



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

1200 New Jersey Ave., S.E.  
Washington, DC 20590

SEP 21 2011

Jay Johnson, DGSA  
Regulatory Compliance Manager  
Inmark  
675 Hartman Road, Suite 100  
Austell, GA 30168

Reference No. 11-0227

Dear Mr. Johnson:

This is in response to your August 3, 2011, and September 1, 2011 e-mails to Mr. Delmer Billings, Senior Regulatory Advisor, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration (PHMSA). He directed your e-mail to my branch for response. A member of my staff responded to you informally by e-mail on September 19, 2011. This is our official response to your inquiry. You ask when PHMSA plans to revise § 173.199(a)(4) to remove the steel rod puncture test from the requirements for Category B infectious substance packagings. We cannot provide you with a specific time frame, but can tell you that this revision is currently under consideration for inclusion in a future rulemaking.

You also ask if a Category B, Division 6.2 (infectious substance) must be capable of surviving the conditioning requirements prescribed in §§ 178.609(e) (water spray), 178.609(f) (cold-conditioned), and 178.609(g) (dry ice dissipation) to demonstrate that it is capable of passing the drop test in § 178.609(d). The answer is no. See page 32247, first paragraph, of the preamble of the final rule PHMSA issued under Docket No. PHMSA-2004-16895 (HM-226A; 71 FR 32244; <http://edocket.access.gpo.gov/2006/pdf/06-4992.pdf>), where PHMSA stated a § 173.199 packaging need not be capable of passing a puncture or other performance tests.

I hope this satisfies your request.

Sincerely,

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

**Edmonson, Eileen (PHMSA)**

Edmonson  
§173.199(a)(4)  
§178.609(d)-(h)  
Infectious Substances  
11-0227

**Subject:** FW: Question about Category B Infectious Packaging

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**From:** Jay Johnson [mailto:jayj@inmarkinc.com]  
**Sent:** Thursday, September 01, 2011 9:40 AM  
**To:** Billings, Delmer (PHMSA)  
**Subject:** RE: Question about Category B Infectious Packaging

Good Morning Del,  
I was wondering if you had had a chance to look at the two questions I had sent you concerning UN3373 package testing?  
Thanks

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**From:** Jay Johnson  
**Sent:** Wednesday, August 03, 2011 12:21 PM  
**To:** 'delmer.billings@dot.gov'  
**Subject:** Question about Category B Infectious Packaging

Hello Del,

I have two questions about the package testing for Biological Substance, Category B and I hope you can help me with this. Currently §§173.199(a)(4) states that packages must be capable of successfully passing the drop tests in §§178.609(d) and (h) of this subchapter.

*173.199(a)(4) The completed package must be designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation. The packaging must be capable of successfully passing the drop tests in §§178.609(d) and (h) of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).*

PHMSA clarified this requirements in an interpretation (PHMSA Interpretation #07-0018 ) that:

*A packaging used to transport a Category B infectious substance must be capable of passing the drop test prescribed in § 178.609(d). The packaging is not required to also be capable of passing the steel rod impact test in § 178.609(h). We will correct this error in a future rulemaking.*

Question 1: Do you know when the rulemaking to correct this error is going to occur?

Question 2: When conducting the drop testing in §§178.609(d) to establish if the packages are capable of passing the drop test, do the samples have to be conditioned as described in the requirements of §§178.609(e), §§178.609(f), and §§178.609(g)?

*§§178.609(e) The samples must be subjected to a water spray to simulate exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.*

*§§178.609(f) The sample must be conditioned in an atmosphere of -18 [deg]C (0 [deg]F) or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the test described in paragraph (d) of this section. Where the sample contains dry ice, the conditioning period may be reduced to 4 hours.*

*§§178.609(g) Where packaging is intended to contain dry ice, a test additional to that specified in paragraph (d) or (e) or (f) of this section must be carried out. One sample must be stored so that all the dry ice dissipates and then be subjected to the test described in paragraph (d) of this section.*

Thanks for your clarification on the matter.

Best regards,

**Jay Johnson DGSA, Regulatory Compliance Manager | Inmark | 675 Hartman Road, Suite 100, Austell, GA 30168**  
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