



U.S. Department
of Transportation

Pipeline and Hazardous
Materials Safety
Administration

1200 New Jersey Avenue, SE
Washington, D.C. 20590

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Amy Berenbaum Goodman
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1512 Larimer Street, Suite 300
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Reference No. 16-0044

Dear Ms. Berenbaum Goodman:

This letter is in response to both your February 8, 2016, email and your April 6, 2016, telephone conversation with a member of my staff requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask how the HMR apply to the transportation by motor vehicle of soiled linen contaminated with a Division 6.2 infectious substance.

The HMR define an infectious substance as a material known or reasonably expected to contain a pathogenic microorganism or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals (see § 173.134(a)(1)). A person who offers, causes to be transported, or transports an infectious substance must comply with the HMR requirements regarding packaging, hazard communication, training, and security (see 49 CFR Part 172, Subparts C through I). Additional requirements may apply, depending on the mode of transportation (e.g., 49 CFR Part 177 applies to transportation by public highway).

A person who offers an infectious substance for transportation must (1) classify the material according to its inherent risks and (2) assign it to either Category A or Category B based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. A Category A infectious substance is in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals upon exposure (see § 173.134(a)(1)(i)). A Category B infectious substance is not in a form generally capable of causing permanent disability or life-threatening or fatal disease (see § 173.134(a)(1)(ii)).

Soiled linen or laundry containing an infectious substance may be transported as one of the following:

- Materials of Trade (MOT; § 173.6);

- Laundry and medical equipment (§ 173.134(b)(12));
- “UN 3373, Biological substance, Category B, 6.2” (Category B; § 173.199);
- “UN 3291, Regulated medical waste, n.o.s., 6.2, PG II” (RMW; § 173.197); or
- Materials known or suspected of being contaminated with the Ebola virus (Category A) using Department of Transportation Special Permit (DOT-SP) 16279.

I have described each of these packaging methods as they apply to Division 6.2 contaminated laundry below.

Materials of Trade

Laundry contaminated with a Division 6.2, Category B material may be transported and described as a MOT when it meets the definition of MOT in § 171.8, complies with the requirements prescribed in § 173.6, and is transported by a private carrier in direct support of a principal business, which may not be the transportation of goods by motor vehicle. Division 6.2 materials that comply with the requirements prescribed in § 173.6 are not subject to any other requirements of the HMR. Division 6.2 MOT must be placed in a combination packaging where the inner packaging is leakproof for liquids and both rigid and puncture resistant for sharps. Additional packaging provisions in § 173.6(a)(4) apply.

Laundry and medical equipment

Laundry and medical equipment contaminated with a Division 6.2 material that conforms to the bloodborne pathogen requirements prescribed in 29 CFR 1910.1030 of the Department of Labor, Occupational Safety and Health Administration, are not subject to the HMR as Division 6.2 materials. This exception includes medical equipment intended for use, cleaning, or refurbishment (e.g., reusable surgical equipment, or equipment used for testing where the outer components essentially function as packaging). This exception does not apply to medical equipment being transported for disposal.

Biological substance, Category B

Section 173.199 requires a Category B infectious substance to be packaged in triple packaging that is designed, constructed, and maintained so that under conditions normally encountered in transportation there will be no release of the hazardous material into the environment. The packages must also be capable of passing the drop tests in § 178.609(d), in accordance with § 173.199(a)(4). While the package must be capable of meeting these requirements, it does not require testing and is not subject to the design qualification testing, periodic retesting, or record retention (i.e., test report requirements) in § 178.601. Laundry contaminated with a Division 6.2, Category B material that is transported for disposal or recycling may also be described and packaged as a RMW.

Regulated medical waste

Section 173.197(b) permits sharps and sharps with residual fluid in a single or combination, non-bulk, puncture-resistant packaging that meets the requirements in 49 CFR Part 178, Subpart M, at the Packing Group II performance level. Paragraphs (c) and (d) of § 173.197

permit RMW in UN standard Large Packagings, non-specification bulk packagings (i.e., wheeled carts (Carts)), and bulk outer packagings (BOPs), respectively. Paragraph (e) of § 173.197 prescribes what inner packagings may be used in Large Packagings, Carts, and BOPs. Section 173.134(c)(1)(ii) states RMW must not be transported on the same vehicle with materials that contain a Division 6.2 waste stock or culture. However, § 173.134(c)(2)(i) permits waste cultures and stocks of a Category B infectious substance to be placed on board the same vehicle with RMW and other materials listed in this section provided the RMW is offered for transportation and transported as RMW; packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030; and transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste.

Ebola virus (Category A) using DOT-SP 16279

DOT-SP 16279 authorizes approved parties permission to transport for disposal materials contaminated with or suspected of being contaminated with the Ebola virus, which is a Category A infectious substance. The special permit prescribes packaging and handling requirements for non-bulk and bulk combination packagings transported by motor vehicle and cargo vessel. If the materials to be transported are too large to use the packaging system described in paragraph 7.b.(1) of DOT-SP 16279, the special permit requires that the materials be placed in larger article packagings prescribed in paragraph 7.b.(2) and that the offeror notify the Pipeline and Hazardous Materials Safety Administration that this packaging method is to be used.

Also, please note soiled linen or laundry that meets the definition of another hazard class or that is a hazardous substance, hazardous waste, or marine pollutant, must be offered for transportation and transported in accordance with the applicable requirements of the HMR.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,



T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standard and Rulemaking Division

INTERPRETATION LETTERS

Requester	Amy Berenbaum Goodman	Date Received:	3/17/2016
Company	Hall, Render, Killian, Heath & Lyman, P.C.	Tracking	16-0044
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Staff	Edmonson	First Draft Due:	4/7/2016
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Concurrence			
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Sign Date		Signor	
Comment		HBP <input type="checkbox"/>	Copy to Docket <input type="checkbox"/>
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