U.S.Department
of Transportation
**Research and
Special Programs
Administration**

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

DEC 13 1999

Ref. No. 99-0298

Mr. Charles N. Hendrix
Vice President
Micro-Med Industries, Inc.
5169 West 12th Street
Jacksonville, FL 32254

Dear Mr. Hendrix:

This responds to your letter, dated October 22, 1999, addressed to Mr. Bill Stevens in the Research and Special Programs Administration's Southern Region Office of Hazardous Materials Enforcement. Your letter addresses inconsistent federal and state regulatory requirements for the transportation of regulated medical wastes.

You are correct that there appear to be some significant differences between the federal transportation requirements applicable to regulated medical wastes in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) and requirements in effect in various states. The federal hazardous material transportation law (49 U.S.C. 5101 *et seq.*) preempts many state and local laws and regulations concerning hazardous materials transportation that are not the same as the federal requirements. (The enclosed index explains that preemption in detail.) Thus, where state requirements do not meet the preemption standards in the law, they are superseded by the HMR.

Your specific questions concerning transportation requirements for regulated medical wastes are paraphrased and answered below.

Q1: Can a physician, clinic, or large facility offer for transport an untreated throat culture that is contaminated with the Streptococcus bacterium? Must the contaminated throat culture be packaged according to UN or Packing Group II guidelines? If UN or Packing Group II packaging is required, is it then acceptable for a solid waste garbage truck to receive and compact the package, thereby destroying its integrity during transport to its final destination at a transfer station or landfill? Are shipping papers required?

A1: Cultures and stocks of infectious substances are considered hazardous materials under the HMR. Thus, a physician, clinic, or facility may offer an untreated throat culture contaminated with the Streptococcus bacterium for transportation if the shipment meets all applicable HMR requirements. For example, under § 173.134(b)(4), a waste culture or stock of an infectious substance may be offered for transportation and transported as regulated medical waste under the following conditions: (1) the waste culture or stock must conform to Biosafety Level 1, 2, or 3 as defined by the Centers for Disease Control (see HHS Publication 93-8395); (2) the waste culture or stock must be packaged in

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packagings conforming to the Packing Group II performance level as specified in Part 178 of the HMR and to the requirements in § 173.197; and (3) the waste culture or stock must be transported by a private or contract carrier using a vehicle dedicated to the transportation of medical waste. Waste cultures and stocks that do not conform to the conditions listed in § 173.134(b)(4) must be transported in packagings that conform to the requirements of § 173.196.

No person may offer for transportation or transport a waste culture or stock of an infectious substance unless the material is handled and transported in accordance with applicable requirements in the HMR, including those applicable to shipping papers, package marking and labeling, emergency response information, and employee training. In addition, the shipment must also conform to the general packaging requirements in Subpart B of Part 173. With specific reference to your question, § 173.24 requires that each package used for the shipment of hazardous materials must be designed, constructed, maintained, filled, and closed so that, under conditions normally incident to transportation, the package will retain its integrity and its contents.

Q2: Can a physician, clinic, or large facility offer for transport blood-contaminated untreated syringes or needles in containers that do not meet UN or Packing Group II guidelines? If UN or Packing Group II packaging is required, is it then acceptable for a solid waste garbage truck to receive and compact the package, thereby destroying its integrity during transport to its final destination at a transfer station or landfill? Are shipping papers required for transport of contaminated syringes?

A2: A syringe or needle contaminated with an infectious substance is considered regulated medical waste under the HMR. Regulated medical waste must be packaged in packagings conforming to the requirements of Part 178 of the HMR at the Packing Group II performance level. In addition, the packagings must be rigid, leak-resistant, impervious to moisture, of sufficient strength to prevent tearing or bursting under normal conditions of use and handling; sealed to prevent leakage during transport; puncture-resistant for sharps; and break-resistant and tightly lidded or stoppered for fluids in quantities greater than 20 cubic centimeters (see § 173.197). Section 173.134(b)(3) of the HMR provides a packaging exception for a regulated medical waste that is transported by a private or contract carrier. In such cases, the regulated medical waste may be packaged in a rigid, non-bulk packaging that conforms to the general packaging requirements in §§ 173.24 and 173.24a and the packaging requirements specified in regulations promulgated by the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1030.

No person may offer for transportation or transport a regulated medical waste unless the material is handled and transported in accordance with applicable requirements in the HMR, including those applicable to shipping papers, package marking and labeling, emergency response information, and employee training. In addition, the shipment must also conform to the general packaging requirements in Subpart B of Part 173. With specific reference to your question, § 173.24 requires that each package used for the shipment of hazardous materials must be designed, constructed, maintained, filled, and

closed so that, under conditions normally incident to transportation, the package will retain its integrity and its contents.

Q3: What is DOT's definition of an "infectious substance"? Does the subjective judgement of the individual determining "infectious" require consideration of OSHA's "universal precautions"? Is untreated discarded blood an infectious substance?

A3: For purposes of the HMR, an infectious substance is a viable microorganism or its toxin that causes or may cause disease in humans or animals. The term includes those agents listed in regulations of the Centers for Disease Control (see 42 CFR 72.3) and any other agent that causes or may cause severe, disabling, or fatal disease. Untreated discarded blood that is contaminated with an infectious substance is considered a regulated medical waste under the HMR. The HMR do not incorporate the "universal precaution" standards that are the basis of OSHA's regulations concerning the handling of bloodborne pathogens in laboratories and other work environments (see 29 CFR 1910.1030).

Q4: Are all offerors of regulated medical waste required to comply with DOT regulations? Do these regulations apply to both small and large facilities?

A4: No person may offer for transportation or transport a regulated medical waste unless the shipment conforms to the requirements of the HMR. The HMR apply irrespective of whether the offeror is a large or small facility. Further, the HMR apply to all shipments of regulated medical waste, even those shipments transported wholly within a single state.

You may know that we are considering revisions to the current requirements in the HMR applicable to infectious substances, including regulated medical wastes. On September 2, 1998, we published an advance notice of proposed rulemaking (ANPRM) in the *Federal Register* requesting comment on: (1) whether the HMR should incorporate international standards for transporting infectious substances, (2) possible revisions to the current exceptions in the HMR for diagnostic specimens and biological products, and (3) additional packaging options for transporting regulated medical wastes. We expect to issue a notice of proposed rulemaking on these issues in the next year. A copy of the ANPRM is enclosed.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Edward T. Mazzullo

Edward Mazzullo
Director, Office of Hazardous Materials Standards

Enclosures

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Micro-Med Industries,Inc.
Medical Waste Services

5169 West 12th Street, Jacksonville, Florida 32254 ☐ Telephone 904/693-3254 ☐ FAX 904/693-3352

October 22, 1999

Mr. Bill Stevens, Hazmat. Enforcement Specialist
United States Department of Transportation
Research and Special Programs Administration
Office of Hazardous Materials Enforcement
P.O. Box 20636
Atlanta, GA 30320

Dear Mr. Stevens,

My company transports regulated medical waste including cultures and stocks of infectious substances in five southeastern states. As you know, most states have regulations concerning regulated medical waste packaging and transportation. We have attempted to educate our customers explaining their responsibility as "offerers" of regulated medical waste (RMW) to comply with both federal and state regulations. In discussions with customers from various states though, there is unquestionably a significant difference between individual state regulations and those of DOT outlined in 49 CFR. Specifically, North Carolina, Georgia and Tennessee regulators refer to their regulations as the governing baseline requirement.

It seems that some explanation for the differences between state requirements can be attributed to interpretation of federal OSHA requirements. It seems also, that though federal DOT regulations have been in place for some time, a combination of general interpretation through many years coupled with lack of communication and lack of enforcement probably played a part in the disparity of each state's ultimate regulations. North Carolina firmly believes that their developed regulations address an acceptable level and was confirmed acceptable by OSHA.

Furthermore, "offerers" in these states often call the state agency and receive confirmation that the state regulations are the governing requirement. Hence our confusion as to where the communication between federal and state agencies lies to establish a standard. Likewise, we are sure this same conflict applies elsewhere and any official record DOT statement as to minimum requirements would suffice in most instances.

For example, North Carolina DEHNR rules (copy enclosed) allow the disposal of contaminated syringes, sharps and other items, including blood in quantities less than 20 cc's, bloody gauze, tubing and dressings to be disposed of as solid waste (reference NCDEHNR reg's .1202(b), .1202(c), .1201(9). Thousands of pounds of regulated medical waste, including thousands of untreated syringes, are transported daily to landfills in North Carolina in apparent violation of federal law. This daily occurrence is a direct contradiction of the intent of all medical waste regulations as this is completely unregulated in both treatment and transportation aspects.

Without outlining each states regulations, we might pose these direct questions for DOT to provide clarification which can be used to educate state officials and "offerers" of regulated medical waste in these states:

1. Can a physician, clinic or large facility offer for transport an untreated throat culture that is contaminated with the Streptococcus bacterium (thousands of positive "strep" cultures are generated by pediatric offices annually)? Must the contaminated throat culture be packaged according to UN or packaging group II guidelines?
   If UN or packaging group II packaging is required, is it then acceptable for a solid waste garbage truck to receive and compact thereby destroying the integrity of the package while in transport to its final destination at a transfer station or landfill?
   Are shipping papers required?

2. Can a physician, clinic or large facility offer for transport blood contaminated untreated syringes or needles in non-UN or packaging group II approved containers?
   If UN or packaging group II approved containers are required, is it then acceptable for a solid waste garbage truck to receive and compact thereby destroying the integrity of the package while in transport to its final destination at a transfer station or landfill?
   Are shipping papers required for transport of contaminated syringes?

3. Given the DOT definition of "regulated medical waste", what is the DOT's definition of an "infectious substance"?
   Does the subjective judgement of the individual determining "infectious" require consideration of OSHA's "universal precautions"?
   Under DOT's definition, is untreated discarded blood an "infectious substance"?

4. Are all offerers of regulated medical waste required to comply with DOT regulations? Do these regulations apply to both small and large facilities?

We applaud DOT's efforts to help clean up the industry and standardize compliance. Further, we appreciate DOT taking compliance enforcement to the generators as offerers of regulated medical waste and infectious substances. We would note however, that a mutual consideration be afforded as we work together to educate and inform the healthcare industry of these directives. It is obvious that all parties involved in the process have been operating at significantly different levels of interpretation and compliance for years.

As the senior enforcement specialist in our southeast region, we appreciate your efforts to meet and discuss these requirements. CFR regulations are not so black and white when applied in the field. We believe that a coordinated schedule of meetings with state regulators open to haulers and generators is very helpful. With published notice, this would provide some structure to the training and information while affording maximum participation.

Thank you for answers or a referral of these questions to clarify this information. A prompt response to these issues is certainly in the interest of minimizing risk to the general public and many downstream garbage workers. Thank you for your help and I look forward to your reply.

Sincerely,

Charles N. Hendrix
Vice President

cc: Mr. Edward Mazzullo
Ms. Eileen Edmonson Mack
Mr. Todd Clark
Ms. Edith Coulter
Ms. Alice Jacobson, Esquire