

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 18, 1990

James L. Boyland, Vice President  
Recovery Corporation of America  
Environmental Affairs  
West 17th Street  
New York, New York 10011

Dear Mr. Boyland:

It is EPA's pleasure to respond to your letter of May 29, 1990 regarding the agency's requirements for mailing sharps from covered states. Your letter requested clarification on specific issues concerning packaging and labeling; sharps container specifications; registered mail return receipts and the requirements for mailing directly to a destination facility or intermediate handler. The information below should provide the clarity that you desire concerning these issues.

1. Packaging and Labeling

Regulated medical waste must meet specific packaging criteria in accordance with 40 CFR Section 259.41(a). These packages must be:

- a.) rigid;
- b.) leak-resistant;
- c.) impervious to moisture;
- d.) have a strength sufficient to prevent tearing or bursting under normal conditions of use and handling; and
- e.) sealed to prevent leakage during transport.

These general performance standards for packaging have been developed to allow the generator to use one or more types of containers. This approach provides the generator with the flexibility to meet the packaging criteria using a variety of methods.

Generators must label each package of regulated medical waste before transporting or offering for transport off-site in accordance with 40 CFR Section 259.44. The packages requiring labeling are those which meet the packaging requirements or performance standards previously states above.

Section 259.44 provides labeling requirements for two categories of regulated medical waste. The first category addressed untreated regulated medical waste. These are regulated medical waste that

have not been treated to substantially reduce or eliminate its potential for causing disease. Therefore, each package of untreated medical waste must have a water-resistant label affixed to or printed on the outside of the container. The label must have the words “Medical Waste”, or “Infectious Waste” or display the universal biohazard symbol. Inner packages, such as red bags, do not require a label.

The second category includes treated regulatory medical waste. These are regulated medical waste that have been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed (i.e., ruined, torn apart, mutilated or made unrecognizable). Therefore, treated regulated medical waste does not require labeling, but are required to be marked according to Section 259.45.

2. Sharps Container Specifications

In addition to requirements stated in item 1 of this letter, generators must package sharps and sharps with residual fluids in packaging that is puncture-resistant.

3. Registered Mail Return Requested

Generators who meet the conditions of Section 259.50 (e) (2) (i) who transport used and unused sharps (as described in Section 259.30(a)) are exempt from the requirements of using a transporter with an EPA identification number and from using the tracking form when mailing used and unused sharps through the U.S. Postal Service. These conditions apply when the below listed criteria has been met, as follows:

- a.) The package is sent by registered mail requiring a return receipt that indicates to whom, signature, date, and the address where the package was delivered; and
- b.) The generator keeps a shipment log and maintains the original receipt and the returned registered mail receipt as required by Section 259.54(b)(3).

The above requirements for the mailing of sharps, are documented in Section 259.5(c).

4. Mailing Directly to a Destination Facility or Intermediate Handler

When the regulated medical waste is being shipped through the U.S. Postal Service to a location other than the destination facility then this facility would be considered a transfer facility and would be required to obtain an EPA transporter ID number.

A copy of the 40 CFR Part 259 is attached for your future reference. If there are any questions concerning this response, please contact Othalene Lawrence at (202) 245-35409.

Sincerely,

Mike Petruska, Chief  
Waste Characterization Branch

Attachment

FaxBack # 11525