



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

JAN 02 2018

Ed Krisiunas
President
WNWN International
P.O. Box 1164
Burlington, CT 06013

Reference No. 17-0041

Dear Mr. Krisiunas:

This letter is in response to your April 25, 2017, emails requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of regulated medical waste, specifically sharps containers and transport of those containers by a private carrier.

We have paraphrased and answered your questions as follows:

- Q1. You ask for confirmation of your understanding that the maximum size for a sharps container that meets part 178, subpart M packaging performance standards at the packing group (PG) II performance level is 40 gallons.
- A1. Packaging size limits for sharps containers are linked to use. The 40-gallon limit you reference is associated with sharps containers intended to be reused as inner packagings of a Large packaging, a wheeled cart (Cart), or bulk outer packaging (BOP). See § 173.197(e)(3). If the sharps container is not intended to be reused, then the size limit is non-bulk. See § 173.197(e)(3)(d)(1)(i); see also § 171.8 for the definition of non-bulk.
- Q2. With respect to Q1, you ask for confirmation that a sharps container can be transported as a stand-alone container.
- A2. Based on our understanding that your intended meaning of “stand-alone container” is the container does not have to be placed in an outer packaging, then your understanding is correct. Section 173.197(b) authorizes use of non-bulk packagings for transportation of sharps. These packagings are not required to be placed in an outer packaging.

Q3. You further ask if an 18-gallon sharps container meeting the PG II performance level can be the primary container of transport for sharps.

A3. With the understanding that the meaning of "primary container" equates to "stand-alone container" in Q2, the answer is yes. Regulated medical waste (i.e., sharps) may be transported in a single non-bulk packaging that must be a UN standard packaging that conforms to the requirements in part 178, subpart M at the PG II performance level. See § 173.197(b) for a full description of performance requirements for the non-bulk packaging.

Q4. Finally, you explain that a private carrier, knowing the exceptions of § 173.134(c) for regulated medical waste, has a sharps container at the PG II performance level that is puncture resistant, and is filled with sharps, secured, but not placed in another container and then loaded in a motor vehicle. You ask if this is acceptable in accordance with §§ 173.134 and 173.197.

A4. The answer is yes if all applicable requirements of § 173.197 are met.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Dirk Der Kinderen', is written over the printed name.

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

Dodd, Alice (PHMSA)

*Ciccarone
§ 173.134
Packaging Genes
17-0041*

From: Edmonson, Eileen (PHMSA)
Sent: Tuesday, April 25, 2017 6:35 PM
To: Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)
Subject: FW: Sharps container...capacity

Hello Alice and Shante,

I don't know which one of you does this but attached is a request for a letter of clarification.

Can you please enter it in filemaker and assign it the next specialist in que?

Thanks,

Eileen Edmonson
USDOT/PHMSA
(202) 366-4481 (work)
(202) 366-8553 (main)
(202) 366-7041 (fax)
1-800-467-4922 (HazMat Info Center)
eileen.edmonson@dot.gov (e-mail)
infocntr@dot.gov (HMIC e-mail)

From: ekrisiunas@gmail.com [mailto:ekrisiunas@gmail.com]
Sent: Tuesday, April 25, 2017 5:29 PM
To: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>
Cc: Foster, Glenn (PHMSA) <Glenn.Foster@dot.gov>
Subject: RE: Sharps container...capacity

Hello Eileen..

Please do submit...

I have an additional question.

I have a PGII tested sharps container. 18 gallons...can this be the primary container for transport?

A private carrier has decided that even though they have an exception per 173.134, they have a container that has met the PG II testing requirements and is puncture resistant. They are loading into a van..it is filled with sharps..securing it ..and driving to the next destination...it is not placed in any other container.

Is this acceptable per DOT 173.134 and 173.197..

Regards

Ed Krisiunas

From: Edmonson, Eileen (PHMSA)
Sent: Tuesday, April 25, 2:15 PM
Subject: RE: Sharps container...capacity
To: Edward Krisiunas
Cc: Foster, Glenn (PHMSA)

Hi Ed,

I apologize for the delay in getting back to you. Under our new administration we are restricted on what and how we can answer inquiries. We can answer those we've answered before, e.g., in rulemakings and letters of clarification. For those we haven't answered before, we must submit them for development as new request for letter of clarification. Your question seems to be about how large a sharps packagings can be when placed in a Large, Wheeled Cart, or Bulk Outer Packaging under § 173.197(e)(3). If I've misunderstood your question, let me know.

I found this language on page 32250 of the final rule that added this provision. Here is the link to the rule: <https://www.gpo.gov/fdsys/pkg/FR-2006-06-02/pdf/06-4992.pdf>.

32244 Federal Register / Vol. 71, No. 106 / Friday, June 2, 2006 / Rules and Regulations

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials

Safety Administration

49 CFR Parts 171, 172, 173, and 175

**[Docket No. PHMSA–2004–16895 (HM–
226A)]**

RIN 2137–AD93

Hazardous Materials: Infectious

Substances; Harmonization With the

United Nations Recommendations

AGENCY: Pipeline and Hazardous

Materials Safety Administration

(PHMSA), Department of Transportation

(DOT).

ACTION: Final rule.

A sharps container placed inside a bulk packaging, such as a UN specification Large Packaging or a non-specification bulk outer packaging or wheeled cart, must be puncture resistant. A sharps container that is 20 gallons or less in volume need not be a UN specification packaging if it is to be placed in a bulk outer packaging. A sharps container that is larger than 20 gallons in volume that is placed inside a bulk packaging must be capable of passing the performance tests in subpart M of part 178 at the Packing Group II performance level. A sharps container that will be placed in a bulk outer packaging for transportation may be reused only if it is specifically cleared or approved by FDA as a medical device for reuse and must have a capacity of between 2 and 40 gallons.

Therefore, the 40-gallon limit applies to reusable sharps containers placed in bulk packagings. To get further clarification on how large a "non-reuseable" sharps container can be under § 173.197(e)(3), I must submit your letter for processing as a new request for a letter of clarification.

Do I have your permission to do this?

Sincerely,

Eileen Edmonson

USDOT/PHMSA

(202) 366-4481 (work)

(202) 366-8553 (main)

(202) 366-7041 (fax)

1-800-467-4922 (HazMat Info Center)

eileen.edmonson@dot.gov (e-mail)

infocntr@dot.gov (HMIC e-mail)

From: Edward Krisiunas [<mailto:ekrisiunas@gmail.com>]
Sent: Tuesday, April 25, 2017 12:40 PM
To: Edmonson, Eileen (PHMSA) <eileen.edmonson@dot.gov>
Subject: Sharps container...capacity

Hello Eileen..

What is the maximum size for a sharps container? Meets PG II requirements..tested per 178 Part M?

I believe it is 40 gallons?

Additionally, this type of container can be transported as a stand alone container - Correct?

Regards,

Ed

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