



U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

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

APR 26 2007

Ms. Alice P. Jacobsohn
Director, Medical Waste Institute
National Solid Wastes Management Association
4301 Connecticut Avenue, NW, Suite 300
Washington, DC 20008

Reference No. 06-0277

Dear Ms. Jacobsohn:

This corrects our January 18, 2007 response to your November 30, 2006 letter concerning the requirements for transporting "Regulated medical waste, 6.2 (infectious), UN 3291, PG II" (RMW) prescribed in sections of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) that were revised in June and December 2006 to harmonize them with international requirements. See Docket Nos. PHMSA-06-25476 (HM-215I, 12/29/06, 71 FR 78595) and PHMSA-2004-16895 (HM-226A, 6/1/06, 71 FR 32243). The correction concerns our original response to your questions concerning the exceptions authorized in § 173.134(c)(2) for the transportation of waste cultures and stocks. We have paraphrased the questions in your November 30, 2006 letter and answered them in the order provided.

- Q1. The final rule issued under Docket No. HM-215I changes the sequence of information required to describe a hazardous material on a shipping paper, but not the sequence of information required on a package marking and label. Is our understanding correct?
- A1. Yes, effective January 1, 2007, the final rule issued under Docket HM-215I revised § 172.202(b) to require the UN identification number of a hazardous material to appear first in its basic description on a shipping paper followed by its proper shipping name, hazard class and packing group for consistency with international requirements. Under § 171.14(e), this new shipping description sequence is mandatory as of January 1, 2013. The sequence of marking and labeling requirements for a hazardous material under the HMR remain unchanged.
- Q2. Under Docket No. HM-226A, the letter "G" was added in Column 1 alongside the entry on the Hazardous Materials Table (HMT; § 172.101), for RMW. Section 172.101(b)(4) requires that HMT entries denoted with this symbol must have the technical name entered in parentheses as a part of the proper shipping description on a shipping paper either after the proper shipping name or at the end of the basic description as is prescribed in § 172.203(k). However, there is no technical name



060277

172.101
173.134(c)(2)
172.203(k)

for RMW and this makes compliance with this requirement difficult. Under Docket No. HM-215I the letter “G” no longer appears alongside this entry. Does the removal of this notation mean a technical name is no longer required as part of the RMW proper shipping description?

A2. Yes.

Q3. Medical waste haulers collect hazardous materials that cannot be separated from RMW, such as contaminated chemotherapeutic wastes the U.S. Environmental Protection Agency also requires to be manifested as hazardous waste. Currently, these materials are packaged and disposed of in compliance with the requirements for their hazard class under the HMR, but may not be transported on the same vehicle as waste cultures and stocks transported in accordance with § 173.134(c)(2). Would the Pipeline and Hazardous Materials Safety Administration (PHMSA) consider expanding this exception to include RMW that may also meet the definition of another hazard class? The Medical Waste Institute (MWI) asserts there is no change or increase in risk by allowing these substances to be transported onboard the same vehicle with RMW when these materials are packaged for their hazard class and transported to facilities designed to handle these materials in conformance with the HMR.

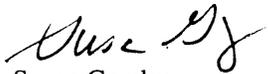
A3. The exception in § 173.134(c)(2) permits Category B waste cultures and stocks to be transported as RMW in a rigid non-bulk packaging conforming to certain general packaging requirements when transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste. An exclusive-use vehicle is one used for the transportation of a single commodity or class of commodities; transportation in an exclusive-use vehicle in accordance with the exception prevents inadvertent contamination of other types of materials, including non-medical waste materials. The transportation of chemotherapeutic waste and other RMW that also meets the definition of another hazard class on the same vehicle as Category B waste cultures and stocks is consistent with the intent of this exception and, therefore, is permitted under current regulatory requirements.

Q4. Under 7 CFR 330.400, the U.S. Department of Agriculture, Plant and Animal Health Inspection Service (APHIS), arranges compliance agreements for the proper disposal of plant and animal materials imported into the United States. The agreements include specific requirements for handling and disposing of these materials, also known as “regulated garbage,” such as inspections by APHIS agents and the use of leakproof covered receptacles. These materials go to the same disposal facilities as those for RMW, but under the HMR cannot be placed on the same vehicle with RMW and take advantage of the dedicated-exclusive use vehicle exception for RMW waste cultures and stocks prescribed in § 173.134(c)(2). Would PHMSA consider expanding this exception to include APHIS regulated garbage? MWI asserts there is no change or increase in risk by allowing these substances to be transported onboard the same vehicle with RMW when these materials are packaged for their hazard class and transported to facilities designed to handle these materials in conformance with the HMR.

A4. As indicated above, the intent of the exception in § 173.134(c)(2) is to prevent inadvertent contamination of other types of materials, including non-medical waste materials. The transportation of APHIS-regulated plant and animal waste appears to meet the intent of this exception. While these materials are not regulated medical waste, as that term is defined in the HMR, the plant and animal waste is considered medical waste and is transported to facilities designated by local authorities and designed for the disposal of medical waste. Further, under § 173.134(c)(2), you may transport medical or clinical equipment and laboratory products on the same vehicle as the waste cultures and stocks covered by the exception, provided they are properly packaged and secured against exposure or contamination. The term “laboratory products” is not defined in the HMR. However, APHIS-regulated plant and animal wastes are generated from laboratories and health care facilities and, thus, may be considered laboratory products for the purposes of the exception.

I hope this information is helpful. Please accept my apology for any confusion our earlier response may have caused.

Sincerely,



Susan Gorsky
Regulations Officer
Office of Hazardous Materials Standards



Institute

4301 Connecticut Ave., NW
Suite 300
Washington, DC 20008
202-364-3724 phone
202-364-3792 fax

Edmonson
§172.101
§172.203 (k)(2)
§173.134 (c)(2)
Applicability Shipping papers
06-0277

November 30, 2006

Ms. Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards
U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
400 Seventh Street, SW
Washington, DC 20590-0001

Dear Ms. Mitchell:

Thank you for meeting with the Medical Waste Institute (MWI) on October 12, 2006. As discussed at the meeting, there are a number of issues for which MWI members need clarification or a change in the PHMSA's Hazardous Materials Regulations (HMR). Below is a description of each of these issues.

1. Interpretation on the Sequence of Information on Package Markings and Labels

During our discussion, we determined that proposed rule HM-2151 would make a change on shipping papers for the sequence of information, but that neither existing nor proposed rules require a sequence of information on package markings and labels.

The MWI requests a written interpretation of this requirement such that members have a letter in the file should a question arise during an inspection and for business planning purposes.

2. Technical Name for Regulated Medical Waste

In the regulations under 49 CFR 171.101(b)(4) when the letter G appears in the symbol column in the hazardous materials table a technical name must be included in parentheses after the proper shipping name on package labeling and shipping papers. The letter G appears in this column for "Regulated medical waste, n.o.s." However, there is not a technical name for regulated medical waste, which makes compliance difficult.

In proposed rule HM-215I, the G no longer appears in the table, which would fix the technical name problem. The issue is whether the proposed rule will be finalized in this format and in a timely fashion. Therefore, MWI requests that the PHMSA finalize HM-215I before October 2007 in the manner proposed (no technical name requirement). If this is not possible, MWI requests that the PHMSA's enforcement office offer relief to the regulated community until rule finalization.

3. "Dual Substances" and Dedicated Carrier Exception

There are a number of materials that medical waste transporters collect on a regular basis that were not fully considered by the PHMSA in the regulations. These include "dual substances" where the regulated medical waste component cannot be separated from the other components that usually are other hazardous materials, i.e., contaminated chemotherapeutic wastes listed as a hazardous waste by the U.S. Environmental Protection Agency and also a regulated medical waste by the PHMSA.

Under the current rules, a package holding these dual substances could not be included in the same vehicle as regulated medical waste, n.o.s. and still allow the transporter to take advantage of the dedicated/exclusive vehicle exception.

These dual substances are disposed of at state-permitted medical or hazardous waste facilities and must be packaged according to PHMSA's HMR packaging and shipping requirements for both or multiple classifications. The MWI is not asking for a packaging exception.

The MWI is asking the PHMSA to extent the dedicated/exclusive carrier exception to allow for transport of these dual substances. MWI asserts that there is not a change or increase in risk from allowing dedicated/exclusive carriers to transport these substances when they are packaged according to the HMR, being managed by knowledgeable people, and traveling to facilities designed to handle these materials.

4. APHIS Waste and Dedicated Carrier Exception

The U.S. Department of Agriculture's Plant and Animal Health Inspection Service (APHIS) arranges "compliance agreements" for the proper disposal of plant and animal materials that are imported to the U.S. See 7 CFR 330.400 (Subpart - Garbage). These agreements include very specific requirements for the handling and disposing of "regulated garbage" such as inspections by APHIS agents and the use of leak-proof covered receptacles. The materials go to the same facilities for disposal as the PHMSA's regulated medical waste.

Under the current PHMSA rules, a package holding these APHIS wastes could not be included in the same vehicle as regulated medical waste, n.o.s. and still allow the transporter to take advantage of the dedicated/exclusive vehicle exception.

The HMR includes an separate exception for other materials managed by the U.S. Department of Agriculture. In this situation, MWI is only asking that the dedicated carrier exception apply to these APHIS wastes rather than a separate exception such that knowledgeable people will still be handling these materials at the same level of risk as already considered in the HMR.

As discussed at our meeting, there are a number of different ways procedurally these issues may be addressed. We agreed that this letter would either serve as a first step or, if a letter of interpretation was possible, that this letter would serve as a sufficient request. If additional information is required, please contact me at 202-364-3724 or alicej@envasns.org. Thank you.

Sincerely,



Alice P. Jacobsohn
Director, Medical Waste Institute
National Solid Wastes Management Association

cc: Ed Mazullo, PHMSA
Eileen Edmonson, PHMSA
MWI Members