



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

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

MAR 5 2010

Mr. Jason Hunt  
State of Wisconsin  
Department of Health Services  
Radiation Protection Section  
One West Wilson Street, Room 148  
P.O. Box 2659  
Madison, Wisconsin 53701-2659

Ref. No. 09-0286

Dear Mr. Hunt:

This responds to your email dated December 3, 2009 requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You describe a scenario in which a nuclear pharmacy ships radioactive material to nuclear medicine departments. The nuclear pharmacy requires the end users to ship the packaging, "ammo can and empty pigs," back to the nuclear pharmacy in accordance with § 173.421 (Excepted packages for Class 7 (radioactive) materials). Your questions pertaining to this scenario are summarized and answered as follows:

Q1) Are licensees required to perform a survey (exposure or contamination) of "ammo cans" that are shipped back to a nuclear pharmacy in accordance with § 173.421?

No. Section 173.421 requires that the radiation level at any point on the external surface of the package does not exceed 0.005 mSv/hour (0.5 mrem/hr). In addition, the nonfixed (removable) contamination on the external surface of the package must not exceed the limits in § 173.443(a). The shipper must ensure that the package is within these regulatory limits when offered for transportation and transported. This generally implies that it is necessary for the shipper to conduct a survey to ensure compliance. However, this regulation provides the shipper with latitude in their methods of ensuring compliance with the radiation and contamination limits; procedures other than measurements, such as quality assurance and quality control, are acceptable means of ensuring compliance.

Q2) If the contamination exposure of the "ammo cans" exceeds the levels in §§ 173.421(a)(2) and (3) and the licensee does nothing, will the licensee be cited?

It is the shipper's responsibility to ensure compliance with § 173.421. Therefore, if the "ammo cans" exceed the radiation level or contamination limits of § 173.421, they would be in violation of the HMR and could be cited.

Q3) Are licensees in violation of § 171.2 when a nuclear pharmacy requires them to ship empty "ammo cans" as "Excepted packages for Limited Quantities of Class 7 (radioactive) materials?"

No. Provided the licensees comply with the requirements of the HMR applicable to Limited Quantity Class 7 (radioactive) materials (see § 173.421).

I hope this answers your inquiry. If you need further assistance, please contact this office at 202-366-8553.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles E. Betts", with a stylized flourish at the end.

Charles E. Betts  
Chief, Standards Development  
Office of Hazardous Materials Standards

**Drakeford, Carolyn (PHMSA)**

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**From:** Betts, Charles (PHMSA)  
**Sent:** Thursday, December 03, 2009 8:40 AM  
**To:** Drakeford, Carolyn (PHMSA)  
**Cc:** Plessas, Karen (PHMSA); Boyle, Rick (PHMSA)  
**Subject:** FW: Interpretation Request

Eichenlaub  
§173.421  
§171.2  
RAM  
09-0286

**Importance:** High

-----Original Message-----

From: Plessas, Karen (PHMSA)  
Sent: Thursday, December 03, 2009 8:35 AM  
To: Betts, Charles (PHMSA); Boyle, Rick (PHMSA)  
Cc: Rogers, Cheryl K - DHS; Schmidt, Paul S - DHS; Sulas, Diana M - DHS; 'Hunt, Jason H - DHS'  
Subject: RE: Interpretation Request

Charlie,  
Jason Hunt from the State of Wisconsin is requesting a formal interpretation on a radioactive materials issue, so I am forwarding his request to you and Rick for disposition.  
Thanks,  
Karen

Karen Plessas  
Radioactive Materials Program Manager  
Office of Hazardous Materials Enforcement Pipeline and Hazardous Materials Safety Administration  
202-366-5267

-----Original Message-----

From: Hunt, Jason H - DHS [mailto:Jason.Hunt@dhs.wisconsin.gov]  
Sent: Wednesday, December 02, 2009 4:40 PM  
To: Plessas, Karen (PHMSA)  
Cc: Rogers, Cheryl K - DHS; Schmidt, Paul S - DHS; Sulas, Diana M - DHS  
Subject: Interpretation Request

Karen

I know I had emailed you awhile back and I'm wondering if I can get a formal interpretation by DOT of this requirement.

Rule Reference:

49 CFR 173.421 Excepted Packages for limited quantities of Class 7 (radioactive) materials

(2) The radiation level at any point on the external surface of the package does not exceed 0.005 mSv/hour (0.5 mrem/hour).

(3) The nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a).

Radioactive Material Regulation Review - December 2008

I understand this states in the note that 'This document is for general guidance only and must not be used to determine compliance with 49 CFR Parts 100-185.

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"This last requirement to ensure compliance with radiation and contamination limits of §§ 173.441 and 173.443 does not require that surveys or direct measurement be made. Both

sections give shippers latitude in their methods of ensuring compliance with the radiation and contamination limits; procedures other than measurements, such as quality assurance and quality control, are acceptable means of ensuring compliance. However, if a compliance inspection during transportation determines that radiation or contamination levels exceed the limit, the shipper is subject to a citation."

The question has arose in our office for Nuclear Medicine Departments that ship (without any material except the empty pigs) ammo cans back to a radiopharmacy under 49 CFR 173.421 (Excepted Packages for limited quantities of Class 7 (radioactive) materials. The Nuclear Pharmacy requires that the licensee ship these ammo cans back under 49 CFR 173.421.

Two questions:

1. Are the licensee's required to perform a survey (exposure or contamination) of these ammo cans, being shipped back under 49 CFR 173.421? If no survey is required what does DOT require, procedures (see guidance paragraph)? Is it then acceptable for the licensee to do nothing with these ammo cans, understanding that if the contamination or exposure exceeding the levels in 49 CFR 173.421 (2)&(3) they will be cited?

2. The licensee's have indicated that by the Nuclear Pharmacy requiring them to ship back these empty ammo cans as Excepted Packages for Limited Quantities of Class 7 (radioactive) materials that they are in violation of 49 CFR 171.2. Is this a correct interpretation by the licensees?

If I can provide any further clarification please let me know.

Jason Hunt

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