



U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

JUN 0 6 2016

Mr. Corey J. Bennett Assistant BioSafety Officer, ARO Griffin Laboratory Wadsworth Center Laboratories New York State Department of Health 5668 State Farm Road Guilderland, NY 12084

Reference No. 16-0028

Dear Mr. Bennett:

This letter is in response to your February 17, 2016, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to state governments and the transportation of infectious substances. We have paraphrased your questions and answered them in the order you provided.

- Q1. It is our understanding that § 171.1(d)(5) excepts from the HMR a state entity that transports hazardous materials by state employees in state-owned vehicles solely for noncommercial, state government purposes. Is this correct?
- A1. The answer is yes. As provided in § 171.1(d)(5), the HMR do not apply to transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a Federal, state, or local government employee solely for noncommercial Federal, state, or local government purposes. Therefore, when the New York State Department of Health transports hazardous materials for its own use, using its own personnel, and in its own vehicles, it is not engaged in transportation in commerce and not subject to the HMR.
- Q2. It is our understanding that an infectious substance that does not meet the definition under § 173.134(a)(1)(i) for a Category A infectious substance may appropriately be classified as a Category B infectious substance as described under § 173.134(a)(1)(ii). Is this correct?
- A2. The answer is yes. If a material meets the definition of an infectious substance (Division 6.2)—a material known or reasonably expected to contain a pathogen—under § 173.134(a)(1) and does not meet the definition of a Category A infectious substance under § 173.134(a)(1)(i), it meets the definition of a Category B infectious substance under § 173.134(a)(1)(ii). Category A is an infectious substance in a form

capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs, whereas Category B is an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals.

- Q3. Do the HMR require that infectious materials regulated as select agents under 42 CFR Part 73 be classified as Category A infectious substances?
- A3. The answer is no. The HMR require shippers and carriers of select agents and toxins that are listed in 42 CFR Part 73 and 9 CFR Part 121 to develop and adhere to in-depth security plans for transporting these materials and to use these plans to train their employees (see § 172.800(b)(13)). The HMR also except from regulation as a Division 6.2 material infectious substances forensic material known or suspected to contain a Category A infectious substance or an infectious substance listed as a select agent in 42 CFR Part 73 when: 1) transported on behalf of a U.S. government, state, local, or Indian tribal government agency; 2) placed in secondary packagings marked with a "BIOHAZARD" symbol that conforms to specifications in 29 CFR 1910.1030(g)(1)(i); 3) containing an itemized list of the packaging's contents between the secondary and outer packaging; and 4) placed in completed packagings capable of meeting the performance test standards for infectious substance packagings prescribed in 49 CFR 178.609 (see § 173.134(b)(15)).

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

Standards and Rulemaking Division

## Dodd, Alice (PHMSA)

Edmonson 8 171.1(d)(5) Definitions 16-18128

From:

Edmonson, Eileen (PHMSA)

Sent:

Friday, February 19, 2016 10:16 AM

To:

Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)

Subject:

FW: request for a letter of interpretation

Ladies,

Please log this letter into Filemaker for reply and assign it to me.

Thanks,

Eileen Edmonson USDOT/PHMSA (202) 366-4481 (work) (202) 366-8553 (main) (202) 366-7041 (fax) 1-800-467-4922 (HazMat Info Center) eileen.edmonson@dot.gov (e-mail) infocntr@dot.gov (HMIC e-mail)

From: Bennett, Corey (HEALTH) [mailto:corey.bennett@health.ny.gov]

Sent: Wednesday, February 17, 2016 12:03 PM

**To:** Edmonson, Eileen (PHMSA) **Cc:** Hill, David (HEALTH)

Subject: request for a letter of interpretation

Dear Ms. Edmonson,

As you have previously discussed with my supervisor, Mr. David Hill, I am writing to request a letter of interpretation regarding two questions that have arisen in response to a recent DOT inspection of our New York State Department of Health Wadsworth Center Laboratories.

Question 1: Under 49 CFR 171.1(d)(5) we believe that as a state entity, the transportation of hazardous materials by state employees in state owned vehicles solely for noncommercial state government purposes is not subject to any of the requirements of the *HMR*. Is this correct?

Question 2: It is our understanding that if an infectious substance does not meet the definition under 49 CFR 173.134(a)(1)(i) for a Category A infectious substance, then the infectious substance may appropriately be classified as a Category B infectious substance as described under 173.134(a)(1)(ii). Are there any requirements under 49 CFR parts 171-180 requiring that infectious materials regulated as select agents under 42 CFR part 73 must be classified as Category A infectious substances?

Thank you in advance for your response to these questions.

Sincerely, Corey J. Bennett

Corey J. Bennett, Asst. BioSafety Officer, ARO NYS Dept. of Health- Wadsworth Center Griffin Laboratory 5668 State Farm Road Guilderland, NY 12084 corey.bennett@health.ny.gov office ph# (518)485-6789