U.S. Department
of Transportation
**Pipeline and
Hazardous Materials Safety
Administration**

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

MAR 19 2007

Ms. Selin Hoboy
Stericycle, Inc.
2333 Waukegan Road
Bannockburn, Illinois 60015

Ref. No. 07-0057

Dear Ms. Hoboy:

This responds to your March 9, 2007 letter requesting clarification of the requirements for transporting regulated medical waste under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask about the exception in § 173.134(c) applicable to the transportation of waste cultures and stocks and for clarification of the types of materials that may be transported on the same vehicle as waste cultures and stocks in accordance with the exception.

The exception in § 173.134(c)(2) permits a waste stock or culture of a Category B infectious substance to be offered for transportation and transported as a regulated medical waste when it is 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. As your letter notes, in a final rule published [insert date] under docket number HM-226A, we amended the language in this section to insert the phrase "used exclusively to transport regulated medical waste" in place of the phrase "dedicated to the transportation of regulated medical waste".

The change in terminology in § 173.134(c)(2) was intended to be a non-substantive editorial change to standardize terminology used throughout the HMR. The terms "dedicated" and "used exclusively" are synonymous. "Exclusive use" is not defined in the HMR, for other than transport of radioactive materials. As used in the HMR, the terms "dedicated" and "used exclusively" mean the vehicle is used for the transportation of a single commodity or class of commodities.

According to your letter, it is difficult to identify and segregate waste cultures and stocks from other types of medical waste generated by laboratories, hospitals, and similar facilities. You note that typically waste cultures and stocks are treated to neutralize any infectious pathogens prior to transportation, although untreated waste cultures and stocks may also be transported. You indicate that waste generators may ask Stericyle to transport other types of medical waste in addition to waste cultures and stocks, including:

- Plant and animal waste regulated by the Animal and Plant Health Inspection Service, U.S. Department of Agriculture;

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173.134

- Waste pharmaceutical materials;
- Laboratory and recyclable wastes, such as fixer/developer, amalgam, lead foil, and disinfectant materials;
- Infectious substances, including Category A infectious substances, that have been treated to eliminate or neutralize pathogens;
- Forensic materials being transported for final destruction;
- Rejected or recalled health care products; and
- Documents intended for destruction in accordance with HIPAA requirements.

You indicate that all these waste materials are transported to facilities designated for the disposal of medical waste.

As described above, the exception in § 173.134(c)(2) permits Category B waste cultures and stocks to be transported as regulated medical waste 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 operations you describe for the transportation of waste cultures and stocks appear to meet the intent of this exception. While the materials you transport on the same vehicle as waste cultures and stocks are not regulated medical waste, as that term is defined in the HMR, all the materials are considered medical waste and are 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, the materials you describe are generated from laboratories and health care facilities and, thus, may be considered laboratory products for the purposes of the exception.

Therefore, it is the opinion of this Office that the transportation operation you describe is consistent with the terms of the exception in § 173.134(c)(2). Therefore, you may transport the types of medical waste described in your letter on the same vehicle you use to transport waste cultures and stocks.

I hope this information is helpful. Please let me know if I can be of further assistance.

Sincerely,

Susan Gorsky
Regulations officer
Office of Hazardous Materials
Standards

Gorsky
§173.134
Exceptions for Medical Waste
07-0057

March 9, 2007

Mr. Edward Mazzullo, Director
Office of Hazardous Materials Standards
400 Seventh Street, S.W.
PHH-10
Washington, DC 20590

RE: FINAL RULE HM 226A - INTERPRETATION OF "EXCLUSIVE" MEDICAL WASTE CARRIER UNDER 49 CFR 173.134

Dear Mr. Mazzullo:

I am writing in reference to a recent language change under Final Rule HM 226A. In this final rule there is a section relating to the transportation of regulated medical waste. Specific section reference is 49 CFR 173.134 (c)(ii)(2) "[Category B waste culture or stock] transported as regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of 173.24 and 173.24a and packaging requirements under 29 CFR 1910.1030 and transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste." Prior to this change the term "dedicated" was used instead of "exclusively". Based on the literal interpretation of these regulations it would mean that materials other than regulated medical waste could not be on the vehicle at the same time.

Although, we recognize that the mixed cultures and stock materials which may be present in the containers is minimal and often more specifically from lab type environments, the potential still exists. It is also typical that wastes generated in these environments are pretreated prior to being disposed of in the regulated medical waste. However, due to the way that generators package their waste to take advantage of this exception, it would be difficult to ensure exclusivity for these materials alone.

We are requesting clarification that this new term does not change the intent of the regulation. Prior to this, the interpretation was that as a private carrier, primarily dedicated to the transport of regulated medical waste, other materials could be present on the vehicle. However, there are other waste streams that are transported as a service to generators for the safe and efficient transport of their waste materials. All drivers and employees are fully trained on the proper handling, transport and emergency response to these other waste materials. This provides generators with an efficient and compliant option for transporting their wastes. Other such wastes which generator's may request to be transported that are not necessarily regulated medical waste by definition may include:

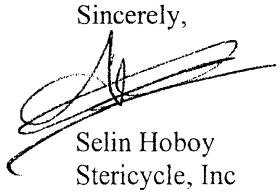
- US Department of Agriculture – Animal and Plant Health Inspection Service – Wastes defined under 7 CFR as regulated garbage, including plant and animal waste, and are required to have specific packaging, documentation and destruction requirements

- Waste pharmaceuticals – pharmaceutical materials which are meant for final destruction and no longer have value by manufacturer definition; packaged in accordance with regulations and separately documented as required
- Lab and Recyclable wastes – for example fixer/developer for recycling, amalgam for recycling, lead foil for recycling, disinfectant materials etc. – Packaged in accordance with regulations and separately documented as required
- Treated Category A infectious substances which generators chose to over classify
- Documents for destruction under HIPAA requirements
- Evidence materials – non weapon law enforcement materials sent for final destruction
- Off specification products from manufacturers due to rejection or recall, normally considered solid waste, which is transported for destruction

Current needs of the industry and generators are that other waste streams, which are also classified, marked and packaged appropriately, could be transported with regulated medical waste without compromising public health and safety. The ability to transport these materials together would also support greater compliance of proper segregation and characterization of materials by the generator leading to a more environmentally responsible disposal of these materials.

We would like to clarify that these additional waste materials can be transported with regulated medical waste so long as all materials are properly classified, marked and packaged appropriately. Additionally, we assume that it was not the intent of the change in words, to change the practices of the medical waste industry. We appreciate your consideration on this matter. Please feel free to contact me if you have any further questions at 847-943-6685/shoboy@stericycle.com.

Sincerely,



Selin Hoboy
Stericycle, Inc

CC: Deputy Robert A. Richard – Deputy Associate Administrator for Hazardous Materials Safety
Joseph Solomey – Assistant Chief Counsel for Hazardous Materials Safety Office of Chief Counsel.
Alice Jacobson, Medical Waste Institute