



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

JAN 30 2002

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

Edward Krisiunas, MT(ASCP), CIC, MPH
Sharps Compliance
9050 Kirby Drive
Houston, TX 77054

Ref. No. 02-0021

Dear Mr. Krisiunas:

This responds to your request during a November 28, 2001 telephone conversation with Ms. Eileen Edmonson of my staff for written confirmation of a response you received from her by electronic mail on November 13, 2001. You asked whether an unmarked sharps-disposal-by-mail combination packaging, approved for use by the U.S. Postal Service (USPS) under authorization no. 035J, fulfills the requirements for a sharps regulated medical waste packaging prescribed in § 173.197 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

You also enclosed in an October 19, 2001 electronic mail message a copy of pages C-19 through C-36 of the USPS Domestic Mail Manual Issue 56 plus Postal Bulletin changes through PB 22060 (10-4-01) that require a sharps packaging approved for use by the USPS to conform to the following packaging performance tests in the HMR: §§ 178.604 (leakproof), 178.606 (stacking), 178.608 (vibration), and 178.609 (infectious substance packaging). On November 8, 2001, you supplied this office with an example of the packaging, a rigid 4.8-quart polyethylene bottle inside a polyethylene bag inside a fiberboard box, but did not provide its performance test results.

Under §§ 178.2 and 178.3, the manufacturer identified on a packaging or the person placing the UN symbol on the packaging is responsible for ensuring that the packaging meets the UN standard to which it is certified. However, based on the information you provided, it is the opinion of this office that the sharps combination packaging you described would conform to §§ 173.197 and 178.609 provided it successfully passes all prescribed performance tests for these packagings in 49 CFR Part 178 and these results are documented and maintained, as required in § 178.601(l). Further, the packaging that complies with § 173.197 must be marked, as required in 49 CFR Part 178, Subpart L, with the symbols representing its design specification.

I hope this satisfies your request.

Sincerely,

John A. Gale
Transportation Regulations Specialist
Office of Hazardous Materials Standards

173.197

Edmonson, Eileen

Nov 28

From: EKrisiunas@aol.com
Sent: Tuesday, November 20, 2001 5:20 PM
To: eileen.edmonson@rspa.dot.gov
Cc: Bkunik@sharpsinc.com; cneal@sharpsinc.com
Subject: Correspondence on mailbacks

Edmonson

§ 173.197
Regulated Medical Waste
02-0021

Dear Eileen:

I would first like to thank you for your assistance during the past few weeks relative to the HMR and the mailback containers used by Sharps Compliance. Your agency has been one of the few that is always responsive to questions and inquiries pertaining to its regulations.

Per our discussions over the past few weeks, am I correct in the following summarization on the topic of mailbacks and the HMR:

Given that the USPS testing standards found in the Domestic Mail Manual (DMM) are equivalent to DOT standards in regard to authorization required, packaging standards and parameters, package documentation, marking and labeling and package testing including periodic re-testing with documentation as well as a complete serialized manifest system with generators' certification and emergency response system, the USDOT acknowledges a USPS permitted regulated medical waste sharps by mail system as meeting the HMR standards in 49 CFR parts 171 - 180.

Please reply whether I am correct or if I have missed something. I can provide a hard copy of this letter via fax or Fed-Ex. It would be beneficial to receive your correspondence in writing as we will share it with our clients as part of our educational outreach on HMR with them.

Sincere regards,

Edward Krisiunas, MT(ASCP), CIC, MPH
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and

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