



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

August 22, 2023

Mr. Timothy W. Wiseman
Partner
Scopelitis, Gavin, Light, Hanson & Feary, P.C.
10 West Market Street, Suite 1400
Indianapolis, IN 46204

Reference No. 22-0070

Dear Mr. Wiseman:

This is in response to your July 14, 2022, letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of used sharps. Specifically, you ask about a plastic film bag used as an inner packaging when transporting sharps in a Large Packaging.

We have paraphrased and answered your questions as follows:

- Q1. In your letter, you note that § 173.197(e)(3) of the HMR specifies that sharps transported in a Large Packaging must be packaged in a puncture-resistant, non-bulk inner packaging (sharps container)—which in your opinion may be similar to the plastic film bag identified in § 173.197(e)(1) used to transport solid regulated medical waste. You ask whether the non-bulk inner packaging (sharps container) may be a plastic film bag provided it is puncture-resistant, and—when exceeding 20 gallons—capable of passing the performance test in Part 178, Subpart M at the Packing Group II performance level.
- A1. Paragraph (e)(1) of § 173.197 specifies the requirements for the inner packaging for solid regulated medical waste transported in a Large Packaging. Sharps are objects that can pierce certain types of packaging, therefore, the inner packaging for sharps transported in a Large Packaging must conform to § 173.197(e)(3). Each puncture-resistant, non-bulk inner packaging (sharps container) used to transport sharps in a Large Packaging must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer and each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in part 178, subpart M at the Packing Group II performance level. A sharps container intended for reuse in a Large Packaging must be approved and certified as a medical device for reuse by the U.S. Food and Drug Administration (FDA) and meet additional requirements under § 173.197(e)(3). Please note, a sharps container may be subject to other requirements, such as The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens standard (see 29 CFR § 1910.1030) and FDA and U.S. Environmental Protection Agency (EPA) requirements.

- Q2. You ask what specific performance test may be required under Part 178, Subpart M for the plastic film bag used as the inner packaging of a Large Packaging when transporting sharps.
- A2. PHMSA has not identified a testing procedure to determine whether a poly bag can resist punctures from hypodermic needles and other sharp objects generated in the medical industry. If you can identify a test standard that demonstrates puncture resistance of a poly bag to objects— such as used hypodermic needles— and provides for an appropriate level of safety for the transportation of hazardous materials, you may ask PHMSA to incorporate by reference a new standard by filing a petition for rulemaking in accordance with rulemaking procedures in §§ 106.95-106.105.

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

Sincerely,

A handwritten signature in blue ink that reads "T. Glenn Foster". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

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

From: [Foster, Glenn \(PHMSA\)](#)
To: [Dodd, Alice \(PHMSA\)](#); [Hillman, Kenetha CTR \(PHMSA\)](#)
Subject: FW: Request for Guidance
Date: Thursday, July 14, 2022 6:17:16 AM
Attachments: [Foster - Request Interpretation 7-13-22.docx](#)

Good morning, Alice and Kenetha.

Please have the attached checked in and assigned as a request for a letter of interpretation.

Thanks,
Glenn

From: Wiseman, Tim <twiseman@scopelitis.com>
Sent: Thursday, July 14, 2022 5:46 AM
To: PHMSA_Guidance <PHMSA_Guidance@dot.gov>
Cc: Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>
Subject: Request for Guidance

CAUTION: This email originated from outside of the Department of Transportation (DOT). Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Please find the attached Request for Guidance, and let me know if you have any questions. Thanks! -Tim

Timothy W. Wiseman, *Partner*
[Scopelitis, Garvin, Light, Hanson & Feary, P.C.](#)
10 West Market Street, Suite 1400, Indianapolis, IN 46204
twiseman@scopelitis.com | T: [317.637.1777](tel:317.637.1777) | D: [317.492.9221](tel:317.492.9221)

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10 West Market Street
Suite 1400
Indianapolis, IN 46204



www.scopelitis.com

Main (317) 637-1777
Fax (317) 687-2414

TIMOTHY W. WISEMAN
twiseman@scopelitis.com

August 23, 2023

Mr. T. Glenn Foster, Chief
Regulatory Review & Reinvention Branch
Standards & Rulemaking Division
U.S. Department of Transportation
Pipeline & Hazardous Material Safety Adm.
1200 New Jersey Avenue, SE
Washington, DC 20590

Re: 49 C.F.R. § 173.197(e)(3)
Request for Interpretation

Dear Mr. Foster:

Pursuant to 49 C.F.R. § 105.20, I write to request guidance with respect to the requirements for the transportation of sharps in a large packaging under 49 C.F.R. § 173.197(e)(3), which provides, in pertinent part, as follows:

Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packing manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance test in Part 178, Subpart M, of this Subchapter at the Packing Group II performance level.

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Mr. T. Glenn Foster, Chief

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My questions pertaining to the particular regulation are as follows:

1. Can the inner packaging referenced in § 173.197(e)(3) be a plastic film bag (similar to the film bag identified in § 173.197(e)(1)) as long as it is puncture-resistant, and, when exceeding 20 gallons, capable of passing the performance test in Part 178, Subpart M at the Packing Group II performance level?
2. If the response to Question #1 is yes, what specific performance test would be required under Part 178, Subpart M, for the plastic film bag used as the inner packaging with a large packing for the transportation of sharps?

If any additional information is needed to consider this request, please do not hesitate to contact me.

Very truly yours,

/s/ Timothy W. Wiseman

Timothy W. Wiseman

TWW/kkc