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

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

AUG 2 2000

Mr. Jeffrey A. Paiste
Vice President, EnviroTech of
America, Inc.
P.O. Box 239
East Syracuse, New York 13057

Reference No. 00-0104

Dear Mr. Paiste:

This is in response to your inquiry and telephone conversations with me and a member of my staff concerning the marking of non-bulk packages that will be used to transport regulated medical waste (RMW) that does not contain a culture or stock of an infectious substance. You asked if a packaging manufacturer is permitted to mark "UN 3291, PG II" on the outside of an empty, knocked-down fiberboard box that has not been performance tested without assuming liability for the marking or the packaging. You also stated the RMW shipments are transported by private or contract carrier.

The answer is yes. RMW that does not include cultures or stocks of an infectious substance, and is transported by a private or contract carrier is not required to be placed in a packaging meeting the Packing Group II performance level. Section 173.134(b)(3) authorizes the use of a non-specification packaging for such materials, if certain requirements are met. Based on the information you provided, your packaging satisfies these requirements.

Further, please note that the proper shipping name "Regulated medical waste" must also be marked on a package containing RMW. See § 172.301.

I hope this satisfies your request.

Sincerely,

Hattie L. Mitchell

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards

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173.134

EnviroTech of America, Inc.

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Via Facsimile

March 28, 2000

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§ 173.134
00-0104

U.S. Department of Transportation
Attn: Mr. Edward T. Mazzullo, Director
Office of Hazardous Materials Standards
400 Seventh Street, S.W.
Washington, D.C. 20590

Facsimile: 1-202-366-3012

Subject: Request for Confirmation of Regulated Medical Waste Packaging and Labeling Requirements

Dear Mr. Mazzullo:

This letter is sent to your office to request written DOT confirmation of the standards which must be met in order to allow manufacturers to imprint the "UN 3291 PG II" identifier on outer packages to be used for the transportation of regulated medical waste (RMW) in cases in which the 49 CFR 173.134 (b)(3) exemption applies.

My company is a commercial RMW transporter permitted by the State of New York, operating in compliance with 6 NYCRR Part 364 requirements for packaging and transportation of RMW. As such, we are able to employ the 49 CFR 173.134 (b)(3) exemption for contract carriers of RMW.

To the best of my knowledge, through compliance with 6 NYCRR Part 364 packaging requirements, the packaging systems used by my company for the transportation of regulated medical waste meet all of the general packaging requirements of 49 CFR 173.197 and the comparable requirements of OSHA's 29 CFR 1910.1030. EnviroTech's packaging systems, through use of rigid outer containers of cardboard or plastic and inner containments of plastic liner bags, sharps containers or fluid containers, sufficiently meet the applicable DOT and OSHA performance standards, in that they are:

1) Rigid;
2) Leak-resistant;
3) Impervious to moisture;
4) Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling;
5) Sealed to prevent leakage during transport;
6) Puncture resistant for sharps and sharps with residual fluids;
7) Break-resistant and tightly lidded or stoppered for fluids in quantities greater than 20 cubic centimeters, and;
8) Labeled with a biohazard symbol.

EnviroTech does not rely on packaging manufacturers to supply complete systems of inner and outer packaging for transportation of regulated medical waste. Instead, as is the practice in our industry, we purchase single-use outer cardboard boxes and reusable plastic outer bins, plastic liner bags, and plastic sharps and fluid containers from numerous vendors. We then provide these packaging

components to our customers, the medical waste generators, who in turn assemble fully contained, leak-proof packages suitable for safe transport of their RMW. (Of note, within New York State, this assignment of medical waste packaging responsibility is dictated by the 6 NYCRR Part 364 regulations, which very clearly make the medical waste generator responsible for assembling the medical waste packaging using the appropriate inner and outer containments.)

The problem we are encountering is that the manufacturers of our outer cardboard and plastic containers do not believe that they are permitted to provide the "UN 3291 PG II" imprint on these outer containers without completion of performance testing of the complete packaging system, yet they are unable to accomplish this performance testing because they do not control or sell the complete packaging system.

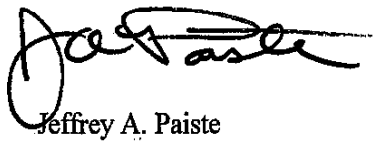
I believe that much of the problem stems from conflicting direction between the 49 CFR 173.134 (b)(3) exemption, which allows avoidance of Section 173.197 requirements and Part 178 specifications and testing so long as the requirements of 173.24 and 173.24a are met, and the section 173.24 (d)(1) requirement to perform Part 178 testing for UN specification packaging. If a UN identifier is required in cases for which the 49 CFR 173.134 (b)(3) exemption applies, then a clarifying statement from the DOT explaining how to resolve this apparent regulatory conflict on package testing is definitely needed.

My understanding of the packaging and labeling requirements applicable when the 49 CFR 173.134 (b)(3) exemption is in force is that manufacturers of our outer packages are authorized to produce these outer cardboard or plastic containers for EnviroTech's use imprinted with the "UN 3291 PG II" identifier without having to conduct any Part 178 performance testing. It is also my understanding that EnviroTech and its medical waste customers, not the outer container manufacturers, bear responsibility for assessment that each complete packaging system employed satisfactorily meets the general DOT and OSHA performance criteria enumerated above.

I believe that a letter from the DOT confirming the correctness of our understanding of these particular packaging and labeling requirements would be sufficient to give our packaging vendors assurance that they are acting in full compliance with 49 CFR regulations when they produce outer medical waste containers imprinted with the "UN 3291 PG II" identifier on our behalf.

I can be reached at either 610-366-0312 early most weeks or 315-463-7178 late most weeks if you'd like more details on our regulated medical waste packaging concerns. Thanks.

Respectfully,



Jeffrey A. Paiste
Vice President