

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

SEPTEMBER 5, 1989

MEMORANDUM

SUBJECT: Interpretations of the EPA Medical Waste
Regulations (Numbers 8-14)

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TO: Regional, State and Territorial Medical Waste Contacts

Attached is the second set of interpretations for the 40 CFR Part 259 regulations for medical waste tracking and management. These answers are EPA's interpretation of some of the issues that were raised in the June seminars with generators and transporters, and other issues that have been raised. If you need clarifications, or if you have other questions you would like to see addressed in future documents, please call Becky Cuthbertson on (202)475-8551, or Mary Jean Osborne on (202)382-7948.

Attachment

40 CFR Part 259 - Questions and Answers

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This document reflects the Environmental Protection Agency's interpretations of the Federal regulations at 40 CFR Part 259 - Standards for the Tracking and Management of Medical Waste. States or localities may have requirements that are more inclusive, or that pose additional restrictions on the management of medical wastes.

8. Two generators share a medical waste incinerator. One generator owns the building in which the incinerator is housed, and the land underneath. The second generator owns an adjoining piece of property, with a building that is physically attached to the first generator's building; the second generator also owns the incinerator (located in the basement of the first generator's building). Medical waste from both generators is burned in the unit. Which generator has responsibility for maintaining the incineration log, and submitting the reports required under 40 CFR 259.62?

Both generators are responsible for maintaining an incineration log as required under 40 CFR 259.61, because the incinerator is "on-site" (as the term is defined in 40 CFR 260.10, incorporated by reference at Section 259.10(a)) for both facilities. The generators may keep separate logs or a combined log for the incinerator. The requirement to report under Section 259.62 is placed on the owner or operator of the incinerator; if the second generator owns it while the first generator operates it, or if both operate it, then the two generators must decide which of them will assume the responsibility for submitting the report. If the same generator both owns and operates the unit, then that generator must submit the report under Section 259.62.

9. A medical waste transporter picks up regulated medical waste from generators in covered states and places the waste in a trailer and seals it. The transporter delivers the sealed trailer to an incineration facility, and then drops it off without being present at the unloading of the trailer. When the facility unloads the trailer, the facility operator signs the tracking form and sends a copy to the transporter who delivered the sealed trailer. Is the transporter in violation of Section 259.74(d)?

Yes. In order to be in compliance with the regulations, a transporter who transports regulated medical waste that was generated in a covered state must obtain the date of delivery and handwritten signature of the facility owner or operator on the tracking form, retain one copy, and give the remaining copies to the accepting facility (see 40 CFR 259.74(d)). A representative of the transporter's company could be present at the facility, to obtain the signature and date of delivery, retain the copy, and give the remaining copies to the accepting facility. This representative need not be the driver of the trailer.

10a. A hospital uses glass containers to hold fluids that are administered to patients intravenously. The fluids are dextrose water, glucose solution, and saline solution. Are the glass intravenous (i.v.) bottles a regulated medical waste when they are discarded?

Generally, if they are used to hold a sugar or saline solution, the glass i.v. bottles are not regulated medical waste because none of the listings in 40 CFR 259.30(a) would describe the i.v. bottle. The listing for sharps, that says "...broken or unbroken glassware that [was] in contact with infectious agents..." would generally not apply because these containers were holding sterile fluids. An exception is if an i.v. bottle became contaminated with excretions or secretions from a patient isolated with a highly communicable disease; in that case, the glass i.v. bottle would meet the listing for waste class 6 (in Section 259.30(a)(6)).

10b. The same hospital also uses glass containers to hold sterile human blood products that are intravenously administered to patients. When the facility discards these containers, they contain residues of human blood. Are the discarded glass i.v. containers regulated medical waste in this situation?

Yes; in this situation the containers meet the listing description for human blood and blood products in 40 CFR 259.30(a)(3); the language that applies is "...products of blood...and their containers, which were used...in patient care..." The blood's sterility is not relevant to whether the bottle meets the Class 3 listing, because the regulation specifically identifies blood containers as regulated medical waste.

10c. A hospital uses plastic i.v. bags to hold sterile sugar or saline solutions that are administered to patients. Are the intravenous bags regulated medical waste when discarded?

Yes. The i.v. bags meet the listing description in 40 CFR 259.30(a)(3) ("...Intravenous bags are also included in this category"). Thus, the intravenous bags are Class 3 regulated medical waste.

11a. In a hospital, a patient is fitted with a catheter and suction container to remove pleural fluid from his chest cavity. The catheter drains the pleural fluid into a glass container. When necessary, a nurse replaces it by removing the glass container and pouring out the pleural fluid into another receptacle. Is the glass container a regulated medical waste? What if it has been emptied by rinsing so that it no longer contains pleural fluid?

The glass container is regulated medical waste if it is dripping with pleural fluid, or caked with dried pleural fluid that was dripping (40 CFR 259.30(a)(2)). A container that has been rinsed so that it no longer contains pleural fluid does not meet the listing for Class 2 regulated medical waste (Section 259.30(a)(2)). However, in some situations this glass container could meet the description for Class 4 regulated medical waste ("...broken or unbroken glassware that [was] in contact with infectious agents..." (Section 259.30(a)(4)) if the patient's pleural fluid contained infectious agents.

11b. In the same hospital, a patient is fitted with a catheter to remove pleural fluid from his chest cavity; in this case, the catheter is attached to a plastic suction container. The other circumstances are as described above, in 11a. Is the plastic pleural fluid container a regulated medical waste?

As in Question 11a, if the plastic container is saturated or dripping with pleural fluid, or caked with dried pleural fluid that was dripping, it is Class 2 regulated medical waste (40 CFR 259.30(a)(2)). However, if it has been rinsed so that it no longer contains pleural fluid, it is not a Class 2 regulated medical waste. It is unlikely to meet the listing for sharps (Class 4 - Section 259.30(a)(4)).

11c. A physician removes a cerebrospinal fluid specimen from a patient and submits the specimen, in its container, to a laboratory to determine whether bacterial pathogens are present. At the laboratory, the technician places the fluid on a culture plate and discards the specimen container. Is the discarded specimen container a regulated medical waste?

Yes. The discarded specimen container meets the listing for Class 2 waste, found at 40 CFR 259.30(a)(2) (“...specimens of body fluids and their containers”).

12. A male patient uses a disposable razor to shave while he is hospitalized; the patient is not isolated to protect others from highly communicable diseases. When he discards the razor, is it regulated medical waste under 40 CFR 259.30(a) (4)?

The razor is not a regulated medical waste, because it is not a “solid waste which is generated in the diagnosis, treatment, or immunization of human beings...” and thus is not medical waste (as defined in Section 259.10(b)). The discarded razor is a personal care item that was generated in the hospital rather than the patient's home only because the patient needed medical attention unrelated to the waste's generation.

13. A female patient is hospitalized for surgery, and begins menstruating while she is residing at the hospital. She is not isolated to protect others from highly communicable diseases. Are the sanitary napkins which she uses regulated medical waste when discarded?

No. In this situation, as in Question 12, the waste sanitary napkin is not a ‘solid waste which is generated in the diagnosis, treatment, or immunization of human beings...” and thus is not a medical waste (as defined in 40 CFR 259.10(b)). The discarded sanitary napkin is a personal hygiene item that became a waste while the patient was in the hospital, rather than at home, merely because the patient was hospitalized for a reason unrelated to the patient's menstruation.

14a. A funeral home has a pathological waste incinerator and a crematory on-site, and accepts waste from local hospitals to burn in its pathological waste incinerator. One of the hospitals claims that body parts that were removed during surgery are excluded from the definition of regulated medical waste, by 40 CFR 259.30(b)(1)(v), and thus that hospital does not fill out a tracking form or keep any logs when shipping the body parts to the funeral home. Are the body parts excluded under Section 259.30(b)(1)(v)?

Whether anatomical parts that are removed during surgery or autopsy are excluded depends on whether the parts are treated as waste, to be incinerated or disposed of in a landfill with other

wastes, or whether the parts are treated as human remains, to be cremated or interred in a cemetery. If the ashes are treated as waste and discarded in a landfill, the anatomical parts were not “intended for interment or cremation,” and thus they are not excluded under Section 259.30(b)(1)(v). However, if the ashes are treated as human remains, and, for example, are given to a relative, the anatomical parts were “intended for...cremation” and thus are excluded from the Part 259 requirements. The terms "cremate" and "incinerate" are sometimes used interchangeably, and although crematories are generally designed somewhat differently than pathological waste incinerators, crematories are sometimes used to incinerate waste. Thus the exclusion does not depend on the type of unit in which the anatomical parts are burned.

14b. A hospital arranges for human remains to be removed to a funeral home for burial preparation. Are the remains regulated medical waste?

Human remains that are intended to be interred in a cemetery are excluded from the regulation by Section 259.30(b) (1) (v).

14c. A hospital arranges for body parts removed during surgery to be transported to a landfill for disposal. Are the body parts regulated medical waste?

In this case, the body parts are not “intended for interment...” and are not excluded by Section 259.30(b)(v).. They meet the listing description for Class 2 regulated medical waste (found at Section 259.30(a) (2)).