

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

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MEMORANDUM

SUBJECT: Interpretations of the EPA Medical Waste Regulations (Numbers 15-23)

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TO: Regional, State and Territorial Medical Waste Contacts

Attached is the third set of interpretations for the 40 CFR Part 259 regulations for medical waste tracking and management. These questions and answers are EPA's interpretation of 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 Mary Greene on (202)475-7736, or Mary Jean Osborne on (202)382-7948.

Attachment

40 CFR - Questions and Answers

September 1989

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.

15a. Waste Class 6 in the Table at 40 CFR 259.30(a) specifies that certain wastes from patients isolated with "highly communicable diseases" are regulated medical wastes. In the preamble to the interim final rule, EPA stated that only certain highly communicable diseases are included in the demonstration program (54 FR 12341, March 24, 1989) and specified as an example, those diseases caused by agents listed in Classification 4 of the Centers for Disease Control's (CDC's) document "Classification of Etiologic Agents on the Basis of Hazard". What are the clinical names for the diseases caused by the infectious agents classified as Class 4 in CDC's 1974 document, "Classification of Etiologic Agents on the Basis of Hazard"?

Listed below are the viruses found in Class 4 and the associated clinical disease, if one has been named.

INFECTIOUS AGENT

- * Variola minor
- * Variola major
- * Monkey pox
- * White pox

- ** Crimean hemorrhagic fever virus
- ** Junin virus
- ** Machupo virus

Herpesvirus simiae (Monkey B)

Lassa virus

Marburg virus

Russian spring-summer

encephalitis virus
Kyasanur forest disease virus
Omsk hemorrhagic fever virus
Central European encephalitis
virus

*Venezuelan equine encephalitis
virus

*Yellow fever virus

DISEASE

Alastrim
Smallpox
Human monkeypox

Crimean hemorrhagic fever
Argentine hemorrhagic fever
Bolivian hemorrhagic fever

Oncogenic in primates

Lassa fever

Marburg virus disease

Russian spring-summer
encephalitis
Kyasanur forest disease
Omsk hemorrhagic disease
Central European encephalitis

Venezuelan equine
encephalitis

Yellow fever

*When used for transmission or animal inoculation experiments.

**CDC has noted that the above listed viruses in the hemorrhagic fever group and other viruses in this group, that are not yet identified, are also classified as Class 4.

15a. continued

The CDC, in cooperation with the National Institutes of Health, has recently developed an updated list of Biosafety Level 4 etiologic agents (comparable to the 1974 CDC classification 4) in its CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" (1988). Diseases caused by agents listed under Biosafety Level 4, that were not listed in the 1974 CDC Class 4 list, include:

INFECTIOUS AGENT

Ebola Virus

Absettarov Virus

Hanzalova Virus

Hypr Virus

Kumlinge Virus

DISEASE

Ebola Virus Disease

Tick-borne Encephalitis

Tick-borne Encephalitis

Tick-borne Encephalitis

Tick-borne Encephalitis

15b. A physician suspects that a patient is infected with the smallpox virus. The patient is isolated until a conclusive diagnosis can be made. Would the wastes generated in the care and treatment of this patient, prior to the confirmation of the diagnosis, be regulated under 40 CFR Part 259?

Yes, if the waste is in Classes 1-4 or 6 in the Table at 40 CFR Part 259.30(a). Wastes which are included in Classes 1-4 are always regulated medical waste regardless of the patient from whom the waste is generated. Additionally Class 6 wastes include "biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans that are isolated to protect others from certain highly communicable diseases". Since the patient was isolated, prior to the completion of the diagnosis, wastes contaminated with blood, excretion, exudates or secretions from that patient are regulated as Class 6 waste.

Note: Smallpox virus is listed in Class 3 and 4, of the CDC document "Classification of Etiologic Agents on the Basis of Hazard". However, smallpox is only categorized as Class 3 when in vitro (in a test tube rather than in a living organism).

- 15c. A hospitalized patient is diagnosed with Lassa Fever, a highly communicable disease. The patient is moved into isolation in a hospital to prevent the transmission of Lassa Fever to others. The nursing staff plans to ensure that all wastes generated in this patient's room are managed as regulated medical waste. Are all wastes generated in the patient's room regulated under 40 CFR 259.30?

Wastes generated from the treatment and care of this patient which fall into Class 1-4 in 40 CFR Part 259.30(a) are regulated medical waste. In addition, 40 CFR 259.30(a) specifies that all biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans isolated to protect others from certain "highly" communicable diseases must be managed as regulated medical waste (Isolation Waste). These are Class 6 wastes. The causative agents of "highly communicable diseases" are listed under Classification 4 in the Centers for Disease Control's 1974 document "Classification of Etiologic Agents on the Basis of Hazard".

However, nothing in the rules prohibits the health care facility from managing additional wastes in the same manner as regulated medical wastes. Since the waste classes specified in 259.30(a) would not include all waste from an isolation patient, if all wastes from the patient's room were managed as regulated medical waste, the staff would be managing more material as regulated medical waste than 40 CFR 259.30(a) requires.

16. An independent physician, located in one of the covered states, generates only small volumes of regulated medical wastes each month. To minimize disposal costs he plans on accumulating these wastes until it is more cost effective to hire a special hauler to remove the waste from his premises. In the 40 CFR Part 259 regulations, are there any limits to the time the regulated medical waste may be stored and accumulated prior to transport off-site?

No, the 40 CFR Part 259 regulations do not provide specific time limits for the on-site storage of regulated medical waste at a generator's facility. However, generators must comply with Section 259.42 storage requirements prior to transport, treatment, destruction, or disposal of regulated medical wastes. Section 259.42(b) requires the generator to maintain the waste in a nonputrescent state, using refrigeration when necessary. This requirement may affect storage time if wastes with a high organic content become putrescent over time. The storage time may also impact other regulatory requirements. For instance, if, by the time the generator is ready to have the waste shipped off-site, the shipment weighs 50 pounds or more, a medical waste tracking form must be initiated to accompany the waste. Finally, we should note that state or local regulations may be in place which limit the time that a regulated medical waste may be stored on-site.

- 17a. In a college Comparative Anatomy class, students are provided with preserved animal specimens which are purchased from a biological supply company. The students study anatomy by dissecting the specimens. Following completion of the course, the animal remains are

collected for disposal. Would these wastes be regulated under 40 CFR Part 259 if the activities took place within one of the covered states?

No, the purpose of the class is to study the anatomical structure of various animal specimens. These wastes would not be regulated under 40 CFR Part 259 because they would not fall within the definition of medical waste (40 CFR 259.10). The wastes were not “generated in the diagnosis, treatment or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.” Therefore, the wastes could be managed as general refuse.

- 17b. A university research facility conducts studies during which the researchers expose animals to a zoonotic agent (an infectious agent transmissible to humans from animals under natural conditions). As part of the study the animals are sacrificed, dissected and studied for pathological changes caused by the infectious agent. After completion of the study the animal remains are collected for disposal. Are the animal carcasses and associated tissues regulated under 40 CFR Part 259?

Yes; the animal carcasses and associated tissues are considered a regulated medical waste. They are a medical waste because they are “solid waste which is generated in the diagnosis...[of] animals, [or] in research pertaining thereto”, and they are a regulated medical waste because they meet the listing description for Class 5 waste in Section 259.30(a), i.e. “contaminated animal carcasses, body parts and bedding of animals that were known to have been exposed to infectious agents during research”. The term “infectious agent” is defined in section 259.10(b) as any organism that is “capable of causing disease or adverse health impact in humans”.

- 18a. A hospital patient is outfitted with a urinary collection system consisting of an in-dwelling catheter connected to a plastic collection bag. A nurse removes the catheter and bag when necessary. Are these items, and the fluid they contain, regulated under 40 CFR Part 259?

No; provided that the patient is not isolated to protect others from highly communicable diseases. Although specific body fluids fall within the Class 2 -Pathological wastes category, urine is not covered by the regulatory definition of “body fluids” (40 CFR 259.10); in this situation the collection bag, catheter and collected urine would not be regulated medical waste.

- 18b. A nurse delivers a urine specimen from the patient described in Question 18a to the pathology lab for testing. Following the tests there is still residual urine in the specimen container. When discarded, is the residual urine and the container a regulated medical waste under 4.0 CFR Part 259?

No; provided that the patient is not in isolation for a highly communicable disease. Urine is not defined as a body fluid in Section 259.10(b), and thus does not fall under

Class 2-Pathological Wastes in 40 CFR 259.30(a). Therefore, the residual urine and its container would not be regulated under 40 CFR Part 259.

- 18c. The patient described in Question 18a goes into surgery, and postoperatively is outfitted with a urinary catheter. During recovery the patient experiences hematuria, or blood in the urine. The nurse removes the catheter and bag as necessary. Are these items, and the fluid they contain, regulated under 40 CFR Part 259 when discarded?

If the urine and/or catheter bag contains blood, these items would be regulated as a Class 3 - Human blood and blood products waste since they are or contain waste human blood (40 CFR 259.30(a)). The catheter tubing is covered by the regulations, if it is saturated and/or dripping with blood, or otherwise meets the listing for Class 3 waste in Section 259.30(a)(3). The collected urine is regulated as Class 3 if it contains blood. If no blood were present in the urine or catheter bag, the urine and bag would not be regulated as discussed in 18a, above.

19. While at an accident scene, the members of an ambulance crew administer emergency health care to the victims. In doing so, they generate gauze pads that are saturated with blood and are subsequently regulated medical waste under Section 259.30(a)(Class 3). If the crew members package the gauze pads in packaging that meets the requirements of 40 CFR 259.41, can they transport the waste to a hospital, under Section 259.51(a)? Would the ambulance crew have to fill out a log to document the shipment?

Any medical materials used during emergency health care procedures outside a medical facility, do not become medical waste, and thus subject to Part 259 regulation, until they are removed from the emergency vehicles and discarded. In this scenario the gauze pads do not require packaging that meets Section 259.41 requirements before they are removed from the emergency vehicle. Ambulances and emergency rescue services are not subject to the 40 CFR Part 259 regulations with respect to materials used during the course of providing emergency medical care. The crew also would not be required to complete a log for transporting the gauze pads to the hospital. The blood-soaked material becomes "regulated medical waste", and thus becomes subject to the Part 259 requirements, when it is removed from the emergency vehicle and is discarded at the medical facility or at the emergency service's place of business.

20. An independent, private physician transports his regulated medical waste to a hospital under the 40 CFR 259.51(a) exemption. In order to transport his regulated medical waste off-site, the physician has properly packaged, labeled, and marked his boxes of regulated medical waste, in compliance with 40 CFR Part 259, Subpart E; he also meets the other conditions of Section 259.51(a) and 259.54(b)(2). For example, he has a written agreement with the hospital accepting his waste and has maintained appropriate shipment logs. When the hospital prepares to ship the physician's regulated medical waste from the hospital, the hospital must fill out a tracking form because the hospital is itself a generator of more than 50 pounds of regulated

medical waste per month (Section 259.52(a)). What party is responsible for signing the tracking form in Box 15 - the hospital or the physician?

In this scenario the physician is exempt from the use of the tracking form under 259.51(a). However, because the hospital is the generator offering the physician's waste for transport, the hospital is required to comply with the tracking form requirements of Section 259.52 for this waste. See Section 259.52(a) It is therefore the responsibility of the hospital to sign the tracking form in Box 15. If the hospital is concerned about its liability in the event the physician has not properly packaged the waste, the hospital could make its own contractual arrangements with the physician (e.g. as part of the "written agreement" required by Section 259. 51(a)(1)(i)) or it could choose to overpack the physician's waste in packaging that meets the Section 259.41 requirements.

21. A clinical diagnostic laboratory provides laboratory technicians who travel to an off-site hospital, remove blood specimens from patients for diagnostic purposes and take the specimens off-site to the laboratory for analysis. In the process of taking the blood specimens, the technicians utilize blood-drawing devices that become regulated medical waste. Can the laboratory's technicians (who collectively generate less than 50 pounds of regulated medical waste per month at the hospital) transport the waste from the hospital under the Section 259.51(a) exemption?

Yes, the 40 CFR 259.51 (a) exemption could be used by the diagnostic laboratory provided that all conditions in 259.51(a) are satisfied including: the generation of less than 50 pounds of regulated medical waste per month; the regulated medical waste is transported to a health care facility, an intermediate handler, a destination facility, or the generator's place of business; the regulated waste is transported in a vehicle owned by the generator or an authorized employee; and the appropriate shipment logs are maintained as required by 259.54(b)(2).

In this scenario the diagnostic laboratory operates as a separate entity from the hospital and thus they are two different generators operating at the same site. If the laboratory generates less than 50 pounds of regulated medical waste per month at the hospital site, it may use the Section 259.51(a)(1) exemption for transporting the waste to the generator's place of business.

22. A generator packages his regulated medical waste and marks the boxes with an intended date of shipment for the following day. However, the transporter is delayed and does not actually remove the waste from the facility for three days. Is the generator required to re-mark each package with the date the transporter picks up the waste?

No, Section 259.45(a)(5) requires the generator to mark the date of shipment on regulated medical waste packages to provide a link between each package and its

associated tracking form. In some cases, the intended date of shipment marked on the packages may differ from the actual date of shipment due to delays in pickup by the transporter, loading of a truck over a period of several days, etc. In this instance, if the actual date of shipment is different than the intended date marked on the packages, the generator should indicate in Box 14 of the tracking form, that the packages were actually shipped on a subsequent day. The intent of 259.45(a)(5) was that there be a unique number (shipping date) which ties that or those packages to a specific tracking form.

- 23a. A farmer treats her diseased livestock with injections of medication. She does this in a barn or in fields next to her residence. Are the used syringes and needles which she generates excluded from the definition of regulated medical waste under the household waste exclusion at 40 CFR 259.30(b) (1) (ii)?

No; the used syringes have not been generated on the premises of a residence and are more akin to veterinary wastes than materials found in waste generated by consumers in their homes, see 54 FR 12339 (March 24, 1989). Thus, the syringes are not excluded under the household waste exclusion. They meet the listing description for sharps (Section 259.30(a)(4)), and are regulated medical waste.

- 23b. A pet owner treats his pet with injections of medication in his home. Are the used syringes and needles regulated medical waste?

In this situation, the used syringes and needles are excluded from the definition of regulated medical waste under Section 259.30(b)(1)(ii). They are domestic waste generated by an individual on the premises of a residence, and thus are "household waste."