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U.S. Department of Transportation

Research and Special Programs Administration

DEPT. OF TRANSPORTATION

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

JAN 11 2001

Dr. J.W. Corso
Corso Biomedical Consulting
8200 NW 69th Street
Oklahoma City, Oklahoma 73132

Ref. No. 00-0289

Dear Dr. Corso:

This responds to your October 10, 2000 letter concerning the transportation of infectious substances under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Your questions are paraphrased and answered below.

- Q1. Is a blood sample being shipped for the purpose of determining a blood cell count considered a diagnostic specimen, even when it is known that the blood contains an infectious substance?
- A1. Yes. For purposes of the HMR, "diagnostic specimen" means any human or animal material, including excreta, secreta, blood, blood components, tissue and tissue fluids, being shipped for purposes of diagnosis (§ 173.134(a)(2)). A diagnostic specimen, even one known to contain an infectious substance, is excepted from the requirements of the HMR unless the material meets the definition of another hazard class (§ 173.134(b)(1)(ii)).
- Q2. Workers at a doctor's office deposit medical waste into waste containers. These same waste containers are used for transporting the medical waste. Are these worker subject to HMR training requirements? If a waste hauler takes possession of the medical waste and agrees to assume shipper responsibilities, must the workers in the doctor's office who fill and close the transport containers be trained?
- A2. Generally, the HMR require hazmat employees to be trained. For purposes of the HMR, "hazmat employee" means a person who is employed by a hazmat employer and who, in the course of employment, directly affects hazardous materials transportation safety. "Hazmat employer" means a person who uses one or more of its employees in connection with, among other things, causing a hazardous material to be transported or shipped in commerce. (For definitions of "hazmat employee" and "hazmat employer," see § 171.8.) In the scenario you describe, workers in a doctor's office who perform offeror functions, such as preparing a package for shipment or generating shipping



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papers, are subject to the training requirements in Subpart H of Part 172 of the HMR. However, it is the opinion of this office that workers in a doctor's office who merely deposit medical waste into waste containers are not performing a function that directly affects hazardous materials transportation safety and thus are not subject to the HMR training requirements.

Under the HMR, there can be more than one offeror for a given shipment. If a doctor's office and a waste hauler split the performance of offeror functions, both the doctor's office and the waste management company are subject to the regulations as offerors. In the scenario you describe, the workers in the doctor's office who prepare a package of regulated medical waste for transportation – such as by selecting a packaging, assuring that the packaging is not overfilled, and securing the closures on the package – are performing offeror functions that directly affect hazardous materials transportation safety and must be trained, even if the waste hauler assumes responsibility for generating a shipping paper and certifying that the shipment conforms to HMR requirements. In this case, both the doctor's office and the waste hauler are performing offeror functions.

The doctor's office would not be an offeror if it contracted with a waste hauler to perform all offeror functions associated with the transportation of its regulated medical waste. The waste hauler would become the offeror of the regulated medical waste and would be responsible for classifying the medical waste, selecting appropriate packagings, assuring that packagings are not overfilled, securing the closures on the packagings, marking and labeling the packages as appropriate, and generating shipping papers in accordance with the HMR. Workers in the doctor's office who perform no offeror functions that affect the transportation safety of the shipment, but merely deposit medical waste in the containers provided by the waste hauler would not be subject to the HMR training requirements.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,



Edward T. Mazzullo, Director
Office of Hazardous Materials Standards



Dr. J.W. Corso, Biomedical Consulting

BAAH

EDWARD MAZULLO

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~~Hazardous Waste~~

Regulated Medical Waste

00-0289
October 10, 2000

Edward Mazullo
U.S. Department of Transportation
Research and Special Programs Administration
Office of Hazardous Materials Safety
400 7th St., S.W.
Washington, DC 20590

Dear Mr Mazullo,

I have some questions regarding the applicability to the US DOT hazardous materials regulations to workers in the healthcare and biomedical research industries.

Question #1: Can a blood sample being sent for a blood cell count still be regarded as a "diagnostic specimen" (as defined by DOT) when it's known the blood is HIV positive?

Question #2: All levels of workers at a doctor's office deposit medical waste (bloody bandages and gauze pads, used syringes, etc.) into waste containers. These same containers are used for transporting the medical waste. Are all these workers subject to US DOT hazmat training requirements?

Question #3: If workers in a doctor's office fill and close transport containers with *regulated medical waste*, but the waste hauler takes possession of the waste at the time of pick-up and agrees to become the shipper (the hauler completes and signs the manifest), does that absolve the doctor's office of all hazmat "shipper" responsibilities including training?

Thank you for your assistance,

Dr. J.W. Corso