



U.S. Department of Transportation
**Pipeline and Hazardous Materials
Safety Administration**

APR 07 2011

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

Ms. Darcy Britt
Global Logistics Compliance Supervisor
BioStorage Technologies
2910 Fortune Circle West Drive, Suite E
Indianapolis, IN 46241

Reference No. 11-0023

Dear Ms. Britt:

This is in response to your February 3, 2011 letter and February 22, 2011 telephone conversation with a member of my staff requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to large numbers of batched patient specimen samples that belong to other companies and for which the hazard class is unknown. Specifically, you state your company places several hundreds of these samples inside low-temperature freezers that it then places in exclusive-use, freight-container truck motor vehicles and transports from one laboratory or long-term storage facility to one of your company's long-term storage facilities.

In your letter, you state your company is describing the samples as "UN 3373, Biological substances, Category B, 6.2 (infectious)" as a precaution. You state most of the samples do not contain additional material, but some may contain a fixed formalin solution as a preservative. In your letter, you describe: (1) the primary packaging as a cryogenic vial that ranges in size from 2 ml to 12 ml; (2) the secondary packaging as a box that contains a sufficient amount of absorbent material in its base to absorb the contents and a grid that holds one vial per compartment, the box is then closed and placed on a rack inside a Sanyo V.I.P. Series Ultra Low Freezer; and (3) the freezer as the outer packaging. You also state the completed package is identical to those authorized under DOT Special Permit DOT-SP 14969, and that your company's employees and authorized agents prepare these packages for transport. You further state the freezers are loaded in a freight container, attached to and operated by a generator, and reach temperatures of -70 °C, -80 °C, or -120 °C. Finally, you state dry ice is sometimes transported on the vehicle as a precautionary refrigeration method, the freight container and packagings are owned by your company, and the truck cabs are owned by Pace Air Freight, Inc. You ask whether these samples as described above are excepted from regulation under § 173.134(b)(10) of the HMR.

The answer is no. Section 173.134(b)(10) excepts from regulation under the HMR patient samples transported for research, diagnosis, investigational activities, or disease treatment or prevention. Samples transported solely for storage, as described in your letter, do not qualify for this exception. In a final rule issued under Docket No. PHMSA-2004-16895 (HM-226A), this

agency stated it permits unknown samples of infectious substances shipped for analysis and diagnosis to be transported in accordance with requirements for Category B infectious substances, because historically, materials meeting this definition have been transported in a similar manner with no adverse safety impact or increased risk to transport workers or the general public (6/2/2006; 71 FR 32244). Therefore, it is the opinion of this Division that patient specimens shipped from a storage laboratory facility to another laboratory facility with no medical knowledge of the patients from whom the specimens were obtained may be identified as "UN 3373, Biological substances, Category B, 6.2." The specimens must be packaged in conformance with the requirements prescribed in § 173.199, and the proper shipping name "Biological substances, Category B" must be marked on the outside of the completed package along with the "UN 3373" diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high (see § 173.199(a)(5)). For those situations where the identity of the agent or pathogen is not known, but sufficient information is available to strongly suspect a Category A infectious substance, the HMR requires those materials to be shipped in accordance with all applicable hazard communication and packaging requirements for Category A infectious substances. The HMR also require that an indication that a sample contains a Category A infectious material be included on the shipping paper (see § 172.203(k)).

Regarding DOT-SP 14969, please note that the packages authorized under this special permit may only be used by the grantee, Pace Air Freight, Inc., and, when prepared by them, may be transported by others provided the package is unchanged. The practices you describe are not in conformance with this special permit and may be in violation of the HMR. Your company may wish to apply for its own special permit to use this packaging. If so, the procedures for applying for a special permit are prescribed in 49 CFR Part 107, Subpart B. Your application should be directed to the Associate Administrator for Hazardous Materials Safety and should include specific and detailed information concerning how you propose to package and transport the materials. You may also obtain this information from our website at "<http://www.phmsa.dot.gov/hazmat/regs/sp-a>."

I hope this satisfies your request.

Sincerely,



T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

2/4/11



BioStorage.
TECHNOLOGIES

Edmonson
\$173.199
\$173.134.
Category B Infectious Substana
11-0023

February 3, 2011

U.S. DOT
PHMSA Office of Hazardous Materials Standards
Attn: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001

To Whom It May Concern:

I would like to ask you for further clarification of exemptions for packaging requirements for Division 6.2, Category B Infectious Substances when transported inside of low temperature freezers within our exclusive use motor vehicle.

Preface

Our business offers long term storage and logistical solutions for their biological specimens. One of our core solutions is the use of a state of the art semi trailer, designed to hold and maintain multiple temperature range freezers, to insure sample integrity during large batched sample relocations. This motor vehicle carries only medical, clinical or laboratory equipment or products.

These batched shipments contain numerous different patient specimens shipped from one storage facility to another storage facility with no knowledge of the patients from whom the specimens were obtained.

During these batched shipments, patient specimens are placed in primary receptacles in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents. Once secure in the primary receptacles, the specimens are placed in secondary packaging, and then loaded onto the freezer shelves.

Once the freezer loading is complete, the freezer is locked and secured inside the trailer so that there is no release of hazardous material under conditions normally encountered in transportation.

Continued on Next Page



BioStorage.
TECHNOLOGIES

Interpretation Request

Our relocation specialists are trained on the packaging requirements of 173.199 for Category B Infectious Substance, and adhere to these regulations in all situations, however, there is some question regarding the eligibility of our freezers as the required rigid outer packaging under 49 CFR 173.199(a) (4).

1. If samples are classified as Division 6.2 materials, Category B infectious substances and transported in our exclusive use, privately operated motor vehicle, do these qualify under 49 CFR 173.134(b) (10) as exempted from the packaging requirements for Category B infectious substances?
2. If exempt, are we correct to interpret 49 CFR 173.134(b) (10) in such a way that packaging requirements in 49 CFR 173.199 do not apply and our freezers will be acceptable as outer ridged packaging for transportation purposes?

Thank you for the opportunity to submit this request for interpretation.

I look forward to your response. Should there be any additional questions regarding this question, please do not hesitate to contact me at 317-452-4820.

Sincerely,

Darcy Britt

Global Logistics Compliance Supervisor

BioStorage Technologies

2910 Fortune Circle West Drive

Suite E

Indianapolis, Indiana 46241