International Isotopes Inc.

December 31, 2012

Mr. Stephen Poy
US Nuclear Regulatory Commission
11545 Rockville Pike, MS T8E24
Rockville, MD 20852

Subject: Response to Request for Additional Information Regarding Application to Amend NR-1235-S-102-S

Dear Mr. Poy,

The following additional information is provided to support my request to amend Sealed Source and Device Registry NR-1235-S-102-S.

1. *Description/Construction*.

1.1. Please provide a drawing of BM06V5, BM06V10, and BM06V20 Series models with the dimension markings clearly shown offset from the representation of the vial.

Response:

A revised drawing is provided.

1.2. Please clearly indicate on the drawing where on the vials the nominal height and nominal diameter are being measured.

Response:

A revised drawing is provided.

1.3. Please provide statements that the assembly methods of the BM06V5, BM06V10, and BM06V20 Series models are the same as the other Model BM06 Series sealed sources in current registration.

Response:

The assembly methods of the BM06V5, BM06V10, and BM06V20 Series models are the same as the other Model BM06 Series sealed sources in the current registration NR-1235-102-S. This method consists of mixing the radionuclide solution in a two part epoxy. The epoxy containing the homogenously distributed radioisotope is then transferred into the source body and allowed to cure. After curing the source body is backfilled with a layer of epoxy that does not contain the radioisotope. After the cold layer has cured the source cap is fixed onto the source body.

1.4. Please provide a statement indicating that the BM06V5, BM06V10, and BM06V20 Series models will also be supplied to the customer in a shielded storage pig.

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Response:

The BM06V5, BM06V10, and BM06V20 Series models will be supplied to the customer in a shielded storage pig.

2. *Labeling*

2.1. Please provide statements indicating that the labeling of the BM06V5, BM06V10, and BM06V20 Series models will be the same as the other models in the current registration.

Response:

The BM06V5, BM06V10, and BM06V20 Series models will be labeled the same as the other Model BM06 Series sealed sources in the current registration NR-1235-102-S.

3. Conditions of Use

3.1. Please provide statements indicating that the conditions of the BM06V5, BM06V10, and BM06V20 Series models will be the same as the other models in the current registration.

Response:

The BM06V5, BM06V10, and BM06V20 Series models are intended to be used under the same conditions as the other models in the current registration, NR-1235-S-102-S, which are intended for use as calibration and reference standards to check the response of dose calibrators used in the assay of research, diagnostic, and therapeutic radiopharmaceuticals.

4. Prototype Testing

4.1. Please provide information indicating that although the prototype tests were conducted on sources of activities up to 220 uCi of Germanium-68, the results are applicable for sources up to 1.2 mCi of Germanium-68.

Prototype testing was conducted on 6 sources ranging in activity from 55.4 uCi to 220 uCi. The prototype sources were constructed from a single batch of epoxy mixed with the Ge-68 isotope. The BM06V20, (a 20 cc vial) contains 220 uCi of Ge-68. The BM06V5 (a 5 cc vial) contains about ¼ the activity of the BM06V20. The BM06V10 (a 10 cc vial) contains about ½ the activity of the BM06V20.

The method of assembly of the source design does not support non-radioactive leakage testing methods described in ISO 9978, *Sealed radioactive sources – Leakage test methods*, therefore the prototype testing must be conducted on sources containing radioactivity. The activity range was selected to ensure that a sufficient amount of radioactivity would be available to detect the presence of leakage and the corresponding maximum activity was low enough to limit the dose received to the individual

conducting the test. It is appropriate to apply the leak test results from the prototype sources to a source at the maximum activity of 1.2 mCi for the following reasons.

(1) All of the prototype sources remained intact following the tests and no radioactivity above the minimum detectable activity (MDA) was detected following each test.

(2) The MDA of the instruments used to obtain the contamination results was low enough to detect contamination at a level that would indicate leakage, even after considering the difference in tested prototype activity and the maximum activity. For example, prototype source BM06V5-1 contained approximately 40 uCi of Ge-68 at the Post 7 day wipe test. The maximum authorized activity of 1.2 mCi is 30 times greater than the activity of the tested source. To satisfactorily pass the leak test, removable contamination cannot exceed 185 Bq. Correlating the results of the 40 uCi prototype source that was tested to a source containing the maximum activity of 1.2 mCi requires reducing the criteria to pass the leak test from 185 Bq to 6.17 Bq, (185 Bq ÷ 30). The MDA of the instrument used in the Post 7 day wipe test was equal to 5.78E-5 uCi or 2.14 Bq, so the result of < MDA is below the 6.17 Bq criteria, indicating a successful test.

4.2. Please provide information indicating that although only prototype tests were conducted on sources containing Germanium-68, the tests are applicable for sources containing the other isotopes included in the sealed source registration (i.e. Cobalt-60, Barium-133, Cesium-137, Sodium-22 and Cobalt-57).

When possible prototype sources are manufactured without any radioactive material and non-radioactive leak testing methods are used to verify the integrity of the source design following the tests. In all of the BM06 series source models, the radioisotope is mixed with a two part epoxy (Emerson and Cuming Stycast 1264 A/B), which is transferred into the source body and allowed to cure. This method of assembly does not lend itself to non-radioactive leak test methods and therefore requires that the prototype sources contain a radioactive element. Ge-68 was arbitrarily selected as the radioisotope for use in the prototype sources that were tested because other studies with Ge-68 were being conducted at the time. The epoxy used in the assembly of the BM06 series source models has been used for over 10 years by International Isotopes Inc. in the manufacturing of nuclear medicine calibration and reference sources containing, Ba-133, Co-57, Co-60, Cs-137, Ge-68 and Na-22. All of the radioisotopes mentioned are contained in an acidic solution (HCl, HNO_3 or CH_3CO_2H) in low enough volumes to allow complete curing of the epoxy. Because there is no adverse chemical reaction between the various solutions containing the radioisotopes and the epoxy we believe it is appropriate to apply the results of the Ge-68 prototype sources to the sources containing the other radioisotopes that are offered, i.e. Ba-133, Co-57, Co-60, Cs-137 and Na-22.

4.3. In the information provided with the prototype testing, each test result under the ANSI/HPS N43.6-2007 Classification lists the tested classification as 22313. Should the tested classification be listed as 22312?

Response:

The puncture test was conducted using a puncture hammer dropped from 1 meter and weighing 13.1 grams, slightly exceeding the hammer weight of the Class 3 puncture test. The weight of the puncture hammer was recorded in the Prototype Testing Notes section on Page 3 of 3 on the International Isotopes Inc. Sealed Source Testing, Evaluation, and Documentation Form. To be consistent with the other BM06 series models a Classification of 22312 is being claimed, even though the prototype sources were tested at the Class 3 puncture test.

5. Radiation Profiles

5.1. In the amendment request letter dated August 24, 2012, it states on page 6 of 6, "Radiation measurements where (sp?) obtained on the prototype sources, corrected to the maximum activity levels and found to be within ± 15% of the modeled results at the 30 cm and 100 cm distances." Please provide the data from the referenced MicroShield calculations and the prototype measurements that supports this statement. In evaluating the data for Models BM06V5-68, BM06V10-68, and BM06V20-68, it is unclear which data is being compared with respect to the information provided in your application. In the prototype testing you have provided six model BM06V series prototype sources containing Ge-68 at levels of activity ranging from 55.4 uCi to 220 uCi. In the provided MicroShield calculations, there are calculations for dose rates for models BM06V5-68, BM06V10-68, and BM06V20-68 for 0.5 mCi of Ge-68. Can you provide information to clarify what data is being compared? Can you provide statements regarding the rationale behind the varying activity levels of the sources being compared?

Response:

Additional radiation profile tables and explanations are provided for clarification.

Radiation profiles for the Models BM06V5-33, BM06V10-33, and BM06V20-33 containing 250 uCi (nominal activity) of Ba-133 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the maximum activity of 500 uCi can be calculated by multiplying the results at the nominal activity by a factor of 2 (500/250). Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-33	250 uCi(1)	432	19	0.8	0.1
BM06V5-33	500 uCi(2)	864	38	1.6	0.2

BM06V10-33	250 uCi(1)	348	18	0.8	0.1
BM06V10-33	500 uCi(2)	696	36	1.6	0.2
BM06V20-33	250 uCi(1)	253	16	0.7	0.1
BM06V20-33	500 uCi(2)	506	32	1.4	0.2
Notes: (1) Nominal Activity, (2) Maximum Activity					

Radiation profiles for the Models BM06V5-37, BM06V10-37, and BM06V20-37 containing 200 uCi (nominal activity) of Cs-137 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the maximum activity of 500 uCi can be calculated by multiplying the results at the nominal activity by a factor of 2.5 (500/200). Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-37	200 uCi(1)	375	16	0.7	0.1
BM06V5-37	500 uCi(2)	937.5	40	1.75	0.25
BM06V10-37	200 uCi(1)	301	16	0.7	0.1
BM06V10-37	500 uCi(2)	752.5	40	1.75	0.25
BM06V20-37	200 uCi(1)	222	14	0.6	0.1
BM06V20-37	500 uCi(2)	555	35	1.5	0.25
Notes: (1) Nominal Activity, (2) Maximum Activity					

Radiation profiles for the Models BM06V5-60, BM06V10-60, and BM06V20-60 containing 50 uCi (nominal activity) of Co-60 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the maximum activity of 100 uCi can be calculated by multiplying the results at the nominal activity by a factor of 2.0 (100/50). Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-60	50 uCi(1)	370	16	0.7	0.1
BM06V5-60	100 uCi(2)	740	32	1.4	0.2
BM06V10-60	50 uCi(1)	297	16	0.7	0.1
BM06V10-60	100 uCi(2)	594	32	1.4	0.2
BM06V20-60	50 uCi(1)	218	14	0.6	0.1
BM06V20-60	100 uCi(2)	436	28	1.2	0.2
Notes: (1) Nominal Activity, (2) Maximum Activity					

Radiation profiles for the Models BM06V5-22, BM06V10-22, and BM06V20-22 containing 200 uCi (nominal activity) of Na-22 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the maximum activity of 500 uCi can

be calculated by multiplying the results at the nominal activity by a factor of 2.5 (500/200). Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-22	200 uCi(1)	1362	59	2.4	0.2
BM06V5-22	500 uCi(2)	3405	147.5	6	0.5
BM06V10-22	200 uCi(1)	1095	57	2.4	0.2
BM06V10-22	500 uCi(2)	2737.5	142.5	6	0.5
BM06V20-22	200 uCi(1)	806	52	2.3	0.2
BM06V20-22	500 uCi(2)	2015	130	5.75	0.5
Notes: (1) Nominal Activity, (2) Maximum Activity					

Radiation profiles for the Models BM06V5-57, BM06V10-57, and BM06V20-57 containing 15 mCi (maximum activity) of Co-57 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the two most common source activities of 10 mCi and 5 mCi can be calculated by dividing the results obtained at the maximum activity by 1.5 (15/10) and 3.0 (15/5) respectively. Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-57	15 mCi(1)	5580	240	9.8	0.9
BM06V5-57	10 mCi(2)	3720	160	6.5	0.6
BM06V5-57	5 mCi(2)	1860	80	3.3	0.3
BM06V10-57	15 mCi(1)	4562	234	9.8	0.9
BM06V10-57	10 mCi(2)	3041.3	156	6.5	0.6
BM06V10-57	5 mCi(2)	1520.7	78	3.3	0.3
BM06V20-57	15 mCi(1)	3445	221	9.9	1
BM06V20-57	10 mCi(2)	2296.7	147.3	6.6	0.7
BM06V20-57	5 mCi(2)	1148.3	73.7	3.3	0.3
Notes: (1) Maximum Activity, (2) Nominal Activities					

Radiation profiles for the Models BM06V5-68, BM06V10-68, and BM06V20-68 containing 500 uCi (nominal activity) of Ge-68 were modeled at 0, 5, 30 and 100 cm using MicroShield 6.22. The radiation profiles at the maximum source activity of 1.2 mCi can be calculated by multiplying the results obtained at the nominal activity by 2.4 (1.2/.5). Dose rates are given in units of mr/hr.

Model	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-68	0.5 mCi(1)	1578	68	2.8	0.3
BM06V5-68	1.2 mCi(2)	3787.2	163.2	6.7	0.7
BM06V10-68	0.5 mCi(1)	1269	66	2.8	0.3
BM06V10-68	1.2 mCi(2)	3045.6	158.4	6.7	0.7

BM06V20-68	0.5 mCi(1)	936	61	2.7	0.3
BM06V20-68	1.2 mCi(2)	2246.4	146.4	6.5	0.7
Notes: (1) Nominal Activity, (2) Maximum Activity					

In addition to the MicroShield model, dose rates were also obtained on the six prototype sources. The range of activity associated with the prototype sources is a function of the active source volume for each of the source geometries. The prototype sources were assembled using a single batch of epoxy mixed with the Ge-68 radioisotope. The BM06V20, (a 20 cc vial) contains 220 uCi of Ge-68. The BM06V5 (a 5 cc vial) contains about ¼ the activity of the BM06V20. The BM05V10 (a 10 cc vial) contains about ½ the activity of the BM06V20. The amount of activity was not selected specifically to measure the radiation profile, but instead was selected to provide a sufficient amount of activity to be able to reliably detect leakage should a source fail a performance test while maintaining the dose rate low enough to reduce the exposure to the individual conducting the tests. It is also important to note that the dose rates were obtained on the sources following a period of decay.

Prototype	Reference Activity (04/16/2012)	Activity at time of survey (08/22/2012)
BM06V5-1	55.4 uCi	39.9 uCi
BM06V5-2	57.7 uCi	41.6 uCi
BM06V10-1	109.7 uCi	79.1 uCi
BM06V10-2	110.4 uCi	79.6 uCi
BM06V20-1	220.0 uCi	158.5 uCi
BM06V20-2	220.0 uCi	158.5 uCi

Net dose rates (gross dose rate – background dose rate), in units of mr/hr, measured from the prototype sources are provided in the table below:

Prototype	Activity(1)	0 cm	5 cm	30 cm	100 cm
BM06V5-1	39.9 uCi	20.91	3.81	0.26	0.02
BM06V5-2	41.6 uCi	20.91	3.91	0.26	0.02
BM06V10-1	79.1 uCi	49.91	6.16	0.46	0.04
BM06V10-2	79.6 uCi	49.91	6.16	0.46	0.05
BM06V20-1	158.5 uCi	79.91	12.91	0.91	0.1
BM06V20-2	158.5 uCi	79.91	19.91	0.91	0.09
Notes: (1) Activity at time of survey					

A comparison can be made between the actual measured dose rates and dose rates calculated via MicroShield. The first step in this comparison is to correct the measured dose rate by multiplying the results by the Modeled Activity ÷ Measured Activity; in the

case of prototype source BM06V5-1 this factor = 500/39.9. Once the measured dose rate has been correct to the modeled activity, the corrected measured dose rate can be compared against the MicroShield modeled dose rate. Comparisons for all of the prototype sources are provided in the table below.

Prototype	Activity	0 cm	5 cm	30 cm	100 cm
BM06V5-1(1)	39.9 uCi	20.91	3.81	0.26	0.02
BM06V5-1(2)	500 uCi	262.0	47.7	3.258	0.251
BM06V5-1(3)	500 uCi	1578	68	2.80	0.30
MicroShield / Corrected:		6.02	1.42	0.86	1.20
BM06V5-2(1)	41.6 uCi	20.91	3.91	0.26	0.02
BM06V5-2(2)	500 uCi	251.3	47.0	3.125	0.240
BM06V5-2(3)	500 uCi	1578	68	2.80	0.30
MicroShield / Corrected:		6.28	1.45	0.90	1.25
BM06V10-1(1)	79.1	49.91	6.16	0.46	0.04
BM06V10-1(2)	500 uCi	315.5	38.9	2.908	0.253
BM06V10-1(3)	500 uCi	1269	66	2.800	0.30
MicroShield / Corrected:		4.02	1.70	0.96	1.19
BM06V10-2(1)	79.6	49.91	6.16	0.46	0.05
BM06V10-2(2)	500 uCi	313.5	38.7	2.889	0.314
BM06V10-2(3)	500 uCi	1269	66	2.80	0.30
MicroShield / Corrected:		4.05	1.71	0.97	0.96
BM06V20-1(1)	158.5	79.91	12.91	0.91	0.1
BM06V20-1(2)	500 uCi	252.1	40.7	2.871	0.315
BM06V20-1(3)	500 uCi	936	61.0	2.70	0.30
MicroShield / Corrected:		3.71	1.50	0.94	0.95
BM06V20-2(1)	158.5	79.91	12.91	0.91	0.09
BM06V20-2(2)	500 uCi	252.1	40.726	2.871	0.284
BM06V20-2(3)	500 uCi	936	61.0	2.70	0.30
MicroShield / Corrected:		3.71	1.50	0.94	1.06
Notes:	(1) Actual measured dose rates (mr/hr)				
	(2) Measured dose rates corrected to modeled activity (mr/hr)				
	(3) MicroShield modeled dose rates (mr/hr)				

In all cases the MicroShield calculated dose rates are significantly higher than the corrected measured dose rates at the 0 cm (on-contact) position. There are two factors

that contribute to this disagreement; one is the limitation with MicroShield when modeling dose rates at close proximity to the source, and a second is the result of the detector being located internal to the survey meter so a true contact measurement is not being obtained.

At the 5 cm position the MicroShield modeled dose rates are somewhat higher than the corrected measured dose rates by factors ranging from 1.42 to 1.71. Again, this disagreement can be attributed to the same factors mentioned above but the effect becomes less as the distance between the source and the survey point increases.

At the 30 and 100 cm positions the MicroShield model and the corrected dose rates are in close agreement.

For purposes of the source registry I suggest that the MicroShield modeled dose rates (mr/hr) associated with the maximum authorized activity be recorded in the radiation profile.

Model	Contact Dose	Dose at 5 cm	Dose at 30 cm	Dose at 100 cm
BM06V5-33	864	38	1.6	0.2
BM06V5-37	937.5	40	1.75	0.25
BM06V5-60	740	32	1.4	0.2
BM06V5-22	3405	147.5	6	0.5
BM06V5-57	5580	240	9.8	0.9
BM06V5-68	3787.2	163.2	6.7	0.7
BM06V10-33	696	36	1.6	0.2
BM06V10-37	752.5	40	1.25	0.25
BM06V10-60	594	32	1.4	0.2
BM06V10-22	2737.5	142.5	6	0.5
BM06V10-57	4562	234	9.8	0.9
BM06V10-68	3045.6	158.4	6.7	0.7
BM06V20-33	506	32	1.4	0.2
BM06V20-37	555	35	1.5	0.25
BM06V20-60	436	28	1.2	0.2
BM06V20-22	2015	130	5.75	0.5
BM06V20-57	3445	221	9.9	1
BM06V20-68	2246.4	146.4	6.5	0.7

6. *Quality Assurance*

   6.1. *Please provide information indicating that for the BM06V5-68, BM06V10-68, and BM06V20-68 Series models, the same Quality Assurance/Quality Control measures will be used as for the other models in the current registration.*

   Response:

   The BM06V5, BM06V10, and BM06V20 Series models will be manufactured and distributed using the same Quality Assurance/Quality Control measures as the other Model BM06 Series sealed sources in the current registration NR-1235-102-S.

Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.

Sincerely,

John J. Miller, CHP

JJM-2012-41