



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

May 7, 2009

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION. APPLICATIONS FOR SEALED
SOURCE AND DEVICE REGISTRATIONS FOR INTERNATIONAL ISOTOPES
MODEL BM10 SERIES SOURCES AND BMCY AND BMNT PHOTON
EMITTING SOURCES

Dear Mr. Miller,

This letter is in response to your applications dated February 23, 2009 for a sealed source and device registration certificate for the International Isotopes BM10 Series sources and the BMCY and BMNT photon emitting sources. A review of your applications indicated that they lack required information to complete our safety review and evaluation. In an Enclosure of this letter, we have summarized the issues that need to be addressed.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty 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 (301) 415-7135 or Mr. Ujagar Bhachu at 301-415-7984.

Sincerely,
/RA/
Stephen Poy
Licensing Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

May 7, 2009

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION. APPLICATIONS FOR SEALED
SOURCE AND DEVICE REGISTRATIONS FOR INTERNATIONAL ISOTOPES
MODEL BM10 SERIES SOURCES AND BMCY AND BMNT PHOTON
EMITTING SOURCES

Dear Mr. Miller,

This letter is in response to your applications dated February 23, 2009 for a sealed source and device registration certificate for the International Isotopes BM10 Series sources and the BMCY and BMNT photon emitting sources. A review of your applications indicated that they lack required information to complete our safety review and evaluation. In an Enclosure of this letter, we have summarized the issues that need to be addressed.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty 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 (301) 415-7135 or Mr. Ujagar Bhachu at 301-415-7984.

Sincerely,
/RA/
Stephen Poy
Licensing Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

DISTRIBUTION: R. Jones, Fees

ML091270468

OFFICE	FSME/LB	FSME/LB	FSME/LB
NAME	Stephen Poy	Ujagar Bhachu	John Jankovich
DATE	5/7/2009	5/7/2009	5/7/2009

ENCLOSURE

A. Questions for the BM10 Series Sources

1. Description/Construction:

1.1 Please clarify the principle use and principle use code.

The principle use is identified in the summary data as being a Medical Reference Source and a code of W is given. Medical Reference Sources are designated as X. Please clarify this discrepancy.

2. Labeling:

2.1 Please provide complete details of the labeling of the product, including information contained on the label and how and where the label is attached. Specifically, address whether the information is engraved or a separate label is attached on to the source. If attached, please describe the method of attachment.

3. Conditions of Use:

3.1 Please provide the estimated working life of the device.

3.2 Please provide information on maximum allowable temperature, vibration, shock, handling, storage, and transport.

4. Prototype Testing/Historical Use:

4.1 Under the section Manufacturer's Safety Analysis of Sealed Source Review, it is stated that 2 prototypes were used and tested as stipulated in ANSI/HPS N43.6-1997. The first contained 100 uCi's and the second contained 250 uCi's of Co-57.

Please provide information applicable to sources containing the maximum activity of 1.0 mCi as well.

5. Withholding of Proprietary Information:

5.1 Drawings B1001000, B1009001, and B003005 are labeled as proprietary. Please provide information as required by 10 CFR 2.390(4)(i)-(v) with regards to withholding this information from public disclosure and please include a notarized affidavit.

6. Reproducible Illustrations:

6.1 Please provide non-proprietary illustrations similar to drawings B1001000, B1009001, and B003005, preferably in electronic form, that are suitable for inclusion in the registration certificate.

B. Questions for the Model BMNT Source

1. Labeling:

- 1.1 Please provide complete details of the labeling of the product, including information contained on the label and how and where the label is attached. Specifically, address whether the information is engraved or a separate label is attached on to the source.

2. Conditions of Use:

- 2.1 Please provide the estimated working life of the device.
- 2.2 Please provide information on maximum allowable temperature, vibration, shock, handling, storage, and transport.

3. Prototype Testing/Historical Use:

- 3.1 Under the section Manufacturer's Safety Analysis of Sealed Source Review, it is stated that a prototype of 1.0 mCi of Co-57 was used and tested as stipulated in ANSI/HPS N43.6-1997.
- 3.2 Please provide information applicable to sources containing the maximum activity of 12.0 mCi as well.

4. Withholding for Proprietary Information:

- 4.1 Drawings RAD020309-1 and B900101 are labeled as proprietary. Please provide information as required by 10 CFR 2.390(4)(i)-(v) with regards to withholding this information from public disclosure and please include a notarized affidavit.

5. Reproducible Illustrations:

- 5.1 Please provide non-proprietary illustrations similar to drawings RAD020309-1 and B900101, preferably in electronic form, that are suitable for inclusion in the registration certificate.