



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

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

JUL 31 2013

Mr. Kieran Toale  
Industrial Hygienist  
and Haz Mat Coordinator  
Safety Department  
Bellevue Hospital Center  
462 First Avenue, Admin. Bldg., Room 742  
New York, NY 10016

Reference No. 13-0077

Dear Mr. Toale:

This is in response to your March 20, 2013 e-mail, which was forwarded to this Office on April 12, 2013, and your May 15, 2013 telephone conversation with a member of my staff concerning how to describe pharmaceutical wastes that are transported from your hospital's healthcare clinic under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

In your letter, you state that when transported from your hospital, these wastes are divided into two categories: those regulated by the Environmental Protection Agency (EPA) that are described as a hazardous waste, and everything else that is described as "UN 3291, Regulated medical waste, n.o.s., 6.2 (infectious), PG II." You also state these wastes typically meet one or more of the following hazard classes or divisions: 2.1 (flammable gas), 2.2 (non-flammable gas), 3 (flammable liquid), 5.1 (oxidizer), 5.2 (organic peroxide), 6.1 (poisonous), 8 (corrosive), and 9 (miscellaneous), but rarely contain a Division 6.2 (infectious) material. In addition, you state the wastes are not regulated as hazardous substances under the EPA's Resource Conservation and Recovery Act. You ask if your understanding is correct that wastes that do not meet the Division 6.2 hazard class may not be offered for transportation described as "UN 3291, Regulated medical waste, n.o.s., 6.2 (infectious), PG II."

Typically, material, including pharmaceutical waste, that does not contain a pathogen, or in which the pathogen has been inactivated or neutralized so that it cannot cause disease, does not meet the definition of an infectious substances prescribed in § 173.134(a)(1) and must not be described or offered for transportation as a Division 6.2 material under the HMR (see § 173.134(b)(1)-(b)(3)). However, the exception prescribed in § 173.134(c)(2) permits waste pharmaceutical materials to be offered for transportation and transported as RMW when 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 RMW (see Docket No. PHMSA-2009-0151 (HM-218F), July 20, 2011 (76 FR 43530)). Waste

pharmaceuticals that meet only one primary hazard class, are chemically compatible, and are placed in one packaging in conformance with the requirements prescribed in § 173.12(b) (lab pack) may be described with generic proper shipping names instead of specific chemical ones, and are excepted from the specification packaging requirements for combination packagings when transported for disposal or recovery by motor vehicle, railcar, or cargo vessel. If the pharmaceutical wastes you describe are not transported in conformance with one of these exceptions, they must be transported in conformance with the requirements prescribed in the HMR for each hazard class they meet. Please note that a person who offers or accepts a package that is not in conformance with the HMR is potentially subject to either a civil or criminal penalty (see §§ 107.329 and 107.333).

I hope this satisfies your request.

Sincerely,



*jm*  
T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division

**Drakeford, Carolyn (PHMSA)**

Edmonson  
§ 173.134  
§ 171.2

**From:** INFOCNTR (PHMSA)  
**Sent:** Friday, April 12, 2013 5:11 PM  
**To:** Drakeford, Carolyn (PHMSA)  
**Subject:** FW: Proper Shipment of Non-RCRA Regulated Pharmaceutical Waste

Regulated Medical Waste  
13-0077

Hi Carolyn,

This caller requested we submit his e-mail as a formal letter of interpretation. The caller was previously referred to letter 02-0244

Thanks,  
Victoria

**From:** Kieran Toale [<mailto:Kieran.Toale@bellevue.nychhc.org>]  
**Sent:** Wednesday, March 20, 2013 11:33 AM  
**To:** INFOCNTR (PHMSA); PHMSA Administrator (PHMSA); [phmsa.chiefcounsel@dot.gov](mailto:phmsa.chiefcounsel@dot.gov); PHMSA HM Hazmat Safety  
**Subject:** Proper Shipment of Non-RCRA Regulated Pharmaceutical Waste

Dear DOT,

I would be grateful if you can please provide me with some guidance on the appropriate shipment of non RCRA regulated pharmaceutical waste from the healthcare facility where I work in New York. Specifically I'd like to know if its acceptable practice to over classify such waste and ship it as regulated medical waste (RMW) on an RMW manifest using the following shipping name?

**UN3291, Regulated Medical Waste, n.o.s., 6.2, PG II (Untreated)**

This decision would be based on the rare possibility of a 5 gallon drum of non RCRA regulated pharmaceutical waste containing a single material or more that could actually be classified as RMW. To clarify the type of pharmaceutical waste that I'm referring to would not meet any of the EPA definitions of being RCRA characteristic and it is not listed as being RCRA waste.

I've reviewed the appropriate DOT regulations shown below and do not believe that over classifying non RCRA regulated pharmaceutical waste for shipment is in compliance with DOT regulations. Would you be in agreement with my interpretation?

**Per 49 CFR 171.2(e)**

"No person may offer or accept a hazardous material for transportation in commerce unless the hazardous material is properly classed, described, packaged, marked, labeled, and in condition for shipment as required or authorized by applicable requirements of this subchapter or an exemption or special permit, approval, or registration issued under this subchapter or subchapter A of this chapter."

**Per 49 CFR 171.2(i)**

"No person may certify that a hazardous material is offered for transportation in commerce in accordance with the requirements of this subchapter unless the hazardous material is properly classed, described, packaged, marked, labeled, and in condition for shipment as required or authorized by applicable requirements of this subchapter or

an exemption or special permit, approval, or registration issued under this subchapter or subchapter A of this chapter."

**Per 49 CFR 172.204(a)**

"This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations the Department of Transportation."

I look forward to receiving your response.

Thanks,

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