



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

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

OCT 18 2000

Mr. Gary Chilcott
CEO/President
Sure-Way Systems, Inc.
310 East Harry Bridges Boulevard
Wilmington, CA 90744

Ref. No. 00-0128

Dear Mr. Chilcott:

This is in response to your letter and telephone conversations with members of this office concerning whether your company's reusable sharps container conforms to the packaging requirements for the transport of a regulated medical waste (RMW) under the Hazardous Materials Regulations (49 CFR Parts 171-180).

You described the sharps container as a rigid, oblong, high-density polyethylene container with absorbent foam at the bottom and a locking lid. Flanges extending from the edge of the container lid are designed to be attached to, and suspended from, a metal cart rack. When offered for transportation, the top, bottom and sides of the cart rack holding the containers are surrounded with 1/8-inch thick polyethylene sheeting. The ends of the cart rack, where the containers are loaded and unloaded, are locked during transportation. You enclosed test reports that state the sharps container meets the Occupational Safety and Health Administration (OSHA) requirements in 29 CFR 1910.1030, and certain other performance criteria. Also, you enclosed several photographs of the containers, which appear to be marked with the OSHA "BIOHAZARD" marking, and the cart racks.

Based on the information you submitted, it is our opinion that the polyethylene container meets the criteria in §§ 171.8, 173.24, and 173.24a for a non-bulk, non-specification package. Under § 173.134(b)(3), the container may be used for RMW (i.e., Regulated medical waste, 6.2, UN 3291, PG II) that does not contain a waste culture or stock provided it is transported by private or contract carrier. Each container must be marked in conformance with the proper shipping name, identification number, etc., as required in 49 CFR Part 172, Subpart D, and with the OSHA "BIOHAZARD" marking. If the markings on the containers are not visible through the



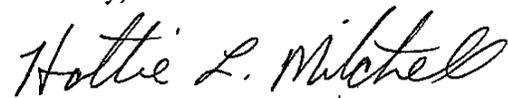
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polyethylene sheeting, the sheeting must be marked according to the requirements for an overpack, as prescribed in § 173.25.

I hope this satisfies your request.

Sincerely,

A handwritten signature in cursive script that reads "Hattie L. Mitchell".

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



Sure-Way Systems, Inc.

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April 16, 2000

Edward Mazzullo, Director
Office of Hazardous Waste Materials Standards
U.S. D.O.T.
400 Seventh St. S.W.
Washington, D.C.
20590

Dear Mr. Mazzullo,

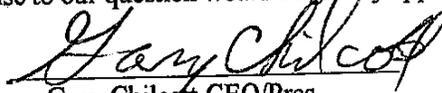
We talked at the National medical waste conference in October about the need for secondary containment of our reusable sharps containers while they are being transported in transport cart racks during shipment to and from the hospital. You had indicated that you thought they did not need to be in certified secondary containment enclosure given the fact we had gone through the D.O.T. testing.

I would like to formally request a letter from your office clarifying the transportation of our FDA cleared sharps containers in our proprietary custom transport (Picture Attached). Our transport carts are specially constructed to insure that the containers are upright and do not rub against each other except at the flange edge of the container. This design best protects the container form any damage while in route to and from the hospital and treatment facility. These carts are also used to transport the containers around the hospital when the empty containers are exchanged with the filled containers.

When the sharps containers are placed in the cart at the hospital, they are each locked with pins which require a special tool for their removal. Independent testing was done on the containers by 2 different companies testing the containers for puncture resistance, ability to hold liquids, drop tests for breakage, and a vibration test was done to simulate 5 years of typical transportation operation usage. The containers that we have are approximately twice as thick as the disposable ones that they are replacing.

We are enclosing a picture of the naked transport rack so the you can see how the containers ride in the transport cart. The carts that we will be using are just like the one in the picture, except they will have 1/8 inch thick polypropylene sheeting on the top, sides, and bottom. The ends of the transport cart, where the containers are loaded and unloaded, are locked during transport to secure the load.

We are attaching the independent test results as will as a picture of the unsheeted cart. Anything that you could do to expedite a response to our question would be greatly appreciated


Gary Chilcott CEO/Pres.
Sure-Way Systems, Inc.

Processing plants Butte, MT Valley City, ND. Wilmington, CA 800-822-3929