



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

September 14, 2010

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

SUBJECT: REQUEST TO AMEND SEALED SOURCE AND DEVICE REGISTRATION
NR-1235-S-102-S

This letter is in response to your amendment request dated August 9, 2010, to increase the maximum activity for source models BM06E-68 and BM06S-68 from 0.5 millicuries to 1.2 millicuries. In reviewing your request, we find that additional information is required to complete our review. In the enclosure of this letter, we have summarized the issues not addressed in your letter.

Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions, please contact me at john.odonnell@nrc.gov or (301) 415-7908.

Sincerely,

/RA/

John O'Donnell, General Engineer
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosure

John J. Miller
International Isotopes, Inc.
September 14, 2010

1 Radiation Profiles

The dose rates provided in the table contained in your letter for the 1.2 mCi sources appear to be simple multiples of the dose rates previously provided for the 0.5 mCi sources by the stated factor of 2.4. In the certificate, it states that you originally measured the BM06E-68 prototype source and corrected for maximum activity. The certificate also states that you calculated the dose rates for BM06S-68 using MicroShield.

- 1.1 Please clarify which dose rates provided in your amendment request were measured and which were calculated or modeled.
- 1.2 Please describe how you validated dose rate modeling. If measurements were used for validation, provide a comparison of the calculated and measured data, preferably in table format. Provide instrumentation description and calibration documentation.

2 Drawings

The revised drawing you provided with the amendment letter dated August 9, 2010, to replace the drawing currently found in Attachment 2 of NR-1235-S-102-S is not of sufficient quality for scanning and including in the registration certificate. The source model identification has been removed from the drawing. The Standard Model Tables no longer specify Vial or Syringe. The Standard Model Table for Model BM06S appears much smaller than in the previous version complicating legibility.

- 2.1 Please provide a reproducible drawing of the attachment, preferably in electronic form (e.g., pdf, jpg) suitable for inclusion in the certificate. The maximum space available for the drawing on the attachment page is approximately 6.5 inches tall by 8 inches wide in a landscape orientation. Please ensure that the tables and text labels in the drawing are legible within these constraints.
- 2.2 Please justify removing the source model numbers from the current drawing or replace them.
- 2.3 Please justify removing Vial and Syringe from the Standards Model Tables or replace them.

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Sincerely,
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John O'Donnell, General Engineer
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosure: As stated

Distribution: SSD Case: 10-37 Registration: NR-1235-S-102-S
R. Jones, Fees

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DATE	9/14/2010		9/14/2010		9/14/2010			

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