



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

1200 New Jersey Ave, S.E.
Washington, D.C. 20590

APR -7 2009

Mr. Edward A. Zdunek
Bard Brachytherapy, Inc.
295 E. Lies Road
Carol Stream, IL 60188

Ref. No. 09-0063

Dear Mr. Zdunek:

This responds to your March 20, 2009 letter requesting clarification of the shipping paper requirements for limited quantities of radioactive materials under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Your questions are paraphrased and answered below.

Q1: In accordance with §§ 173.421 and 173.422, when offering for transportation “UN2910, RQ, Radioactive material, excepted package-limited quantity of material,” are shipping papers required?

A1: The answer is yes. In accordance with § 173.422, “Additional requirements for excepted packages containing Class 7 (radioactive) materials,” a Class 7 (radioactive) material that meets the definition of a hazardous substance or a hazardous waste must comply with the shipping paper requirements of subpart C of Part 172. However, in accordance with § 173.421(b), a limited quantity of Class 7 (radioactive) material that is also a hazardous substance or hazardous waste is not subject to the provisions in § 172.203(d) or § 172.204(c)(4).

Q2: If § 172.203(d) is not required when preparing a shipping paper, would we be required to comply with the quantity requirements in § 172.202(a)(6)?

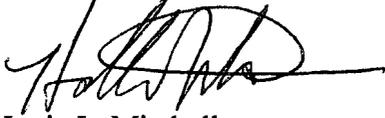
A2: The answer is yes. Irrespective of the requirements in § 172.203(d), for transportation by aircraft, when preparing a shipping paper for a Class 7 (radioactive) material, the quantity of radioactive material must be shown by activity.

Q3: Does the shipping description of “UN2910, RQ, Radioactive material, excepted package-limited quantity of material, Class 7, I-125 Metal, Solid, Packages X 1” meet the shipping paper activity requirement in § 172.202(a)(6)?

A3: The answer is no. For transportation by aircraft, the quantity of radioactive material must be shown by activity (i.e., the activity of the radioactive per unit mass of the nuclide).

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hattie L. Mitchell', with a long horizontal flourish extending to the right.

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Bard Urological Division

3/20/2009

Radioactive Material License:IL-02062-01

Device Registry: IL-1074-S-101-S

Mr. Michael Stevens
US DOT

Nickels
§ 172.202(a)(6)
§ 173.421(b)
Shipping Papers
09-0063

Dear Mr. Stevens,

I am requesting a letter of interpretation concerning the limited shipping paper requirement for the shipments of Iodine-125 (I-125) limited quantity, RQ that are made from the Bard Brachytherapy Inc. (BBI) facility, Carol Stream, IL. The interpretation I am requesting involves why BBI is exempted from the additional shipping paper requirements of 172.203(d), which are very detailed, but not exempt from the immediately preceding regulation 172.202(a)(6) a nonspecific regulation. I also request the USDOT to review the interpretation that by virtue of the shipping description used the total activity is described.

Background

We ship the I-125 limited quantity, RQ with a limited shipping paper. This limited shipping paper includes "UN2910, RQ, Radioactive material, Excepted Package-Limited Quantity of Material, Class 7, I-125 Metal, Solid, Packages X 1" on the document.

Included with this letter are copies of inspections by two agencies of the DOT that occurred four years ago within a month of each other. The same shipping paper was reviewed in detail at that time and a copy of the limited shipping paper was given to the inspector, also included. There were no compliance issues with the document at that time. I have reviewed the changes in the regulations since that time and have not been able to find any changes to the regulations that would affect the document in question.

In November 2008 during an inspection by Orde Duplessis, Hazardous Material Specialist with the Federal Aviation Administration (FAA), an issue concerning regulation 173.421(a)(6) and (b) was identified.

- The subpart 173.421(a)(6) refers to 173.422, which identifies further requirements specifically to comply with subpart C of 172 for shipping papers.
- 173.421(b) specifically exempts this shipping paper from 172.203(d) and 172.204(c)(4).
- 172.203(d) is the section that calls out the requirement to identify the radioactive material in specific units.

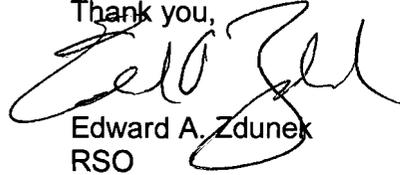
Interpretation

I have interpreted the 173.421(b) exemption to state that there is no requirement to list the activity on the shipping paper. This is a conflict with the less specific requirement in 172.202 (a)(6). Mr. Duplessis indicated that this does not exempt us from 172.202 (a)(6) which requires that we list the activity on the shipping paper, but does not specifically call out the units required.

If my interpretation above is inaccurate, I would also like to contend that we meet the requirements of 172.202 (a)(6). BBI 's limited shipping paper lists "UN2910, RQ, Radioactive material, Excepted Package-Limited Quantity of Material, Class 7, I-125 Metal, Solid, Packages X 1" as the proper shipping description. I contend that the information present in this shipping description is a description of activity in the package. Because the radionuclide is listed as I-125 the regulations specifically indicate the limited quantity for this radionuclide as 3000 MBq (81 mCi) and the RQ value as 370 MBq (10 mCi). The shipping description is an indication of activity within the package. All packages that have this description would have an activity between 3000 MBq (81 mCi) and the RQ value as 370 MBq (10 mCi) at the time of shipment.

If there are any questions about this letter please contact me at (630) 933-7618.

Thank you,

A handwritten signature in black ink, appearing to read "Ed Zdunek", written over the typed name and title.

Edward A. Zdunek
RSO