



U.S. Department
of Transportation

Pipeline and Hazardous
Materials Safety
Administration

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

OCT 23 2014

Nicholas Pagerly
Quest Diagnostics
159 Air Museum Dr.
Reading, PA 19605

Ref. No.: 14-0132

Dear Mr. Pagerly:

This responds to your June 24, 2014 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to Category B infectious substances packaged with dry ice. In your letter, you describe a packaging system that was certified by Ten-E Packaging Services, Inc. for Quest Diagnostics. The packaging system is comprised of a leak-proof primary packaging, contained in a secondary (95kPa compliant) packaging, consolidated in a third bag which is closed by a leak-proof seal. You note that dry ice is then poured on top of this third bag, and that if the completed package is not full, any additional space is filled with dunnage to prevent interior components from shifting during transportation. As such, you state that even when the dry ice sublimates, there is little to no additional room within the package for the secondary packaging to shift during transportation. You ask whether this certified Ten-E Packaging system is in compliance with the HMR.

The answer is yes. As described in your letter, it is the opinion of this Office that your packaging system for your Category B infectious substances packaged with dry ice would meet these requirements. As required by § 173.199(d)(1), dry ice must be placed outside the secondary packaging or in an overpack. Interior supports must be provided to secure the secondary packaging in the original position. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle and secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft they could be subjected to if refrigeration were lost, and sufficient absorbent material must be provided to absorb all liquid, including melted ice. Furthermore, as required by § 173.199(d)(2), the package must be marked "Carbon dioxide, solid" or "Dry ice" and an indication that the material being refrigerated is used for diagnostic or treatment purposes (e.g., frozen medical specimens).

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

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

Nickels
173.199
Diagnostic Specimen Training
14-0132



June 24, 2014

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

Dear Sirs,

In support of our business, Quest Diagnostics ships Class 6.2 Infectious Substances via commercial air. These materials are packaged in a proprietary packaging system that was certified by Ten-E Packaging Services, Inc., for Quest Diagnostics.

Some of our shipments are packaged with dry ice, which is used as a refrigerant. In accordance with the packaging instructions, the (leak-proof) primary packaging is contained in a secondary packaging (95kPa compliant). Multiple secondary packagings are then consolidated in a third bag, which is closed by a leak-proof seal. If the package contains dry ice, the dry ice is then poured on top of this third bag. The total quantity of dry ice amounts to five pounds or less per package.

When the packaging system was designed, the dimensions were dictated by the size of the intended load. Therefore, the interior load occupies the majority of the space within the package. This leaves just enough internal room to add the dry ice at the top of the packing system (if it is required). The Quest Diagnostics packaging SOP specifies that if the package is not full, then any additional space must be filled with dunnage to prevent the interior components from shifting during transport. The result is, that even when the dry ice sublimates, there is little to no additional room within the package for the secondary packagings to shift during transport.

49 CFR §173.199(d)(1) states in part:

- (d) Refrigerated or frozen specimens (ice, dry ice, and liquid nitrogen). In addition to complying with the requirements in this paragraph (d), dry ice and liquid nitrogen must be offered for transportation or transported in accordance with the applicable requirements of this subchapter.
- (1) Ice or dry ice must be placed outside the secondary packaging or in an overpack. Interior supports must be provided to secure the secondary packagings in the original position.

Quest Diagnostics is seeking confirmation from the Office of Hazardous Materials Standards that our approved packaging system, as described, provides for the support required by 49 CFR 173.199(d)(1).

Best Regards,

Nicholas Pagerly

Nicholas Pagerly, Hazmat Regulatory Compliance
Quest Diagnostics
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