



Pipeline and Hazardous Materials Safety Administration

SEP 1 3 2018

Mr. Thomas Brennan Vice President Strategic Accounts & Life Sciences Global First 10337 Allen Road Pickerington, OH 43147

Reference No. 18-0059

Dear Mr. Brennan:

This letter is in response to your April 16, 2018, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to transporting cadaveric specimens. You ask for written confirmation of answers you received during an April 13, 2018, telephone conversation with a member of my staff.

You state the specimens are tested and determined to not contain bloodborne pathogens; therefore, they are considered non-infectious. In an April 13, 2018, telephone conversation with a member of my staff you also state the specimens do not meet any other hazard class, but when transported in formalin, they are described as "UN3373, Biological substance, Category B, 6.2 (infectious substance)."

We have paraphrased your questions and answered them as follows:

- Q1. You seek confirmation of your understanding that cadaveric tissues, corpses, human remains, and anatomical parts used in research and education to and/or from biomedical skills laboratories are excepted from § 173.134(b)(1), (b)(5), and (b)(14) of the HMR applicable to Division 6.2 (infectious substance).
- A1. You are correct that § 173.134(b)(14) provides that corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory are not subject to the requirements of the HMR as Division 6.2 materials. Further, a material that is not known or suspected to contain an infectious substance and does not meet the definition of another hazardous material is not regulated under the HMR (see §§ 171.2(k) and 173.134(b)(1)–(5)). Provided the described materials do not meet the definition of any other hazard class or division, the transportation of the remains is not regulated under the HMR.

- Q2. You note that the cause of death is sometimes determined after transportation has ended. You ask if a material may be considered non-infectious and not further regulated as a Division 6.2 material in transportation in commerce if the cause of death is found to not require the material to be transported as a Division 6.2, Category A or B material, e.g., from pneumonia or sepsis.
- A2. Section 172.101(c)(11) permits a material for which the hazard class is uncertain and which must be determined by testing to be assigned a tentative proper shipping name, hazard class, identification number and packing group, if applicable, based on the shipper's tentative determination (see § 173.22). If a shipper determines, based on their knowledge of the material, that it is non-hazardous, the provisions of the HMR do not apply to that material.
- Q3. You seek confirmation of your understanding that it is a violation of the HMR to designate non-infectious cadaveric specimens as "UN3373, Biological substances, Category B, 6.2."
- A3. Section 171.2(k) states that no person may, by marking or otherwise, represent that a hazardous material is present in a package, container, motor vehicle, rail car, aircraft, or vessel if the hazardous material is not present.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

T. Glenn Foster

Chief, Regulatory Review and Reinvention Branch

Standards and Rulemaking Division

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Edmonson 173.134 Exceptions 18-0059

January, Ikeya CTR (PHMSA)

From:

Edmonson, Eileen (PHMSA)

Sent:

Monday, April 16, 2018 3:51 PM

To:

January, Ikeya CTR (PHMSA)

Subject:

FW: 49 CFR 173.134 Interpretation

Importance:

High

Hi Ikeya,

Can you please log the letter below in and assign it to me?

Many thanks,

Eileen Edmonson USDOT/PHMSA (202) 366-4481 (work) (202) 366-8553 (main) (202) 366-7041 (fax) 1-800-467-4922 (HazMat Info Center) eileen.edmonson@dot.gov (e-mail) infocntr@dot.gov (HMIC e-mail)

From: Tom Brennan [mailto:tbrennan@globalfirst.biz]

Sent: Monday, April 16, 2018 2:31 PM

To: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>

Subject: 49 CFR 173.134 Interpretation

Importance: High

Eileen.

Thank you again for the phone call on Friday to discuss 49 CFR 173.134 and in particular the transport of Cadaveric Specimens and thank you for your support in helping me clearly understand the DOT's regulations governing the transportation of Exempt Human Specimens.

We are sometimes asked by customers about the DOT's regulations surrounding the transport of Cadaveric tissues, Corpses, Human remains and anatomical parts used in research and education to/from Bio Skills labs. These specimens have been serologically tested for infectious diseases such as HIV, Hepatitis B and Hepatitis C and are found to be negative.

It is my understanding that these specimens would be exempt from these 6.2 regulations based on 49 CFR 173.134 (b), (1), (5), or (14)

173.134 Class 6, Division 6.2—Definitions and exceptions.

- (b) Exceptions. The following are not subject to the requirements of this subchapter as Division 6.2 materials:
- (1) A material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.
- (5) A material with a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include: Foodstuffs; environmental samples, such as water or a sample of dust or mold; and substances that have been treated so that the pathogens have been neutralized or deactivated, such as a material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(14) Corpses, remains, and anatomical parts intended for interment, cremation, or medical research at a college, hospital, or laboratory.

Additionally, the cause of death can, at times, be determined after transport to be from Pneumonia or Sepsis but this still does not constitute a requirement to transport as a 6.2 Category A or B as these are not part of the group defined as infectious substances.

Lastly, it is my understanding that to classify and ship specimens that fit under the 49 CFR 173.134 (b), (1), (5), or (14) exception as UN 3373 shipments within and of itself would be a violation of these rules and in times of emergencies take focus away from what is really a UN3373 or other hazards.

I thank you again Eileen for your time and education.

Regards,

Thomas Brennan

Vice President Strategic Accounts & Life Sciences



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