U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

January 22, 2024

Kristi Jenkins
North Carolina Department of Health and Human Services
State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607

Reference No. 23-0087

Dear Ms. Jenkins:

This letter is in response to your September 29, 2023, email, and subsequent emails requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the reuse of a rigid outer packaging when shipping a Category B infectious substance. You state that facilities are shipping Category B infectious substances in a "triple packaging"—consisting of a new primary receptacle, a new secondary packaging, and a reused rigid outer packaging—and that the completed packaging is appropriately marked and labeled as required. It is your understanding that the reused rigid outer packaging is permitted for Category B infectious substances provided it is not contaminated or damaged in any way; however, you seek clarification and ask questions regarding the drop test and recordkeeping requirements for reused packagings.

We have paraphrased and answered your questions as follows:

Q1. As required by § 173.199(a)(4), you ask how the 1.2 meter (3.9-ft.) drop test is verified when a rigid outer packaging is reused for a Category B infectious substance package.

A1. The HMR requires a Category B infectious substance to be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid outer packaging. Although Category B infectious substances are not subject to any other requirements in the HMR when following § 173.199, we note that as defined in § 171.8 an outer packaging means the outermost enclosure of a composite or combination packaging together with any absorbent materials, cushioning and any other components necessary to contain and protect inner receptacles or inner packagings. Further, a "rigid packaging"[1] is a packaging that is sufficiently stiff and unyielding as to always retain its original shape and dimensions under all conditions of transportation. A person can verify drop test capability from the manufacturer or distributor of the packaging or perhaps a previous shipper (consignor) of a Category B infectious substance package. Note, if a

person is unable to verify drop test capability of a Category B infectious substance packaging such that there is uncertainty in complying with performance standards of § 173.199, it is recommended that a person should not reuse the rigid outer packaging for Category B shipments.

Q2. You ask how a person can verify the 1.2 meter (3.9-ft.) drop test capability when reusing an outer "brown box" as the rigid outer packaging of a Category B infectious substance package. You state that the "brown box" was previously used to transport reagents or other materials.

A2. Capability may be demonstrated by testing, assessment, or experience. This may be satisfied using a number of methods, including actual previous handling and transportation experience, design, construction, filling, and closure instruction information, or absent such methods, through the performance of a drop test. It is the shipper's responsibility to ensure that the "brown box" rigid outer packaging—in combination with the other packaging components—meet the performance standards of § 173.199. Based on the photograph you provided as a reference, the "brown box" must be a "rigid outer packaging" in accordance with § 173.199(a)(1).

Q3. You ask whether a person reusing a "brown box" rigid outer packaging and marking it as a Category B infectious substance for transportation is permitted to do so without obtaining proof that the "brown box" rigid outer packaging has passed the 1.2 meter (3.9ft.) drop test as required in § 173.199(a)(4).

A3. The HMR do not define a specific method for validating package capability, however the person filling and marking the package as a Category B infectious substance assumes responsibility for the package capability. Please note examples of verification methods in answer "A2."

Q4. You ask how a shipper complies with the record retention requirements—i.e., keeping a copy of the packaging instructions for one year—if a person reuses a "brown box" rigid outer packaging as part of a Category B infectious substance package.

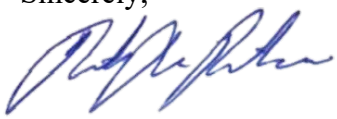
A4. If a shipper uses a completed Category B infectious substance package, they should be provided clear instructions on filling and closing a packaging from the manufacturer and subsequent distributor in accordance with § 173.199(a)(10). If a shipper is reusing a "brown box" as a rigid outer packaging as part of a Category B infectious substance package where the (re)shipper has not been provided filling and closure instructions by the original shipper (consignor), a downstream shipper would then assume the role as the "manufacturer" subject to the requirements of § 173.199 and would be responsible for creating their own filling and closure instructions—to include complying with record retention requirements. Note, a shipper must perform due diligence to obtain instructions on filling and closing of a packaging from the manufacturer or subsequent distributor if unable to obtain these instructions from a previous shipper.

Q5. You ask whether a person who prepares the completed Category B infectious substance package—i.e., not the packaging manufacturer or subsequent distributors of the packagings—is excepted from the record retention requirements for filling and closure instructions as prescribed in § 173.199(a)(10).

A5. See answer A4.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,



Dirk Der Kinderen
Chief, Standards Development Branch
Standards and Rulemaking Division

Baker

23-0087

From:	Baker, Yul (PHMSA)
To:	Dodd, Alice (PHMSA)
Cc:	Jones, Jessie Jane CTR (PHMSA); DerKinderen, Dirk (PHMSA)
Subject:	FW: Category B regulations interpretation
Date:	Tuesday, October 3, 2023 11:42:59 AM
Importance:	High

Morning Alice,

Can you please upload the following e-mail below into our interp database as a request for interpretation and assign the request to me?

Thank you,

Mr. Yul Brenner Baker Jr.
Transportation Regulations Specialist, Standards Development

USDOT, PHMSA
Pipeline and Hazardous Materials Safety Administration
1200 New Jersey Ave, SE, Washington, DC, 20590
Office number: 717-688-9977

From: Jenkins, Kristi W <kristi.jenkins@dhhs.nc.gov>
Sent: Friday, September 29, 2023 2:36 PM
To: Baker, Yul (PHMSA) <yul.baker@dot.gov>
Subject: FW: Category B regulations interpretation
Importance: High

Good afternoon, Yul. I have not been able to get my email request below to go through; it has been rejected since I'm not a member of the group. So I was provided your email and am hoping you can help answer my questions or direct me to someone who can provide an interpretation of the regulations in regards to my questions below.

Thank you so much!

Kristi Jenkins, MT(ASCP)
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From: Jenkins, Kristi W
Sent: Friday, September 29, 2023 11:58 AM
To: hazmatinterps@dot.gov
Cc: Martin, Luke (PHMSA) <luke.martin@dot.gov>; Hatfield, Clayton (PHMSA) <clayton.hatfield@dot.gov>
Subject: Category B regulations interpretation
Importance: High

To Whom it May Concern:

I provide the packaging and shipping training for infectious substances here in North Carolina and have a few questions that I need some interpretation for to ensure I am training staff correctly. Any guidance you could provide would be greatly appreciated!

Due to limited funding, facilities are re-using boxes instead of using a new Category B box each time they have a shipment. They are triple packing as required and relabeling the outside of the box with appropriate Category B markings and labels. My understanding has always been that this is appropriate as long as the box is not contaminated or damaged in any way. However, this has raised some questions that I can't seem to reconcile with the regulations.

1. How is the 4 ft drop test requirement verified when packing material is being re-used? If something happens to a Cat B package in transit, how would staff verify this requirement if just using a brown box from a previous shipment and triple packing it? Is it safe to assume that all packages received, passed that requirement at the manufacturer's end, or is that only a requirement for Category B packing material?

2. How do shippers comply with the record retention requirement of keeping a copy of the packing instructions for 1 year if they are re-using boxes that did not come with packing instructions? I recently discovered that 173.199(a)(10) says a copy of the instructions must be kept by the **manufacturer and subsequent distributors** for at least one year from the date of issuance. Does this mean that shippers are exempt from this requirement?

Thank you for your assistance!

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