



U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

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

AUG 22 2006

Ms. Jane Swerdlow
Chief Operating Officer
Laboratory Medicine Consultants
3059 South Maryland Parkway
Las Vegas, NV 89109-6209

Ref. No.: 06-0181

Dear Ms. Swerdlow:

This is in response to your July 28, 2006 letter, requesting clarification of the diagnostic specimen requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if your couriers may use the Materials of Trade (MOTS) exception in § 173.6 to pick up and deliver diagnostic specimens (e.g., biopsies in 10% formalin, pap smears, and body fluids) for testing.

Under current HMR requirements, the MOTS exception may be used to transport Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product, or regulated medical waste. A diagnostic specimen is any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. Provided the biopsies, pap smears, and body fluids are being transported by your employees in support of your business and do not contain a Risk Group 4 infectious substance you may take full advantage of the MOTS exception.

In addition to the MOTS exception, you may also utilize the exception in § 173.134(b)(6) to transport diagnostic specimens. In accordance with this paragraph, diagnostic specimens are excepted from all requirements in the HMR provided they are transported by private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products.

On June 2, 2006 we published a final rule under Docket HM-226A (71 FR 32244) entitled, "Hazardous Materials: Infectious Substances; Harmonization with the United Nations Recommendations." The rule, which becomes effective on October 1, 2006, will align the HMR with international regulations applicable to the transportation of Division 6.2 materials. The most significant change is the adoption of a two-tiered classification system for Division 6.2 materials comprised of Category A and Category B materials in place of the current four-tiered risk group system. The final rule will not change the applicability of the MOTS or private/contract carrier exceptions to your operation.



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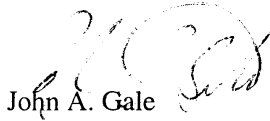
173.6
173.134(b)(6)

However, we suggest you review the changes prior to October 1, 2006. The final rule is available at the following URL:

<http://hazmat.dot.gov/regs/rules/final/71fr/docs/71fr-32243.pdf>

I hope this information is helpful. Please contact us if you require additional assistance.

Sincerely,

A handwritten signature in dark ink, appearing to read "John A. Gale", is written over a circular stamp or seal that is partially obscured by the signature.

John A. Gale
Chief, Standards Development
Office of Hazardous Materials Standards

July 28, 2006

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office Of Hazardous Materials Safety
400 7th St., S.W.-
Washington, DC 20590

Supko
§ 173.134(b)(6)
§ 173-6
Definitions & Exceptions
06-0181

Re: Request for Interpretation

I am requesting an interpretation regarding the regulations governing ground transportation of medical laboratory specimens. Our laboratory couriers pick up and deliver medical specimens, primarily biopsies in 10% buffered formalin, pap smears and body fluids, for diagnostic testing. It is our understanding these specimens meet the definition of a diagnostic specimen as described in CFR49 173.134 Class 6, Division 6.2 (4) and are an exception from Division 6.2. Therefore these specimens do not need an UN identification number. They are packaged for shipment according to CFR 173.6 (4).

As an organization we want to make sure our interpretation is correct and they we do not need any separate DOT designation for transportation of these specimens.

If you have any questions, my direct telephone number is 702-938-9904 or my e-mail address is swerdlow@lmclabs.com. Thank you for your assistance.

Sincerely,

Jane Swerdlow
Chief Operating Officer
Laboratory Medicine Consultants