International Isotopes Inc.

November 16, 2006

Dr. John Jankovich
US Nuclear Regulatory Commission
Mail Stop 8F5
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852

Subject: Request to Amend NR-1235-S-102-S.

Dear Dr. Jankovich,

International Isotopes Inc. requests to amend Registry of Sealed Sources and Devices Safety Evaluation of Sealed Source Number NR-1235-S-102-S to include a source geometry that replicates that of a syringe. International Isotopes Inc. considers the syringe geometry as an improvement over the standard 30 ml vial source geometry which is commonly utilized by many nuclear medicine facilities to calibrate instruments used to comply with § 35.63 *Determination of dosage of unsealed byproduct material for medical use* of Title 10 of the Code of Federal Regulations. As with the current BM06 Model, International Isotopes Inc. is the contracted manufacturing for the source which is distributed under the Bench/mark by RadQual label. Both companies are committed to provide the nuclear medicine industry with a calibration source geometry that closely resembles the actual dosage geometry. The companies have contracted with the United States National Institute of Standards and Technology to develop a NIST traceable standard for the syringe geometry.

The current NR-1235-S-102-S describes the Model BM06 series source. International Isotopes Inc. believes that it would be appropriate to include the new geometry in the current safety evaluation because:

(1) The syringe geometry has been successfully tested against the criteria listed in ANSI N 43.6 – 1997 and meets the classification 96C22312.

(2) The method of manufacturing the source matrix of the syringe and vial geometry utilizes the same methods and materials, (2 part high impact epoxy casting resin).

(3) Both geometries will be utilized for the same purpose and will be classified as a Medical Reference Source.

(4) Maximum source activities between the two geometries are the same along the model line.

(5) Source labeling, limitations of use and anticipated working life for both geometries are the same along model line.

The following suggested revisions to the current NR-1235-S-102 are provided with supporting justification provided as necessary.

Page 1. MODEL: Revise the Model to read; BM06E and BM06S Series.

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Website: www.intisoid.com

Page 2. DESCRIPTION: Revise the first paragraph to read:

"The Model BM06 Series are intended for use as reference standards to check the response of dose calibrators used to measure research, diagnostic, and therapeutic radiopharmaceuticals. The BM06 Series offers these reference standards in two differing geometries. The first of these is the 30 ml Vial Geometry referred to the BM06E. The second geometry is the 5 cc Syringe Geometry referred to as the BM06S. Both the BM06E and S Series consists of a radioisotope in a chloride or nitrate complex uniformly dispersed in high impact epoxy casting resin (Emerson & Cuming Stycast 1264 or equivalent) color coded to visually differentiate the radioisotopes, which is then cured in either a 30 ml dose calibrator vial or a facsimile a 5 cc syringe. The BM06E epoxy containing the dispersed radioactivity is sandwiched between two layers of epoxy which does not contain radioactive material. A rubber septum or equivalent material is chemically welded into the neck of the vial and a color coded (to visually differentiate the radioisotopes) screw top cap is chemically welded onto the vial so that disassembly without destruction of the vial is not possible. The syringe geometry consists of a body and cap manufactured with a translucent acrylic. The body is filled with a layer of epoxy containing dispersed radioactivity which is sealed beneath a layer of epoxy containing no radioactive material. A screw type acrylic cap, color coded to match the epoxy matirx is chemically welded into the body of the syringe so that disassembly without destruction of the syringe is not possible. Refer to the drawing provided in Attachment 2. Each source is supplied to the customer in a shielded storage pig".

As you will note that the source matrix in the syringe geometry is not "sandwiched" between two layers of cold epoxy. The reason for this is that the bottom of the "syringe body" has a slight taper to better simulate the taper found at the bottom of an actual syringe, filling this taper with inactive epoxy would negate this design feature.

Page 2. DESCRIPTION: Revise the second paragraph to read:

"The BM06 Series consists of tweleve models encompassing two geometries and six isotopes. The Table below summarizes the BM06 Series Model lines:

The BM06 Series Model Line		
Model Number	Isotope	Geometry
BM06E-33	Barium-133	30 ml vial
BM06E-37	Cesium-137	30 ml vial
BM06E-60	Cobalt-60	30 ml vial
BM06E-22	Sodium-22	30 ml vial
BM06E-57	Cobalt-57	30 ml vial
BM06E-68	Germanium-68	30 ml vial
BM06S-33	Barium-133	5 cc syringe
BM06S-37	Cesium-137	5 cc syringe
BM06S-60	Cobalt-60	5 cc syringe
BM06S-22	Sodium-22	5 cc syringe
BM06S-57	Cobalt-57	5 cc syringe
BM06S-68	Germanium-68	5 cc syringe

The Model BM06E is approximately 1.25 inches in diameter and 3.5 inches in height. The Model BM06S is approximately 0.625 inches in diameter and 2.94 inches in height".

Additional detail regarding the dimensions and the materials of these geometries is provided in the attached drawing.

Page 3, LABELING: Revise the labeling paragraph to read:

"Each source and storage pig is conspicuously labeled with the source isotope and activity and bears the warning "Caution: Radioactive Material" as well as the trefoil radiation symbol in magenta on a yellow background, the designer's name, and the name of the manufacturer. Each label also contains the source model number, serial number and a reference date for the source activity. The label will be affixed to the exterior of the source and will be laminated so that the label remains legible and is not degraded as a result of normal use. Refer to Attachment 1".

Page 3, PROTOTYPE TESTING: Revise the prototype testing paragraph to read:

"A prototype vial source, containing Co-57, designated as Model BM06E-57, was constructed and tested in accordance with ANSI N43.6-1997 and achieved a sealed source classification of ANSI 96C22312 (Calibration Source). Only a prototype BM06E-57 because the maximum activity of this model was significantly higher than the other models and a failure of the source that would release radioactive material would be more readily detected. There is no difference in the construction materials or assembly methods for the different models in the BM06E Series sources.

A prototype syringe source containing approximately 5 mCi of Co-57, designated as Model BM06S-57 was constructed and tested in accordance with ANSI/HPS N43.6-1997 and achieved a sealed source classification of ANSI 96C22312 (Calibration Source). Only the prototypes BM06S-57 was tested because the maximum activity of this model was significantly higher than the other models and a failure of the source that would release radioactive material would be more readily detected. There is no difference in the construction materials or assembly methods for the different BM06S Series sources".

Refer to the attached Sealed Source Testing report, Enclosure 1, for detail regarding the prototype test. Please note the test report summary references the Source Model Number as BM06-057-05. The original manufacturing plan had considered four syringe geometries, a 5 cc, 10 cc, 15 cc and 20 cc. Prototype testing was conducted on the 5 cc and 20 cc geometry. It was later decided to pursue an evaluation for the 5 cc geometry because the vast majority of doses are distributed in either a 3 or 5 cc syringe. Limiting the source model to a single syringe geometry supported simplifying the model identifiers to BM06E and BM06S. The safety evaluation could be amended at a future date should customer demand warrant manufacturing of the 10, 15 or 20 cc syringe geometry.

Page 4, EXTERNAL RADIATION LEVELS: Revise this section as follows:

"Radiation levels (in mrem/hr) associated with the Model BM06 Series Sources at the maximum authorized activity are provided in the table below:

Model	Activity	Contact	5 cm	30 cm	100 cm
BM06E-33	0.5 mCi	39	10	1.4	0.1
BM06E-37	0.5 mCi	45	12	1.6	0.1
BM06E-60	0.1 mCi	160	30	1.0	0.2
BM06E-22	0.5 mCi	470	78	6.0	0.6
BM06E-57	15 mCi	293	68	5.9	1.2
BM06E-68	0.5 mCi	219	37	3.0	0.4
BM06S-33	0.5 mCi	456	49	1.7	0.2
BM06S-37	0.5 mCi	558	60	2.1	0.2
BM06S-60	0.1 mCi	352	38	1.4	0.1
BM06S-22	0.5 mCi	891	95	3.4	0.3
BM06S-57	15 mCi	1382	158	12	2.4
BM06S-68	0.5 mCi	377	40	1.4	0.1

Note: Dose rates for Models BM06E-57, BM06E-68 and BM06S-57 where measured on prototype sources manufactured by International Isotopes Inc. and corrected to the maximum activities for these sources. Dose rates for Models BM06E-33, 37, 60 and 22 where measured on NIST traceable sources of similar construction and geometry and corrected to the maximum activities for these sources. Dose rates for Models BM06S-33, 37, 60, 22 and 68 where calculated using MicroShield® Version 6.1."

A new source label is provided for use in Attachment 1.

An updated drawing is provided for use in Attachment 2.

The sealed source testing procedure and results are provided as Enclosure 1.

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

November 16, 2006
JJM-2006-40

Enclosure 1

Sealed Source Prototype Testing

Model BM06S

1.0 Purpose

1.1 To provide a standardized method of leak testing Syringe Dose Calibrator (BM06XXX-SXX) Sources in order to qualify these products as Sealed Sources.

2.0 Potential Hazards

2.1 The potential of radiation exposure and/or contamination exists during the performance of this procedure. Dosimetry and appropriate PPE should be worn and caution exercised while performing this procedure. This procedure is to be performed by trained operators who must take appropriate steps to minimize radiation exposure to themselves and surrounding personnel and must follow all radiation and safety procedures.

3.0 Applicability and Limitations

3.1 This procedure is to be used to leak test Syringe Dose Calibrator (BM06XXX-SXX) Sources in order to qualify these products as Sealed Sources

4.0 Definitions

4.1 None

5.0 Responsibilities

5.1 **I4 Quality** – Oversee the performance of this procedure and review the testing results.

5.2 **I4 Technician** – Assist with the performance of this procedure as required.

6.0 Equipment and Materials

6.1 Sealed Source prototype, fabricated per draft instructions.

6.2 Dry Ice

6.3 Antifreeze Bath

6.4 Oven

6.5 Testing Hammer #1, 200 grams, used for the impact test

6.6 Testing Hammer #2, 1 gram, used for the puncture test

6.7 Steel plate, used as backing for the impact and puncture tests

7.0 Procedure

7.1 Preparation and Staging for Sealed Source Testing

7.1.1 Verify that the prototype sources are complete and ready for testing.

Verification performed by _____ Date 9/25/06

7.1.2 Stage the required materials and equipment in the testing area(s).

Materials staged by _____ Date 9/25/06

7.2 Impact Tests

7.2.1 Place the steel plate on the floor where the impact testing will be performed.

7.2.2 Place the source on the steel plate.

7.2.3 Position the 200 gram testing hammer at least 1 meter above the source.

7.2.4 Drop the testing hammer on the source.

7.2.5 Perform a dry wipe test on the source as follows:

7.2.5.1 Wipe all external surfaces of the source with a piece of dry filter paper.

7.2.5.2 Measure the activity on the filter paper and record on the data page at the end of this procedure.

7.2.6 Repeat Section 7.2 for other source variations to be tested.

7.3 Puncture Tests

7.3.1 Place the steel plate on the floor where the puncture testing will be performed.

7.3.2 Place the source on the steel plate.

7.3.3 Position the 1 gram testing hammer at least 1 meter above the source with the pin down.

7.3.4 Drop the testing hammer on the source.

7.3.5 Perform a dry wipe test on the source as follows:

7.3.5.1 Wipe all external surfaces of the source with a piece of dry filter paper.

7.3.5.2 Measure the activity on the filter paper and record on the data page at the end this procedure.

7.3.6 Repeat Section 7.3 for other source variations to be tested

7.4 External Pressure Test

7.4.1 Place the source in the testing chamber.

7.4.2 Seal the Test Chamber.

7.4.3 Draw a vacuum on the test chamber of at least 9.8 psiv.

7.4.4 Hold the vacuum for five minutes.

7.4.5 Vent the chamber and allow it to return to atmospheric pressure.

7.4.6 Draw a vacuum on the test chamber of at least 9.8 psiv.

7.4.7 Hold the vacuum for five minutes.

7.4.8 Vent the chamber and allow it to return to atmospheric pressure.

7.4.9 Remove the source from the testing chamber and perform a dry wipe test as follows:

7.4.9.1 Wipe all external surfaces of the source with a piece of dry filter paper.

7.4.9.2 Measure the activity on the filter paper and record on the data page at the end of this procedure.

7.4.10 Repeat Section 7.4 for other source variations to be tested

7.5 Low Temperature Test

7.5.1 Prepare a bath of antifreeze solution sufficient to immerse the source completely.

7.5.2 Place the dry ice in the bath.

7.5.3 Monitor the temperature of the bath.

7.5.4 When the temperature of the bath reaches –40°C (–40°F), place the source in the bath and record the start time on the data page at the end of this procedure).

7.5.5 Monitor the bath temperature for at least twenty minutes.

NOTE: The bath temperature must remain below -40°C (–40°F) for at least Twenty minutes.

7.5.6 Record the stop time on the data page at the end of this procedure.

7.5.7 Remove the source from the bath and perform a dry wipe test as follows:

7.5.7.1 Wipe all external surfaces of the flood source with a piece of dry filter paper.

7.5.7.2 Measure the activity on the filter paper and record on the data page at the end of this procedure.

7.5.8 Repeat Section 7.5 for other source variations to be tested

7.6 High Temperature Test

7.6.1 Preheat the oven to 80°C (176°F), record the start time on the data page at the end of this procedure.

7.6.2 Monitor the oven temperature for at least sixty minutes.

NOTE: The oven temperature must remain above 80°C (176° F) for at least sixty minutes.

7.6.3 Record the stop time on the data page at the end of this procedure.

7.6.4 Remove the source from the oven and perform a dry wipe test as follows:

7.6.4.1 Wipe all external surfaces of the source with a piece of dry filter paper.

7.6.4.2 Measure the activity on the filter paper and record on the data page at the end of this procedure).

7.6.5 Repeat Section 7.6 for other source variations to be tested

7.7 Data Analysis

7.7.1 I4 Quality review the data collected and recorded on the data page.

NOTE: THE SOURCES SHALL PASS AS LEAK FREE IF THE MEASURED ACTIVITY ON EACH OF THE SWIPES IS LESS THAN 5 NCI.

7.8 Conclusion

7.8.1

Source	Pass	Fail	Data Analysis Performed By
BM06-XXXS5	X		
BM06-XXX20S	X		

8.0 References

8.1 ANSI/HPS N43.6-1997

Date - 9/26/06

Test	BM06-XXXS05 – 5mL Syringe Dose Calibrator Source Test Results			
Low Temp	Start Time 1030	Stop Time 1100	Swipe Results 51	Recorded By
High Temp	Start Time 0900	Stop Time 1015	Swipe Results 41	Recorded By
External Pressure	Start Time ~~0900~~ 1115	Stop Time 1200	Swipe Results 50	Recorded By
Impact	Start Time 0830	Stop Time 0840	Swipe Results 45cpm	Recorded By
Puncture	Start Time 0840	Stop Time 0850	Swipe Results 42cpm	Recorded By

Test	BM06-XXXS20 – 20mL Syringe Dose Calibrator Source Test Results			
Low Temp	Start Time 1030	Stop Time 1100	Swipe Results 50	Recorded By
High Temp	Start Time 0900	Stop Time 1015	Swipe Results 40	Recorded By
External Pressure	Start Time 1115	Stop Time 1200	Swipe Results 46	Recorded By
Impact	Start Time 0830	Stop Time 0840	Swipe Results 48cpm	Recorded By
Puncture	Start Time 0840	Stop Time 0850	Swipe Results 41cpm	Recorded By

Source Model Number:	BM06-057S05

Instrument Data

Instrument	Serial No.	Cal. Due	Efficiency	Background Count Rate R_b (cpm)	Sample Count Time t_s (min)	Background Count Time t_b (min)	MDA (uCi)
Ludlum 2000	99223	6/1/07	20%	49	1 minute	10 minutes	6.1E-5

$$MDA = 4.5E\text{-}7 \times \{3 + 3.29[(R_b t_s(1+(t_s/t_b))^{1/2}]\}/\{Efficiency \times t_s\}$$

Wipe Test Results

Test	Start time	Stop time	Gross Count Rate (cpm)	Net Count Rate (cpm)	Activity (uCi)	Recorded By
Low Temp:	1030	1100	51	2	<MDA	
High Temp:	0900	1015	41	-8	<MDA	
External Pressure:	1115	1200	50	1	<MDA	
Impact:	0830	0840	45	-4	<MDA	
Puncture:	0840	0850	42	-7	<MDA	

Radiation Profile Record

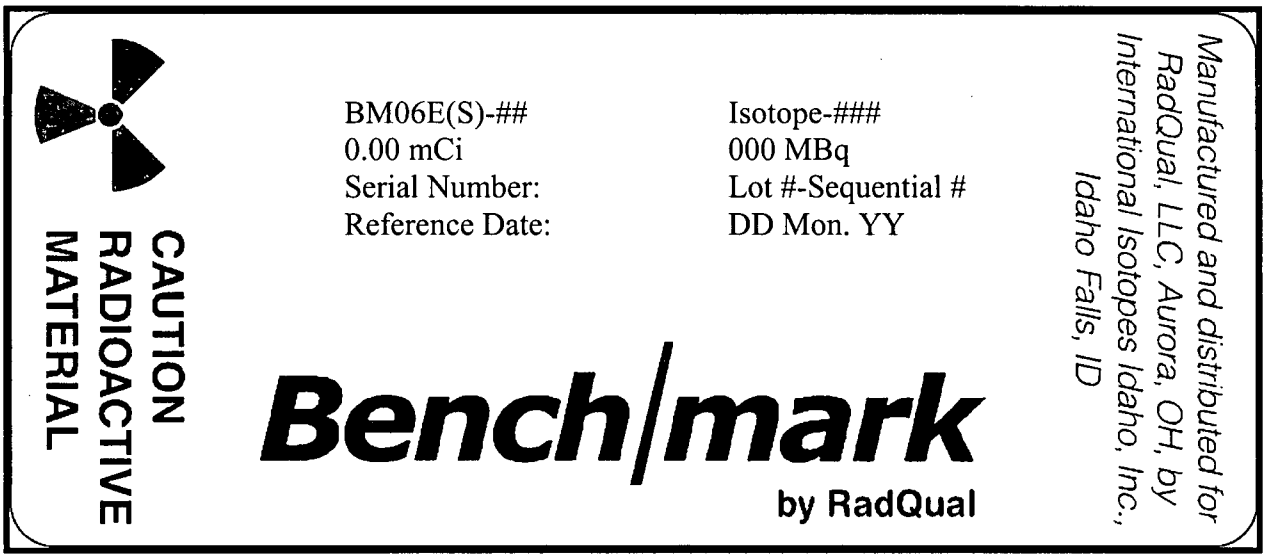
Instrument	Serial No.	Cal. Due		Source Activity:	3.8 mCi
Bicron Micro rem	B346V	6/1/06		Isotope:	Co-57
Ludlum Model 5	194973	7/12/06		Reference Date:	10/5/06

Exposure rates recorded by: Date: 10/5/06

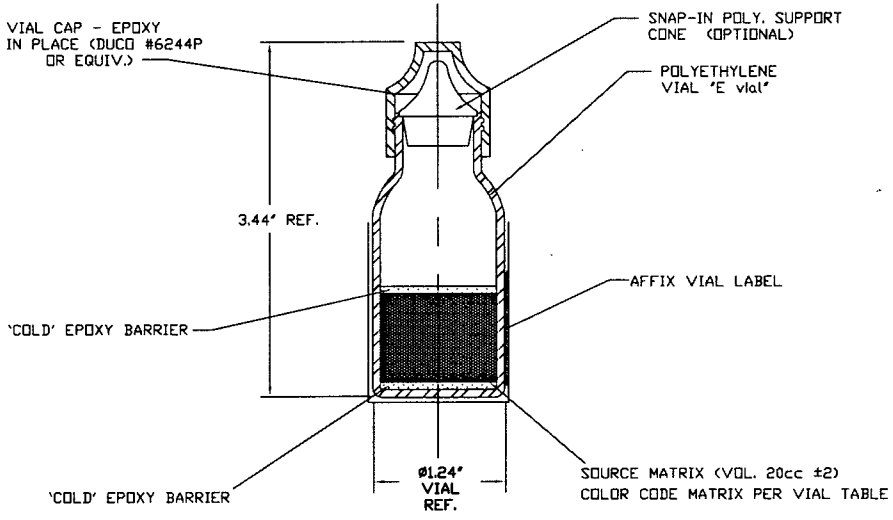
Location	Perpendicular to the YZ Plane		Perpendicular to the XZ Plane	
On-contact	350 mR/hr		350 mR/hr	
5 cm	40 mR/hr		40 mR/hr	
30 cm	3 mR/hr		3 mR/hr	
100 cm	0.6 mR/hr		0.6 mR/hr	

Additional Comments

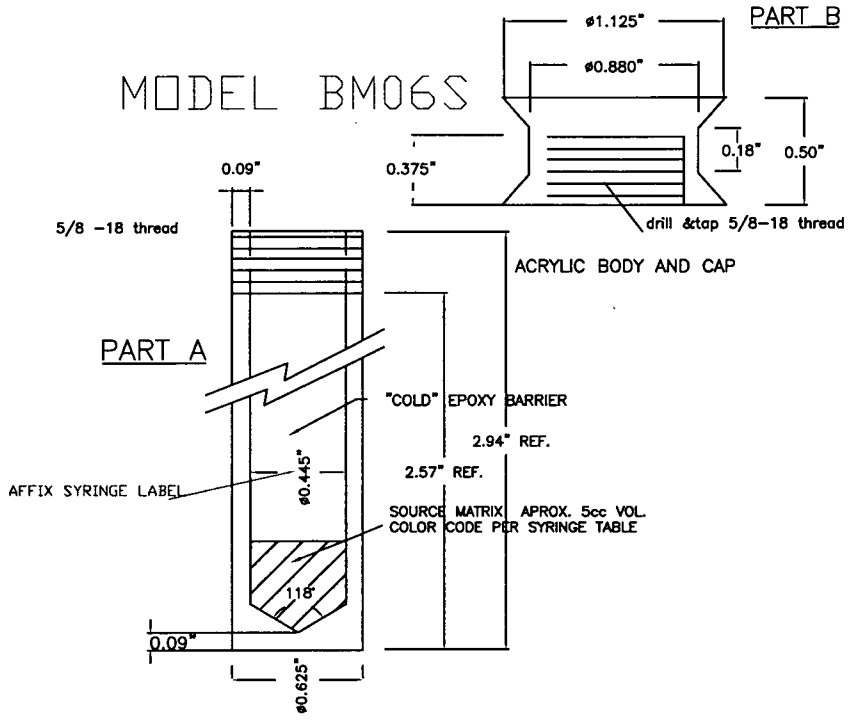
Source Label Example



MODEL BM06E



MODEL BM06S



VIAL STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	MAXIMUM ACTIVITY	COLOR CODE
-01	BM06E-22	Na-22	0.50 mCi	YELLOW
-02	BM06E-60	Co-60	0.10 mCi	BLUE
-03	BM06E-37	Cs-137	0.50 mCi	GREEN
-04	BM06E-33	Ba-133	0.50 mCi	BLK/GRY
-05	BM06E-57	Co-57	15.0 mCi	RED
-06	BM06E-68	Ge-68	0.50 mCi	WHITE

NOTES

1. SOURCE ACTIVITY CONSISTS OF RADIONUCLIDE DISPERSED UNIFORMLY IN A HIGH IMPACT EPOXY RESIN. RESIN MAYBE COLOR CODED PER TABLE USING EPOXY COLORING APPROPRIATE FOR STYCAST EPOXY (OR EQUIV).
2. PRODUCT ACTIVITY SHALL BE REFERENCED TO LABEL DATE. PRODUCT ACTIVITY TOLERANCE SHALL NOT BE > +20% NOR < -10% AT TIME OF SHIPMENT.
3. CONTAMINATION/LEAKAGE TESTING OF EACH SOURCE SHALL BE PER PROCEDURE FOR CONTAM./LEAK. TEST OF REF. SOURCES'. LIMIT 5 X 10^{-3} uCi.
4. **ANSI N43.6-1997 PERFORMANCE CLASSIFICATION OF 96C22212 FOR CALIBRATION SOURCES**

SYRINGE STANDARD MODEL TABLE				
ASS'Y. P/N	MODEL NO.	NUCLIDE	MAXIMUM ACTIVITY	COLOR CODE
-01	BM06S-22	Na-22	0.50 mCi	YELLOW
-02	BM06S-60	Co-60	0.10 mCi	BLUE
-03	BM06S-37	Cs-137	0.50 mCi	GREEN
-04	BM06S-33	Ba-133	0.50 mCi	BLK/GRY
-05	BM06S-57	Co-57	15.0 mCi	RED
-06	BM06S-68	Ge-68	0.50 mCi	WHITE