ion	ls Descript	Hazardous Materials Description

SAFETY CONTROL MEASURES:

a. LIMITATIONS ON SOLID MATERIALS THAT HAVE BEEN CONTAMINATED WITH THE EBOLA VIRUS:

- (1) This special permit authorizes the transportation in commerce of materials that have been contaminated with or are suspected to have been contaminated with the Ebola virus in the packaging system described below.
- (2) Inner packagings must be placed into the outer packagings in such a manner as to minimize the risk of damage to the packagings.
- b. PACKAGING The prescribed packagings are as follows, a combination packaging consisting of these components:
- (1) Outer Packaging is either of the following:
- i. A triple walled UNIGW corrugated drum with a 6 mil polyethylene liner.
- (a) The drum has a maximum capacity of 55 gallons and is approximately 22.25 inches X 22.25 inches X 39.25 inches. The drum is tested and certified to the PGII Level for a maximum net mass of 500 lbs; or
- (b) The drum has a maximum capacity of 35 gallons and is approximately 22.25 inches X 22.25 inches X 26.50 inches. The drum is tested and certified to

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the PGII Level for a maximum net mass of 325 lbs; or

- ii. A 96 gallon cart tested and certified as a UN4H2 solid plastic box at the PG II level. If the cart is used as the outer packaging a third inner film bag case may the 96 gallon carts be filled for transportation after October $4,\ 2014.$ meeting the requirements below is required. A total of drums are available, the carts may no longer be used under the terms of this special permit. Once the UNIGW not more than 30 carts of waste may be transported for transportation under this special permit. In no
- minimum of three inner film bags as described below: (2) Inner Packagings: The waste materials must be placed in
- 1709, "Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method". The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel having passed the tests prescribed for tear resistance in ASTM D 1922, "Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method" and for impact resistance in ASTM D The film bags used under this special permit must have a minimum film thickness of 1.5 mils (0.0015 inch) and must be marked and certified by its manufacturer as perpendicular planes with respect to the length of
- tying the bag to prevent the release of any material from the bag when inverted. individually closed and sealed securely by balloon (ii) Each of the two inner most film bags must be
- disinfectant used to treat the waste material (iii) The inner packagings must be compatible with the
- closed with a zip tie to seal the bag. If the corrugated drums are used, the drum liner will serve as the third bag closure instructions. and will be sealed in accordance with the manufacture's third film bag must be used. The third bag must be securely (3) When the 96 gallon cart is used as an outer packaging,

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taping the lid closed with duct tape and by securing the lid with additional mechanical means such as ratcheting web straps or bungee cords. (4) The 96 gallon cart must be securely closed by securely

- within the liner of the corrugated drum whichever is breach must be placed in the bottom of the 96 gallon cart or all free liquid (if any) in case of an inner packaging (5) A quantity of absorbent material sufficient to absorb
- (6) The exterior of the 96 gallon carts must be disinfected prior to loading in the transport vehicle.

OPERATIONAL CONTROLS -

- PHMSA, and then transported to the nearest appropriate disposal facility available at the time the material is offered for transportation without additional loading of the directed by State or local authorities, after notifying Hospital, Dallas, TX or another location within Texas as Transportation may only be from Texas Health Presbyterian transport materials under the terms of this special permit. Only vehicles operated by Stericycle may be used to
- inner packaging the waste material must be treated with a disinfectant that is recommended by the Centers for Disease Control and Prevention for use as a disinfectant for the Ebola virus. (2) Prior to placement of the waste material in the primary
- the Ebola virus. Disease Control and Prevention for use as a disinfectant or exterior surface of that inner packaging must be treated with a disinfectant that is recommended by the Centers for (3) After the primary inner packaging is sealed, the
- inner packaging must be placed into a secondary plastic bag meeting the requirements specified in paragraphs 7.b.(2)(i), (ii) and (iii) of this permit. After the second plastic bag Ebola virus. Control and Prevention for use as a disinfectant or the disinfectant that is recommended by the Centers for Disease is sealed, the exterior surface must be treated with the Prior to loading into the outer packaging, the primary

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(5) The sealed primary and secondary inner packagings must then be placed into the third plastic film bag or drum

- (6) The outer packagings must be closed except when inner packagings of the material authorized by this special permit are being loaded into the outer packaging.
- transportation. sealed to prevent the release of any material during the grantee must assure that the package is closed and Before loading the package into a transport vehicle
- (8) Loading and unloading the vehicle must be performed using manual means. Fork trucks or other mechanicals means may not be used for loading or unloading the vehicle.
- outer packaging is being loaded or unloaded into the being used to transport the material authorized by this special permit must be closed and locked except when an While in transportation, the doors on the motor vehicle
- (10) Prior to transportation, the carrier must perform an external visual inspection of the transport vehicle to determine that it is closed and free of leakage.
- applicable laws for treatment or disposal of such materials, the material to a final destination that is authorized by vehicle leaves the grantee's premises. The carrier may only transport the vehicle loaded with unnecessary delay from the time the carrier's motor
- materials and for personal protective equipment to be carried on the vehicle and used to protect its employees that includes provisions for the decontamination of spilled from contact with infectious materials in any form. The carrier must have a written spill response plan
- material and decontamination of the release site, vehicle release from a package that occurs during transportation. The response must include complete removal of any spilled surfaces and external surfaces of the package involved. The carrier must respond to any release or suspected

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(14) Each motor vehicle used under the terms of this permit must be decontaminated in accordance with applicable October 3, 2014

federal, state and local laws.

- transportation after October 4, 2014. however, opening the inner packagings and repackaging is not required. In no case may the 96 gallon carts be filled for accordance with the all of requirements of this permit; film bags which have not been prepared and sealed in (15) Initial shipments of the 96 gallon carts may have inner
- this operation must be made available for a CVSA Level I hazardous materials inspection prior to transport. Should any violations of the CVSA North American Standard Out-of-Service Criteria (2014 edition) be discovered during the transporting hazardous materials under this special permit inspection, the violation(s) must be corrected prior to (16) Each commercial motor vehicle and driver involved in
- 8 SPECIAL PROVISIONS: A current copy of this special permit must be maintained at each medical or treatment facility where the package is offered for transportation.
- 9 MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.
- 10 practicable use hazardous materials routes where designated and packages covered by this special permit. The carrier shall must be carried aboard each motor vehicle used to transport MODAL REQUIREMENTS: A current copy of this special permit
- 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 $\underline{\text{et}}$
- permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180. All terms and conditions prescribed in this special
- Persons operating under the terms of this special permit must comply with the security plan requirement Subpart I of Part 172 of the HMR, when applicable.
- 0 Registration required by § 107.601 et seq., when applicable.

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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.

Title 49 of the United States Code, Section 5117 (a)(2) now authorizes a special permit (formally an "exemption")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

Dr. Magdy El-Sibaie

Associate Administrator for Hazardous Materials Safety

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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

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prohibited.