



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

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

FEB 25 2003

Mr. Paul Brinton
Assistant Vice President
ARUP Laboratories
500 Chipeta Way
Salt Lake City, Utah 84108

Ref. No.: 03-0042

Dear Mr. Brinton:

This responds to your February 11, 2003 email concerning requirements for shipping infectious substances under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask about requirements applicable to the shipment of cultures and stocks and diagnostic specimens. Your questions are paraphrased and answered below.

- Q1. The regulations do not specifically address transportation requirements for cultures and stocks. Under what standards should cultures of unknown organisms be shipped? Known organisms not in Risk Group 4?
- A1. A culture or stock of an infectious substance must be transported in accordance with regulatory requirements applicable to Division 6.2 materials. A culture or stock known or suspected to contain an infectious substance in Risk Group 2, 3, or 4, therefore, must be classed as Division 6.2, described as an infectious substance, assigned to UN 2814 or UN 2900, as appropriate, and packaged in conformance with the requirements in § 173.196 of the HMR.
- Q2. Would medical specimens obtained from a patient previously diagnosed with an infectious disease not in Risk Group 4 (e.g., HIV, Hepatitis C) for the purpose of quantifying the infectious component, determining possible mutation, or determining treatment options specific to the infectious agent be considered an infectious substance?
- A2. A specimen that meets the definition for "diagnostic specimen" in § 173.134(a)(4) – that is, a human or animal sample being transported for diagnostic or investigational purposes – may be transported as a diagnostic specimen even if it is known to contain an infectious substance in



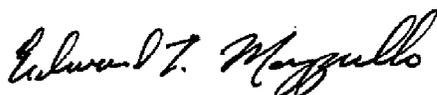
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Risk Group 2 or 3. Thus, medical specimens of the type you describe may be transported in accordance with requirements applicable to diagnostic specimens in § 173.199.

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

Gorsky, Susan

Gorsky
§ 173.134

From: Brinton, Paul [brintonph@aruplab.com]
Sent: Tuesday, February 11, 2003 4:56 PM
To: 'susan.gorsky@rspa.dot.gov'
Subject: FW: DOT Infectious Substance/Diagnostic Specimen Transport Regulations

Infectious Substance
03-0042

Susan, I am attaching the original email. I thought I was sending it to you. Please let me know that you received it. Thank you.

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-----Original Message-----

From: Brinton, Paul
Sent: Friday, January 24, 2003 16:35
To: 'infocntr@rspa.dot.gov'; Susan Gorsky (E-mail)
Cc: Shotorbani, Khosrow; Hannah, Dina; Ahlin, Peggy; Garr, Sue; Bale, Martha; Brown, Mike; Fisher, Michelle
Subject: DOT Infectious Substance/Diagnostic Specimen Transport Regulations

Susan, a few weeks ago we spoke and you told me you may be able to clarify some points in reference to the new DOT standards going into effect on February 14th, 2003. We at ARUP Laboratories have reviewed the document from the Federal Register dated Wednesday, August 14th, 2002, and have created these questions. If you could answer them in a letter on hard copy, we would be most appreciative.

1. The classifications for Diagnostic Specimens, Biological Product, and Regulated Medical Waste contain instructions on how they must be shipped. The definition for cultures and stocks does not include any shipping instructions. Under what standard should cultures of unknown organisms be shipped? Known organisms not in Risk Group 4?
2. Would medical specimens obtained from a patient previously diagnosed with an infectious disease not in Risk Group 4 (e.g. HIV, Hepatitis C) for the purpose of quantifying the infectious component, determining possible mutation or determining treatment options specific to the infectious agent, be considered as an infectious substance according to 49 CFR Part 171-180?

Thank you for your help.

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