U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

DEC 7 1999

Ref. No. 99-0124

Mr. Paul Jackson Rice
Arent Fox Kintner Plotkin & Kahn, PLLC
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036

Dear Mr. Rice:

This responds to your letters of May 10 and September 7, 1999, and telephone conversations with Ms. Eileen Mack of my staff, concerning the transportation requirements applicable to used sharps under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Please accept my apology for our delay in answering your inquiries.

Sharps are objects that can penetrate the skin, such as needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires. Used sharps that are not contaminated with an infectious substance or any other material meeting one of the hazard classes defined in the regulations are not subject to the HMR.

For purposes of the HMR, used sharps that are contaminated with an infectious substance are considered regulated medical waste, Division 6.2. Regulated medical waste is a waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in: (1) the diagnosis, treatment, or immunization of human beings or animals; (2) research pertaining to the diagnosis, treatment, or immunization of human beings or animals; or (3) the production or testing of biological products. A package containing a regulated medical waste is subject to the HMR, whether or not that regulated medical waste is commingled with non-regulated waste. 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).

The HMR include several exceptions applicable to the transportation of regulated medical waste. For example, a regulated medical waste that is transported by a private or contract carrier is excepted from the requirement that it be labeled with an INFECTIOUS SUBSTANCE label provided that the outer packaging is marked with a BIOHAZARD marking in accordance with the regulations of the Occupational Safety and Health

173.134

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Administration (OSHA) governing bloodborne pathogens (29 CFR 1910.1030). A regulated medical waste that is transported by a private or contract carrier is also excepted from the specific packaging requirements of § 173.197 provided it is 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 29 CFR 1910.1030.

Medical equipment that meets the definition of a Division 6.2 material and is prepared for transportation in conformance with the OSHA requirements in 1910.1030(d)(2)(xiv) is not subject to any of the requirements in the HMR (see § 173.134(b)(1)(iii). This OSHA provision applies to equipment that has been decontaminated to the fullest extent practicable. This exception was incorporated into the HMR in 1995 to relieve generators of regulated medical waste from the burden of complying with both the HMR and the OSHA regulations. For a discussion of the reasons for and applicability of this exception, see the preamble to the final rule published September 20, 1995 (60 FR 48780). The exception applies to medical equipment that is intended for reuse. The exception does not apply to medical equipment that is being transported for disposal. For purposes of this exception, medical equipment includes equipment used for diagnosis, research, or treatment, such as reusable surgical equipment or equipment used for testing where the components within which the equipment is contained essentially function as packaging. Used sharps are not considered medical equipment for purposes of this exception.

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

Sincerely,

Edward T. Mazzullo

Edward T. Mazzullo
Director, Office of Hazardous Materials Standards

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ATTORNEYS AT LAW

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September 7, 1999

VIA FACSIMILE AND U.S. MAIL

Edward Mazzullo
Director, Office of Hazardous Materials Standards
Research and Special Programs Administration
400 7th Street, S.W.
Washington, D.C. 20590

RE: Request for Regulatory Interpretation - 49 C.F.R. § 173.134

Dear Mr. Mazzullo:

This letter follows up on my May 10, 1999 letter that requested a regulatory interpretation of 49 C.F.R. § 173.134 from the Research and Special Programs Administration ("RSPA"). The May 10, 1999 letter (a copy of which is enclosed for your convenience) sought guidance with respect to the circumstances under which used medical instruments that are sharp, such as scalpels and needles (hereinafter, "used sharps") are subject to the Hazardous Materials Regulations ("HMR"). As of today, we are not in receipt of any formal response from your office.

While checking on the status of our request, we were put in contact with Ms. Eileen Mack, the RSPA technical writer assigned to handle the matter. During a June 29, 1999 telephone conversation between Ms. Mack and Adam Cramer, one of my associates, Ms. Mack advised that RSPA's response to our request was still in draft form, and that the draft response may still need to be reviewed by RSPA counsel. Ms. Mack explained that the regulation at issue, 49 C.F.R. § 173.134, was complex and also contained certain references to Occupational Safety and Health Administration ("OSHA") regulations. Ms. Mack encouraged us to contact her again to check on the status of the draft response.

Subsequent to our June 29, 1999 phone conversation, we received a voice-mail message from Ms. Mack advising us that because of the OSHA reference in 49 C.F.R. § 173.134, OSHA would be in a better position to respond to our request for regulatory interpretation.[1/] Indeed, Ms. Mack even provided a name and telephone number of an individual at OSHA. While we do appreciate Ms. Mack's efforts, we hesitate to rely on an OSHA interpretation of a RSPA regulation.

1/ Subsequent to Ms. Mack's voice-mail, we attempted, unsuccessfully, to contact her.

We are particularly interested in a written response from your office given RSPA's long running practice of helping the regulated community by providing written interpretations of the HMR, and that RSPA, rather than OSHA, is the agency responsible for enforcing the HMR. Therefore, we respectfully request that RSPA either provide the regulatory interpretation originally sought in the May 10, 1999 letter, or advise us in writing that RSPA will defer to all aspects of OSHA's interpretation of 49 C.F.R. § 173.134, whatever those interpretations may be.

This issue is of consequence to a client, and a prompt response would be greatly appreciated. Please contact me, or Adam Cramer (202/857-6414) if we can be of any assistance to you in this request.

Sincerely,

Paul Jackson Rice

cc: Adam B. Cramer, Esq.
Eileen Mack

Mack
§ 173.134

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99-0124

May 10, 1999

VIA FACSIMILE AND U.S. MAIL

Edward Mazcullo
Director, Office of Hazardous Materials Standards
Research and Special Programs Administration
400 7th Street, S.W.
Washington, D.C. 20590

RE: Request for Regulatory Interpretation - 49 C.F.R. § 173.134

Dear Mr. Mazcullo:

The purpose of this letter is to request a regulatory interpretation of 49 C.F.R. § 173.134 from the Research and Special Programs Administration ("RSPA"). More specifically, we are interested in the circumstances under which used medical instruments that are sharp, such as scalpels and needles (hereinafter, "used sharps") are subject to the Hazardous Materials Regulations ("HMR"). To further focus this request, we pose the following three questions:

(1) Are used sharps that do not contain an infectious substance subject to the HMR?

(2) Are used sharps that are believed to contain an infectious substance, but handled and transported consistently with the Occupational Safety and Health Administration ("OSHA") regulations pertaining to blood-borne pathogens, 29 C.F.R. § 1910.1030, exempt from the HMR?

(3) If used sharps that contain an infectious substance are commingled with other used sharps, and the aggregate collection of used sharps is handled and transported consistently with 29 C.F.R. § 1910.1030, is this commingled collection exempt from the HMR?

Our reading of the HMR suggests that used sharps free from infectious substances are not subject to the HMR, and that if used sharps contain an infectious substance, such used sharps are exempt from the HMR to the extent they are handled and transported according to 29 C.F.R. § 1910.1030. The analysis that supports our reading of the HMR follows.

Regulated Medical Waste

The HMRs define Regulated Medical Waste ("RMW") in pertinent part:

> (4) A regulated medical waste means a waste or reusable material . . . that contains an infectious substance and is generated in —
>
> > (i) The diagnosis, treatment or immunization of human beings or animals.[1/]

According the definition of RMW, a used sharp is classified as RMW only when the used sharp contains an infectious substance.[2/] Alternatively, a used sharp free from infectious substances (such as the needle from a simple blood test) does not meet the definition of RMW, and thus is not considered a hazardous material under the HMR.

Exceptions Under the HMR for Regulated Medical Waste

Although used sharps that contain an infectious substance fit the HMR definition of RMW, there appear to be significant regulatory exceptions if the used sharp is handled and transported according to certain OSHA regulations. Section 173.134(b) provides in pertinent part:

> (1) The following are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of this subchapter:
>
> . . .
>
> > (iii) Laundry or medical equipment that conforms to 29 CFR 1910.1030 of the regulations of the Occupational Safety and Health Administration of the Department of Labor.[3/]

It appears that a used sharp that contains an infectious substance, and thus is a RMW under the HMR, is nonetheless exempt from the HMR if handling and transportation of the used sharp conforms with OSHA regulations at 29 C.F.R. § 1910.1030. Indeed, it seems that when transporting used sharps that meet the definition of RMW, a regulated entity is effectively given a "choice" to follow either the HMR *or* the OSHA regulations at 29 C.F.R. § 1910.1030.

1/ 49 C.F.R. § 173.134(a)(4) (1998).

2/ Infectious substance is defined under the HMR at 49 C.F.R. § 173(a)(1) (1998).

3/ 49 C.F.R. § 173.134(b)(1) (1998).

The exception at 49 C.F.R. § 173.134(b)(1) is conditioned on the requirement that materials being transported not contain any "material otherwise subject to the requirements of this subchapter." We interpret this condition as applying to circumstances where the RMW has some additional attribute (other than containing an infectious substance) that makes it a hazardous material under the HMR such as, ignitability or corrosivity. Indeed, reading the condition any other way would appear to make the entire exception in 49 C.F.R. § 173.134(b) superfluous.

Commingling

If the transportation of used sharps that contain an infectious substance, regardless of OSHA compliance, is not excepted from the HMR, then it appears that a commingled package of used sharps (some of which contain an infectious substance, some of which do not) would be treated, as far as the HMR are concerned, as RMW.

Conclusion

In short, it appears that used sharps that do not contain an infectious substance do not meet the HMR definition of a RMW, and thus are not subject to the HMR. Used sharps that contain an infectious substance meet the definition of RMW, but if such used sharps are handled and transported consistently with OSHA regulations regarding blood-borne pathogens, they are excepted from the HMRs. Please advise whether our interpretation (and the reasoning underlying the same) of 49 C.F.R. § 173.134 is accurate. If our interpretation is incorrect, please explain RSPA's interpretation of 49 C.F.R. § 173.134.

Please contact me, or Adam Cramer (202/857-6414) if we can be of any assistance to you in this request.

Sincerely,

Paul Jackson Rice

cc: Adam B. Cramer, Esq.