



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

APR 30 2010

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

Mr. Ken Ali
Radiation Safety Officer
Nuclear Diagnostic Products
101 Roundhill Drive
Rockaway, NJ 07866

Ref. No.: 10-0039R

Dear Mr. Ali:

This responds to your letter concerning whether it is a violation of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to place the RQ designation on a Dangerous Goods Declaration for "Iodine 131" (131) shipped by aircraft under the HMR.

According to your letter, a small percentage of your company's product is shipped by aircraft via FEDEX. For these shipments, you use a Dangerous Goods Declaration, as packages are classed as Radioactive Yellow II or Radioactive Yellow III. The main radionuclide your company ships is "Iodine 131" in a liquid compound form. When shipping "I-131" in amounts greater than 10 millicuries (0.37GBq), you use the RQ designation on packages and shipping documents in compliance with the definition in §171.8 for hazardous substances listed in §172.101, Appendix A, Table 2. You ask if your understanding is correct that since the amount being shipped is greater than the RQ for "I-131" [0.01 Ci (.00037TBq)] and qualifies as a hazardous substance, the HMR requires that you include the RQ designation on the Declaration of Dangerous Goods document.

Your understanding is correct. Based on the scenario described above, you are shipping a hazardous substance as defined in §171.8 since I-131 is listed in Table 2 to Appendix A in §172.101 and you are shipping in a quantity in one package in excess of the reportable quantity listed in the table. Thus, the letters "RQ" are required to be entered on the shipping paper per §172.203(c)(2) and shown on the package per §172.324(b).

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,

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

NUCLEAR DIAGNOSTIC PRODUCTS

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1/26/2010

Mr. Edward Mazzullo
Office of Hazardous Materials Safety Administration
US Department of Transportation
122 New Jersey Ave SE
Suite E 21316
Washington, DC 20590

Engram
§172.101
§172.201(a)(4)
Shipping Papers
10-0039

Dear Mr. Mazzullo:

My name is Ken Ali and I am the Radiation Safety Officer at Nuclear Diagnostic Products (NJ State License 10649/01 and former NRC Lic. # 29-30500). This is a commercial nuclear pharmacy located in Rockaway New Jersey, producing radioactive diagnostic imaging drugs for Nuclear Medicine departments at hospitals and other medical institutions.

A small percentage of our product is shipped via FedEx in which case we use a Dangerous Declaration Form, as packages fall under the DOT classification as Radioactive Yellow II or Radioactive Yellow III. The main radionuclide we ship by this method is Iodine 131 in a liquid compound form. When shipping I-131 amounts greater than 10 millicuries, (0.37GBq) we use the designation RQ on the package as well as on the shipping manifest / Dangerous Goods Declaration Form. This is in compliance with table 2 of 49CFR 172.101 that the Reportable Quantity for Iodine 131 is 0.01 Curies (10 millicuries) or (0.37GBq).

It is my interpretation that since the amount being shipped is greater than the RQ amount, the material in question now qualifies as a **Hazardous Substance** under the definition set forth in Section 172.101 paragraph 6 and table 2 and section 171.8-Hazardous Substance paragraph 2.

On Wednesday January 20, 2010, the Federal Aviation Authority inspected this facility and found no violations. As part of the general counseling and discussions about forms and changes in the future, we discussed the placement of the letters RQ on the Dangerous Goods Declaration form. Subsequent to the Inspector's visit I received a communication from him stating that he did not advise using the RQ designation for Class 7 RAM (Radioactive Materials) on the manifest. To support his rationale, the inspector cited the interpretation of PHMSA document Ref.# 05-0247R.

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I was of the opinion that the inspector did not take into consideration the amount (in millicuries) of material being shipped, which automatically qualifies it as a Hazardous Substance. This is so based on quantity only, regardless of presence/absence of any specific chemical or other harmful properties and must be designated by the RQ marking on manifest as well as the package.

On January 22, 2010, I spoke to Andrew and later Rob from your department who agreed with my interpretation of the requirements of the regulations with reference to the directive of Reference letter 05-0247R.

In a conversation earlier today 1/26/2010, the FAA inspector *still maintains* the position that the RQ designation is not necessary on our packages even when the radioactive material Iodine 131, being shipped exceeds the RQ value of 0.01Curies.

While I have the utmost respect for the rule and interpretation of the letter of the law by the regulatory agencies, I do sincerely believe that there is a slight misinterpretation by the FAA Inspector of the content of your ruling 05-0247R and its applicability to product being shipped from this facility.

Your written guidance is now sought as to whether we should continue with the practice of identifying RQ amounts on manifests and packages containing greater than 0.01Curies(0.37GBq) of Iodine 131, offered for shipment, which my humble interpretation supports, or whether we should discontinue such practice based on the content of your directive Reference 05-0247R.

Regards



Ken Ali

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