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

1200 New Jersey Avenue, SE
Washington, DC 20590

March 27, 2024

John J. Miller, CHP
Radiation Safety Officer
International Isotopes Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

Reference No. 24-0002

Dear Mr. Miller:

This letter is in response to your January 8, 2024, letter and subsequent emails requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to a shipper's certificate for radioactive material transported aboard a passenger-carrying aircraft. Specifically, you describe the offering and transportation of shipments containing short-lived radiopharmaceuticals—including radioisotopes—that are active pharmaceutical ingredients used in the production of radiopharmaceuticals. You explain that you are uncertain regarding the return shipment of "empty" packages intended to be reused for these products when transported aboard a passenger-carrying aircraft, as many of these packages utilize depleted uranium as shielding, which results in the "empty" packages being returned for reuse having an external dose rate exceeding 0.005 mSv/h (0.5 mrem/h). Furthermore, you explain that this requires the "empty" packages to be shipped to the radiopharmaceutical's supplier as an LSA-I shipment and not as "UN2908, Radioactive material, excepted package-empty packaging, 7." Therefore, regarding the requirement found in § 172.204(c)(4) for the shipper's certificate for radioactive material transported aboard a passenger-carrying aircraft, you ask for clarification regarding the phrase "intended for use in, or incident to, research, or medical diagnosis or treatment" as it relates to these "empty" packages.

Note that § 173.448(f) details the requirement linked to § 172.204(c)(4) and specifies that no person shall offer for transportation aboard a passenger-carrying aircraft any Class 7 (radioactive) material unless that material is intended for use in, or incident to, research, medical diagnosis, or treatment.

We have paraphrased and answered your questions as follows:

Q1. You ask whether an "empty" package that was used for the shipment of radiopharmaceuticals containing either residual radioactive material or depleted uranium shielding can be considered radioactive material intended for use in, or incident to, research, or medical diagnosis or treatment when it is returned to the radiopharmaceutical supplier.

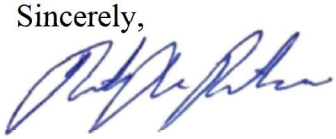
A1. The answer is yes. It is the opinion of this Office that an "empty" package that contains residual radioactive material or depleted uranium shielding as described in your letter that is being returned to the radiopharmaceutical supplier for reuse would meet the intent of a radioactive material offered aboard a passenger-carrying aircraft for research, medical diagnosis, or treatment.

Q2. You ask whether disused sealed sources such as Cobalt-57 (Co-57) flood and line sources, Germanium-68 (Ge-68) phantoms and line sources, and Sodium-22 (Na-22) markers that were used in or incidental to medical diagnosis or treatment can be considered to meet the requirements of being a radioactive material that is intended for use in, or incident to, research, medical diagnosis, or treatment when it is shipped back to the source manufacturer for end-of-life management. When one of these sources is returned to the manufacturer, the contact dose rate on the package can exceed 0.5 mrem/h and the source would then be returned as "UN2915, Radioactive material, Type A package non-special form, non-fissile or fissile excepted, 7."

A2. The answer is yes.

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

24-0002

From: INFOCNTR (PHMSA)
To: Dodd, Alice (PHMSA)
Cc: Hazmat Interps
Subject: FW: Request for interpretation
Date: Wednesday, January 10, 2024 4:49:54 PM
Attachments: image001.png
JJM-2024-02 Request for Interpretation.pdf

Hi Alice,

Please see the attached interpretation request.

Let me know if you need anything.

Regards,

-Breanna

From: John J. Miller <jjmiller@intisoid.com>
Sent: Monday, January 8, 2024 2:59 PM
To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Cc: Sumrall, Matthew (PHMSA) <matthew.sumrall@dot.gov>
Subject: Request for interpretation

John J. Miller
Radiation Safety & Regulatory Compliance Officer

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International Isotopes, Inc. | RadQual

International Isotopes
INCORPORATED

January 8, 2024

Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration,
Attn: PHH–10
U.S. Department of Transportation, East Building,
1200 New Jersey Avenue, SE., Washington, DC 20590–0001
Via email: infocntr@dot.gov

Subject: Request for an interpretation to § 172.204 (c) (4)

To whom it may concern,

The purpose of this letter is to formally request an interpretation to the scope of the phrase "incident to medical diagnosis or treatment" as used in §172.204 (c) (4), which reads.

Radioactive material. *Each person who offers any radioactive material for transportation aboard a passenger-carrying aircraft shall sign (mechanically or manually) a printed certificate stating that the shipment contains radioactive material intended for use in, or incident to, research, or medical diagnosis or treatment*.

Background:

The use of passenger aircraft is imperative to ensure timely delivery of shipments containing short-lived radiopharmaceuticals, including radioisotopes that are active pharmaceutical ingredients (APIs) used in the production of those radiopharmaceuticals. These shipments are clearly considered to contain radioactive materials intended for use in, or incident to medical diagnosis or treatment and are certified by the shipper to contain radioactive material intended for use in or incidental to medical diagnosis or treatment.

The request for interpretation regards the return of empty packagings used for the shipment of these products. Many of these packages are multi-use packages that utilize depleted uranium as shielding. On most of these packages, the depleted uranium shield results in an external dose rate exceeding 0.005 mSv/h (0.5 mrem/h), which requires the package to be returned to the supplier as an LSA-1 shipment and not as an Empty package, UN2908. With a limited package fleet available for use, it is just as important to have these packages returned to the supplier so that they can be reused to ship radiopharmaceuticals or radioisotopes used in the production of radiopharmaceuticals.

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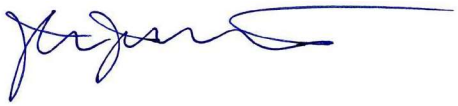
Question 1: Would the return to supplier of empty packages that had been used for the shipment of short-lived radiopharmaceuticals or radioisotope APIs containing residual radioactive material or depleted uranium shielding be considered to contain radioactive materials intended for use in, or incident to medical diagnosis or treatment?

A similar scenario occurs with medical devices that contain radioactive materials. Sealed sources used in the calibration of patient dosing instrumentation, (dose calibrators) and medical imagining devices, patient reference markers, and those used for therapeutical purposes are registered with the US Food and Drug Administration as Class 1 medical devices. When these products are shipped from the source manufacturer, the use of passenger aircraft ensures timely delivery to the customer. In most cases the customer returns disused sealed sources to the source manufacturer using the package that the new replacement source was provided in. This scenario leads to my second question.

Question 2: Would a disused sealed source that had been used in or incidental to medical diagnosis or treatment still be considered to meet the criteria when it is shipped back to the source manufacturer for end of life management?

Please contact me by phone at 208 524-5300 or email at jjmiller@intisoid.com if you have any questions regarding this letter or require additional information.

Sincerely,



John J. Miller, CHP
Radiation Safety Officer

JJM-2024-02
cc: Mr. Matt Sumrall, CHP
US Department of Transportation
Pipeline and Hazardous Materials Safety Administration
1200 New Jersey Avenue SE, Washington, DC, 20590
Via email.