



International Isotopes Inc.

May 21, 2009

Mr. Stephen Poy
Licensing Branch
Office of Industrial and Medical Nuclear Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Response to NRC Request for Additional Information – Applications for Sealed Source and Device Registrations for Models BM10 and BMCY/BMNT Photon Emitting Sources.

Dear Mr. Poy

The purpose of this letter is to provide you with a written response to your request for additional information (RAI) regarding the applications for sealed source device registrations for Model BM10 and Models BMCY/BMNT photon emitting sources. I have duplicated the RAIs that you identified in your May 7, 2009 letter and addressed each in the attached enclosure. In addition to hard copy drawings contained in the enclosure copies will be provided in electronic format as requested.

Should you have additional questions regarding the response to the RAIs please contact me at 208.524.5300 or via email at jjmiller@intisoid.com.

Sincerely,

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

cc:

J. J. Miller file (JJM-2009-40)

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.

Response to A. 1.1: This was a typographical error; the Principal Use is “Medical Reference Source (X)”.

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.

Response to A. 2.1: Each source and storage shield is conspicuously labeled with the radioisotope, the activity, the reference date (MM/YY) a unique serial number, the radioactive tri-foil symbol and the words, “Caution Radioactive Material”. The surface of this label material is a combination of rubber (latex) and paper. Below the surface is a thin film barrier coating to provide added strength. The material is flexible and water resistant. The label has an adhesive backing. Once applied to the source and shield a second clear label is applied over the data label to ensure the data remains legible throughout the life of the source. Refer to Drawing B1001000 for label placement. There is no intention to engrave the source.

3. Conditions of Use

3.1. Please provide the estimated working life of the device.

Response to A. 3.1: These sources are intended to be used in a laboratory or medical environment, not subjected to harsh conditions. Therefore the estimated working life of the source is most dependent on the half-life of the radioisotope. For Ge-68 and Co-57 models a working life of 2 years is typical. For Cs-137 and Ba-133 models the working-life of the source is estimated to be 10-15 years. However so long as the source satisfies the 6 month leak test criteria and the labeling remains intact, there is no reason to remove the source from service.

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

Response to A. 3.2: As mentioned above these sources are utilized in a laboratory or medical setting and are not subjected to harsh conditions during

normal operation. As mentioned in the application, prototype sources were successfully tested against ANSI/HPS N43.6-1997 classification, 97C22212, as such the source should not be subjected to conditions that exceed these test parameters which for clarity sake are provided below:

- Temperature: - 40°C to + 80°C
- External Pressure: 25 kN/m² abs
- Impact: 50 g from 1 m and free drop 10 times to steel surface from 1.5 m.
- Vibration: No test required for Class 1.
- Puncture: 1 g from 1 m.

In regards to handling and storage; the description of the source provided in the application as well as Drawing B1001000 indicates that the radionuclide is confined to the tip of the rod (the pointer). When not in use the pointer is threaded into the shield, this is the storage configuration. When the source is in use it is intended to be handled at the end opposite the pointer (the non-active end). The non-active end is threaded as well so that the shield can be threaded onto this end were it can act as a stand and to allow for the source to be handled comfortably in the palm of the hand. Note that a sufficient amount of distance between the pointer and the non-active end of the rod reduces the dose to the extremities when the source is being handled as intended with the pointer out of the shield. International Isotopes, Inc. distributes these sources to customers licensed by the NRC or an Agreement State or when sources are exported, licensed or authorized by the appropriate foreign authority.

The storage configuration mentioned above is also the transport configuration. These sources will be transported in compliance with the applicable requirements of Title 49 of the Code of Federal Regulations for Class 7 radioactive material. Newly manufactured sources are typically transported to the customer in a Type A package with Yellow II label. When decayed beyond their useful activity sources are expected to be returned as a limited quantity of radioactive material.

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.

Response to A. 4.1: Whenever possible, (internal void volume of the source exceeds 0.1 mL) INIS conducts ANSI/HPS N43.6-1997 testing using prototype sources that do not contain any radioactivity. These prototypes are

then leak tested through non-radioactive analysis. When leak testing cannot be conducted utilizing non-radioactive means, INIS tests prototype sources which contain a nominal amount of radioactivity. There is no reason to suspect that a prototype source containing the maximum activity of 1.0 mCi would perform any differently when subjected to the same test parameters than the two prototype sources tested. INIS believes it is completely justified to apply the test results obtained from the two prototypes to sources that contain the maximum quantity of radioactivity and that it would be unnecessary and contradictory to established radiation protection practices to test prototype sources at the maximum activity.

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)(l)-(v) with regards to withholding this information from public disclosure and please include a notarized affidavit.

Response to A. 5.1: Following careful consideration, INIS and RadQual, LLC agree that the details contained within the drawing can be released to the public. These drawings are provided containing a statement to this affect.

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.

Response to A. 6.1: Comment addressed in Response to A.5.1. Also note that Drawing B1001000 is intended for inclusion in the registration certificate. Drawings B1009001 and B003005, while authorized for public disclosure were included in the application package as part of the testing documentation and are not applicable and should not be included 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.

Response to B. 1.1: Each source (and storage shield provided as an option to customers that do not currently have a shield) is conspicuously labeled with the radioisotope, the activity, the reference date (MM/YY) a unique serial number, the radioactive tri-foil symbol and the words, "Caution Radioactive Material". The surface of this label material is a combination of rubber (latex) and paper. Below the surface is a thin film barrier coating to provide added strength. The material is flexible and water resistant. The label has an adhesive backing. Once applied a second clear label is applied over the data label to ensure the data remains legible throughout the life of the source. The data label will be applied to the side of the source. There is no intention to engrave the source.

2. Conditions of Use

- 2.1. Please provide the estimated working life of the device.

Response to B. 2.1: These sources are intended to be used in a laboratory or medical environment, not subjected to harsh conditions. Therefore the estimated working life of the source is most dependent on the half-life of the radioisotope. For Ge-68 and Co-57 sources a working life of 2 years is typical.

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

Response to B. 2.2: As mentioned above these sources are utilized in a laboratory or medical setting and are not subjected to harsh conditions during normal operation. As mentioned in the application, prototype sources were successfully tested against ANSI/HPS N43.6-1997 classification, 97C22312, as such the source should not be subjected to conditions that exceed these test parameters which for clarity sake are provided below:

Temperature: - 40°C to + 80°C
External Pressure: 25 kN/m² abs
Impact: 200 g from 1 m.
Vibration: No test required for Class 1.
Puncture: 1 g from 1 m.

In regards to handling and storage; several options, such as a

removable handle or flexible basket have been considered to limit the dose to the user while handling the source. None of these options are integral to the source itself and have not been included on the drawings or in the application itself. It is also expected that some end-users will currently have handling attachments and storage shields from previous sources and will procure a source without any options. Customers will be provided with the option to procure handling apparatus and storage shields. International Isotopes, Inc. will distribute these sources to customers licensed by the NRC or an Agreement State or when sources are exported, licensed or authorized by the appropriate foreign authority.

These sources will be transported in compliance with the applicable requirements of Title 49 of the Code of Federal Regulations for Class 7 radioactive material. Newly manufactured sources are typically transported to the customer in a Type A package with Yellow II label. When decayed beyond their useful activity sources are expected to be returned as a limited quantity of radioactive material.

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.

Response to B. 3.2: Whenever possible, (internal void volume of the source exceeds 0.1 mL) INIS conducts ANSI/HPS N43.6-1997 testing using prototype sources that do not contain any radioactivity. These prototypes are then leak tested through non-radioactive analysis. When leak testing cannot be conducted utilizing non-radioactive means, INIS tests prototype sources which contain a nominal amount of radioactivity. There is no reason to suspect that a prototype source containing the maximum activity of 12.0 mCi would perform any differently when subjected to the same test parameters than the 1.0 mCi prototype source tested. INIS believes it is completely justified to apply the test results obtained from the two prototypes to sources that contain the maximum quantity of radioactivity and that it would be unnecessary and contradictory to established radiation protection practices to test prototype sources at the maximum activity.

4. Withholding of Proprietary Information

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

Response to A. 4.1: Following careful consideration, INIS and RadQual, LLC agree that the details contained within the drawing can be released to the public. New drawings are provided containing a statement to this affect.

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.

Response to B. 5.1: Comment addressed in Response to B.4.1.