



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

1200 New Jersey Avenue, SE  
Washington, DC 20590

December 5, 2023

Justin Roth  
Senior Biosafety Officer  
The University of Alabama at Birmingham  
933 19th St. S. CH19 412P  
Birmingham, AL 35294

Reference No. 23-0082

Dear Mr. Roth:

This letter is in response to your August 22, 2023, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the disposal of an animal carcass (i.e., a mouse carcass) engrafted with human tissues and then infected with the human immunodeficiency virus (HIV) for therapy research. Specifically, you ask whether a mouse carcass used as a model to study HIV infection/viremia would be considered “a culture” and whether such animal carcasses must be classified as Category A waste.

The answer is no. “Culture” is defined in § 173.134(a)(3) to mean an infectious substance containing a pathogen that is intentionally propagated. This typically refers to pathogens cultivated in a growth medium. It is the opinion of this office that “culture” does not include animals infected with a pathogen.

A material is not a Category A infectious substance if it is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs and may appropriately be classified as a Category B infectious substance under § 173.134(a)(1)(i). Category B wastes derived from biomedical research, which includes the production and testing of biological products and, in this instance, these animal carcasses, would be considered “Regulated medical waste or clinical waste or (bio) medical waste” and must be transported in accordance with § 173.197.

Note that ultimately it would be the offeror's responsibility to evaluate and properly classify a hazardous material using the criteria specified for Category A or Category B infectious substances (waste) found in § 173.134.

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

Sincerely,

A handwritten signature in blue ink, appearing to read "Dirk Der Kinderen". The signature is fluid and cursive, with a prominent initial "D".

Dirk Der Kinderen  
Chief, Standards Development Branch  
Standards and Rulemaking Division

Casey

23-0082

**From:** [INFOCNTR \(PHMSA\)](#)  
**To:** [Dodd, Alice \(PHMSA\)](#)  
**Cc:** [Hazmat Interps](#)  
**Subject:** FW: Request for interpretation  
**Date:** Monday, August 28, 2023 11:24:31 AM

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Hi Alice,

Please see the below interpretation request.

Let us know if you need anything.

Regards,

-Breanna

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**From:** Roth, Justin <jcroth@uab.edu>  
**Sent:** Tuesday, August 22, 2023 11:16 AM  
**To:** INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>  
**Subject:** Request for interpretation

**CAUTION:** This email originated from outside of the Department of Transportation (DOT). Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Hello,

We would like guidance on how to classify the following research waste stream:

We have a new investigator starting who will be using humanized mice (i.e., mice engrafted with human thymus, liver, lung, and blood stem cells) to study HIV therapies. Engrafting these human tissues results in mice that are reconstituted with human blood cells. This allows the mice to be infected with HIV. The HIV-infected mice are used to study HIV replication, and various treatment strategies for suppressing it.

Does the fact that the mice are used as a model to study HIV infection/viremia make the animal “a culture,” according to the regulations? We are trying to determine whether the carcass waste can be disposed of through our regulated medical waste vendor, or if it the carcasses/waste must be classified as Cat A waste, requiring the material to be autoclaved first. All other studies with RG3 materials occur in BSL-3 facilities, which require all waste to be autoclaved. HIV is one of the few RG3 pathogens that can be studied in a BSL2 facility, so the waste streams are not autoclaved by default.

I would really appreciate your guidance classifying this waste.

Kind regards,

Justin

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**Justin Roth, PhD, RBP | Senior Biosafety Officer**

Environmental Health & Safety, [Biosafety Program](#)

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*Safety is a part of research excellence—let's be excellent!*