



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

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

SEP 6 2001

Mr. Clint Giannetti  
Specialist I  
Case Western Reserve University  
2220 Circle Drive, First Floor  
Cleveland, OH 44106-7227

Reference No. 01-0030

Dear Mr. Giannetti:

This is in response to your letter requesting clarification on the definition and exceptions in § 173.134 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for a diagnostic specimen, biological product, and infectious substance. Your questions are paraphrased and answered as follows:

Question #1: A diagnostic specimen is defined in § 173.134(a)(2) as "any human or animal material including, but not limited to, excreta, secret, blood, blood components, tissue, and tissue fluids, being shipped for purposes of diagnosis." What types of analyses are covered under the term "diagnosis"?

Response #1: The term "diagnosis" as it is used in § 173.134(a)(2) includes any type of analysis used to study a diagnostic specimen to determine its type or condition.

Question #2: Does a diagnostic specimen that is known to be infectious qualify for the exception in § 173.134(b)(1)(ii)?

Response #2: Yes. 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. However, please be aware that shipment of a diagnostic specimen that is infectious may be subject to the regulations of other federal agencies with responsibilities for these materials, such as the U.S. Postal Service; the Department of Health and Human Services' Centers for Disease Control and Prevention, and Food and Drug Administration; the Department of Labor's Occupational Safety and Health Administration; or the U.S. Department of Agriculture's Animal Plant and Health Inspection Service. Also, under the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, if a diagnostic specimen is known or suspected of being infectious, it would be classed as a Division 6.2 material. Similarly, RSPA proposed to remove the current exceptions for diagnostic specimens and biological products in a notice of proposed rulemaking published earlier this year (Docket No. RSPA 98-3971 (HM-226), 66 FR 6942, 1/22/01).



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173.134(a)(2)

Question #3: It is my understanding that when there is no proper shipping name for a substance, when it is not possible to classify the hazard without testing or analysis, and it is not possible to tentatively classify according to § 172.101(c)(11), the material is not regulated under the hazardous materials regulations. Am I correct?

Answer #3: No. If the material is a diagnostic specimen, it is excepted from the HMR. The same is true if the material is a Division 6.2 biological product. See § 173.134(b)(1)(i) and (b)(1)(ii).

If the material is not being shipped for diagnosis, such as cultures and stocks shipped to laboratories for storage purposes, it is not a biological product and it is suspected of being a Division 6.2 material, the material is to be assigned the tentative proper shipping description of "Infectious substances, affecting humans, 6.2, UN 2814," or "Infectious substances, affecting animals, 6.2, UN 2900," as provided by § 172.101(c)(11) when shipped for testing. The intent of § 172.101(c)(11) is to permit a hazardous material sample to be shipped to a laboratory for testing to determine which hazard class, if any, it meets. Because the shipping names "Infectious substances, affecting humans or animals," are generic, as denoted by the letter "G" that appears before the entries in the § 172.101 Table, § 172.203(k) requires that each proper shipping description be accompanied by a technical name. A technical name, as defined in § 171.8, can be the name of the suspected microbiological agent or microbiological group. If the material is being shipped for disposal, it is to be assigned the proper shipping description "Regulated medical waste, 6.2, UN 3291, PG II."

I hope this information is helpful.

Sincerely,



Hattie L. Mitchell  
Chief, Regulatory Review and Reinvention  
Office of Hazardous Materials Standards



CASE WESTERN RESERVE UNIVERSITY

January 30, 2001

Edmonson  
§ 173.134(a)(2)  
Diagnostic  
Specimen

01-0030

Edward Mazzullo  
Director for the Office of Hazardous Materials Standards  
US DOT/RSPA (DHM10)  
400 7<sup>TH</sup> Street SW  
Washington D.C. 20590-0001

Dear Mr. Mazzullo:

On January 4<sup>th</sup>, 2001, I contacted the Hazardous Materials Information Center with questions pertaining to shipment of diagnostic specimens, biological products, and infectious substances. After speaking to the information specialist, I was told several things on which I would like clarification. These points as far I understand them are as follows:

1). The definition of diagnostic specimen in 173.134 (a)(2) mentions materials being shipped "for diagnosis." It is my understanding that diagnosis is not specifically defined, but can include almost any type of analysis that may be conducted on the material. Is this true, or if not, what types of analysis qualify under the aforementioned definition?

2). Shipments of materials for the purpose of diagnosis or analysis, which are known to be infectious, can also take advantage of the diagnostic specimen exemption. Is this a correct interpretation?

3). It is my understanding that when there is no proper shipping name for a substance, when it is not possible to classify the hazard without testing or analysis, and it is not possible to tentatively classify according to 171.101 (c)(11), the material is not regulated under the hazardous materials regulations. Is this a correct interpretation?

Sincerely,

Clint Giannetti  
Specialist I

Cc: Richard Dell  
David Sedwick  
Marc Rubin

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