

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

April 20, 1990

Rebecca Roberts
Safe Way Disposal Systems, Inc.
90 Industrial Park Rd.
Middletown, CN 06457

Dear Ms. Roberts:

Thank you for your letter of February 26, regarding the packaging requirements for Class 4 regulated medical waste (RMW), as defined in Section 259.30(a). Class 4 wastes are sharps generated during the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The waste description for Class 4 includes items such as hypodermic needles, syringes, scalpel blades, etc. These items pose a substantial physical hazard if they are not managed appropriately. This class also contains items such as pasteur pipettes, blood vials, culture dishes, slides and cover slips, and glassware (broken and unbroken) which have been in contact with infectious agents. These items pose a substantial hazard when they are broken and have a great potential to break during the waste management activities at a health-care facility.

The packaging requirements found in Section 259.41 (a) and (b) would apply to these waste items. The packaging requirements are written as general performance standards to allow generators the greatest amount of flexibility in meeting the regulations. Section 259.41(a) requires the generator to package the RMW, prior to off-site transportation. One or more containers can be used to ensure the packaging meets the following general requirements as found in Section 259.41(a):

1. Rigid;
2. Leak resistant;
3. Impervious to moisture;
4. Sufficient strength to prevent tearing and breaking; and
5. Sealed to prevent leakage.

Packages of RMW which contain sharps require containers of sufficient integrity to prevent the waste from puncturing the container package. In addition to the requirements found under Section 259.41(a), sharps must be packaged in puncture-resistant containers as noted in Section 259.41(b)(1). This requirement was included not only to protect the integrity of the package during transport, but to protect the waste handler from injury during waste handling.

As the regulation implies, one or more types of containers can be used to meet the above requirements.

If the RMW items contained greater than 20 cc of fluid, the generator would also need to comply with Section 259.41 (b) (2), and package this waste in break resistant and tightly lidded or stoppered containers to prevent leakage of the fluids.

Your letter asks if items included in the description of Class 4 RMW (i.e., unbroken culture dishes, blood vials, etc.) which may not present a substantial physical hazard when unbroken could be packaged in containers which are puncture-resistant but less expensive than the commonly used rigid plastic needle disposal units. The example which you indicated in your letter was break-resistant corrugated box that is also "puncture resistant."

While a corrugated box could be used by the generator to meet part of the packaging requirements (i.e., rigidity) this type of container alone generally would not meet all the Section 259.41(a) packaging requirements (i.e., leak-resistant, impervious to moisture, and ability to be sealed during transport). The Agency recognizes, however, that items such as unbroken culture dishes and blood vials may not require the same type of container as items such as needles or scalpel blades in order to prevent the waste items from puncturing the container/package. The basic objectives in establishing these packaging requirements are: to ensure the all wastes are properly contained without leakage or release into the environment and to provide flexibility in how parties may meet the standards.

If you have further questions or need additional information please contact Mary Greene at 202-475-7736.

Sincerely,

Matthew Strauss, Acting Director
Characterization and Assessment Division

cc: Austine Frawley, Reg. I
William Howard, Connecticut Health Department
George Meyers, Reg. II

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