U.S. Department
of Transportation

1200 New Jersey Avenue, SE
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

JUN 7 2007

Mr. John V. Currie
Administrator
The Council on Safe Transportation
of Hazardous Articles, Inc.
7803 Hill House Court
Fairfax Station, VA 22039

Reference No. 07-0087

Dear Mr. Currie:

This is in response to your February 20, 2007 letter to Mr. Bob Richard, Deputy Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, concerning how to transport packages that contain blood and urine samples that do not meet the definition for a hazardous material under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You state these samples are placed in packages that are pre-printed with the words "Diagnostic Specimen." Your letter was forwarded to the Office of Hazardous Materials Standards for reply. We paraphrased and answered your questions below.

Q1. To ensure continued compliance with the HMR, must a carrier ask the offeror if every package displaying the marking "DIAGNOSTIC SPECIMEN" contains an infectious substance to learn whether or not it contains this material? If carriers do not ask the offerors this question, are they at risk of committing a probable violation of the HMR based on their potential knowledge of the contents?

A1. The answer to both questions is no. Effective October 1, 2006, under Docket No. PHMSA-2004-16895 (HM-226A; 6/2/06), we replaced the proper shipping name and marking "Diagnostic specimen" with "Biological substances, Category B" and a diamond-shaped mark containing the letters and numbers "UN 3373" printed at least 6 mm (0.24 inches) high. See § 173.199(a)(5). Although the HMR do not prohibit the words "Diagnostic specimen" from being marked on a package, on and after October 1, 2006, these words may no longer be used to denote a Division 6.2 (infectious) material. Note, however, in accordance with § 172.101(l), stocks of preprinted shipping papers or package markings may continue in use until depleted or for one year after the October 1, 2006 effective date, whichever is less. A carrier is not required to question the offeror on whether or not a package marked "DIAGNOSTIC SPECIMEN" contains a Division 6.2 material; however, it may be in the carrier's best interest to do so to ensure he or she is not inadvertently transporting an item meeting the definition of a hazardous material.

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172.101
173.199(a)(5)

Q2. Do the HMR prohibit shippers from displaying the words "DIAGNOSTIC SPECIMEN" on all packages? Are we correct in assuming it is not a prohibited marking?

A2. The HMR do not prohibit display of the words "DIAGNOSTIC SPECIMEN" on a package.

Q3. May a shipper offering patient specimens exempt from regulation under the HMR to an international transport carrier call them diagnostic specimens when transporting these materials in the United States?

A3. Yes.

I hope this satisfies your request.

Sincerely,

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

Edmonson
§173.134
§172.303
§173.199
Diagnostic Specimen/ Marking
07-0087

February 20, 2007

Dr. Robert A. Richard
Deputy Associate Administrator
US DOT PHMSA
400 7th St. SW, Suite 8421-D
PHH-70 Room 8431
Washington, DC 20590-0001

Dear Dr. Richard:

The recent amendments to the HMR pertaining to infectious substances have raised some questions that continue to cause confusion between shippers and carriers. COSTHA would respectfully request a written clarification that could be disseminated to effected persons in the industry.

There are numerous pre-printed packages currently in transportation that continue to display the previously required "Diagnostic Specimen" marking. There is a very high probability that these specimen shipments do not meet the definition of a "Biological Substance, Category B", much less the definition of an infectious substance. The majority of these shipments are offered for transportation from clinics, hospitals, and doctor's offices and are typically blood or urine samples from otherwise healthy individuals.

COSTHA's question remains, what must the carrier do to ensure continued compliance with the HMR? Must the carrier question every single package displaying the marking "DIAGNOSTIC SPECIMEN"? This would require expenditure of resources of immense proportions and will undoubtedly continue for some time to come. In reality, the term Diagnostic Specimen is no longer a regulatory term. But if the carriers continue the transportation of these packages so marked, are they at risk of possible regulatory scrutiny based on potential "constructive knowledge" of the contents?

Do the HMR now require that shippers must immediately discontinue display of the term "Diagnostic Specimen" on all packages? Since the term is no longer used to describe a regulated hazardous material and

thus the term is no longer recognized by the regulations, are we correct in assuming it is not a prohibited marking? Would you concur that a shipper offering what would be considered patient exempt specimens to a carrier in international transport, could also call them diagnostic specimens for transport within the US?

This has been identified as a significant issue in the foreseeable future and we ask that PHMSA provide an expeditious response in order that COSTHA may assist in distribution of a guidance document to enhance safe and efficient transportation.

Thank you in advance for your prompt consideration of this issue.

Sincerely yours,

COSTHA Administrator

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