



# Quality Control Products for Molecular Imaging

## Catalog of Sources



# About RadQual

RadQual LLC is a wholly owned subsidiary of International Isotopes Inc. and has been providing high quality products to the nuclear medicine industry since 2001. We manufacture all of our products in Idaho Falls, Idaho, USA and are the only company manufacturing these products solely in the U.S. We have a dedicated team of employees with more than 150 years of manufacturing, distribution, quality and sales experience.

RadQual manufactures a complete line of calibration and reference standards for nuclear pharmacies and SPECT/PET imaging systems. RadQual, through our parent company International Isotopes Inc. (INIS), utilizes NIST Traceable Standard Reference Materials (SRMs) to ensure our measurements are traceable to NIST, and as a result, all calibrated RadQual products are accurate and traceable to NIST standards.

RadQual is also certified and fully compliant to the current editions of the ISO 9001 standard for quality management systems and 13485 standard for medical devices. Our staff is fully trained in current Good Manufacturing Practices as per United States Food and Drug Administration 21 CFR Part 820, and all applicable U.S. Department of Transportation requirements for shipping and handling of dangerous goods. With our excellent history of high quality manufacturing performance and products, we back up all of our sales with a lifetime warranty against manufacturing defects. You can be confident in RadQual.

RadQual has a successful record of developing innovative products that have proven valuable to the industry.

- RadQual was the first to introduce the [RadShield™ \(page 5\)](#) a new lighter weight shield material that provides equivalent shielding to the much bulkier and heavier transport cases. The RadShield™ enables the flood source to be more easily and safely transported from storage to other locations for use.
- RadQual has developed and patented the new syringe style dose calibrator (“S-Vial”). [The S-Vial \(page 10\)](#) reference standard allows daily calibration of ion chambers for both syringe and unit vial geometries. Providing a specific geometry of matching syringes improves the accuracy of daily quality control measurements.
- RadQual developed and patented the first, and only, directly traceable NIST [dose calibrator reference \(page 22\)](#) standard for measuring F-18 and Cu-64 using Ge-68/Ga-68 in our S-Vial configuration.
- RadQual developed, designed, tested, and certified the [RadLite Shipper \(page 7\)](#), a new lightweight Type A shipping package for flood sources. This package reduces shipping costs not only for outgoing products but also significantly reduces customer costs on expended flood source return shipments. It’s also reusable and recyclable, which makes sense for the environment.
- The new patent pending [Simulated Sodium Iodide - I-131 \(page 13\)](#) calibration standard. These source designs allow direct calibration of the dose calibrator I-131 channel using NIST traceable quantities of Ba-133 in specially designed configurations.

And our efforts continue for new product innovation. Our work today will enhance and improve nuclear imaging tomorrow. Our goals ... Quality products, fair prices, superior customer service. We sincerely thank you for your interest in our products!

The RadQual Team

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Series	Weight	Overall Dimensions (in)	Co-57 Matrix (in)	Thickness (in)	Activity
BM01L	5 lb	24.1 x 16.7	23.8 x 16.4	0.35	5, 10, 15 or 20 mCi
BM02	5 lb	20.3	18.5	0.7	5, 10 or 15 mCi
BM04	5 lb	19.6 x 15.6	18 x 14	0.7	10, 15 or 20 mCi
BM05	2 lb	11.22 x 11.22	10 x 10	0.7	0.5, 3, 10, 15 or 20 mCi
BM07	3 lb	15.8 x 9.5	15.5 x 9.3	0.3	7.5, 10 or 15 mCi
BM55	2 lb	11.22" x 10.26	10 x 10	0.7	20 mCi

### RadQual RadLite™ flood sources...Lite Done Right!

60% lighter, 60% thinner.

RadQual flood sources are available in a wide range of activities for both circular and rectangular shaped gamma camera detectors. See our flood source cross reference charts on the following pages to determine which source is needed for your camera make and model, or contact your RadQual dealer.

For flood source camera cross reference charts see pages 26-28.



RadShield™ was designed to provide an easier alternative for transferring your source to the camera with minimal exposure without moving a much heavier case around your Nuclear Medicine Department. As a result of customer feedback, RadShield is in its' third generation. While weighing only 30 pounds it provides similar radiation dose reduction as the typical hard case, by shielding the surface of the source not an oversize case.

### Exposure levels (millirem/hour/ millicurie)

Distance	RadShield	Hard Case
@ Contact	0.1	0.07
@ 30 cm	0.04	0.03
@ 1 m	0.01	0.01

*Based on a 15 mCi Co-57 source using a Bicon MicroRem meter with Co-56/Co-58 levels below 0.08% combined.*

Model No.	Fits
BM00-01	BM01 Series
BM00-02	BM02 Series
BM00-04	BM04 Series
BM00-05	BM05 & BM55 Series
BM00-07	BM07 Series



RadScooter was designed to provide an alternative for transferring your source to the camera with minimal exposure without manually carrying a heavy case around your Nuclear Medicine Department. Storage requirement for the RadScooter is no larger than a typical hard case.

Available for BM01, BM02, and BM04 model sources only.

Physical Dimensions:  
7 inches wide (18 cm) x 30.2 inches long (77cm) x 32.5 inches high (83cm)



RadQual developed, designed, tested, and certified the RadLite Shipper, a new lightweight shielded Type A shipping package for flood sources. This package reduces shipping costs not only for outgoing products but also significantly reduces customer costs on expended flood source return shipments. It's also reusable and recyclable, which makes sense for the environment.

Size	Fits
Large RadLite Shipper	BM01, BM02, BM04
Small RadLite Shipper	BM05, BM07, BM55



### D-SPECT System (BM83-12)

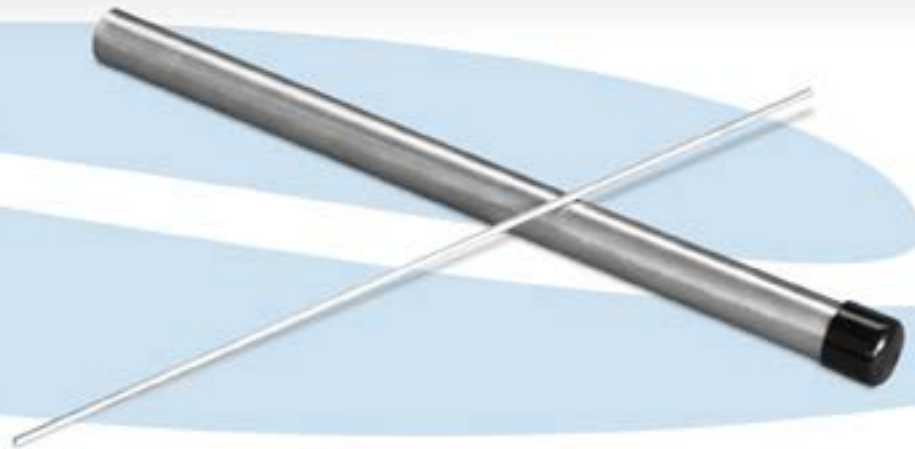
Stainless steel, doubly encapsulated, Co-57 line source designed specifically for the Spectrum Dynamics D-SPECT system. Containing 12 mCi (444 MBq). Overall length of 295 mm (11.6"); Active length of 260mm (10.24"); <1.00 mm active diameter.

### Veriton System (BM83-XL)

Stainless steel, doubly encapsulated, Co-57 line source designed specifically for the Spectrum Dynamics Veriton system. Containing 12 mCi (444 MBq). Overall length of 420mm (16.54"); Active length of 400mm (15.75"); <1.00 mm active diameter.

Model No.	Nuclide	Activity
BM83-12 (D-SPECT)	Co-57	12 mCi (444 MBq)
BM83-XL (Veriton)	Co-57	12 mCi (444 MBq)

Uniformity for both sources are measured in 1 cm segments. All segments are within 5% of any two points over the active length. Neighboring segments are within 2% uniformity.





## Gd-153 Line Source

- The BM53-10 is a stainless steel, doubly encapsulated, Gd-153 line source intended for use in the Siemens Symbia SPECT/CT systems with Auto Quality Control (AQC) option. Total Length of Source is 485 mm. Active Volume is 3 mm dia x 467 mm length in a uniformly dispersed epoxy matrix.
- Uniformity is measured in 1 cm segments. All segments are within 5% of any two points over the active length. Neighboring segments are within 2% uniformity.

Model No.	Nuclide	Activity
BM53-10	Gd-153	10 mCi (370 MBq)
BMSY-057	Co-57	50 $\mu$ Ci (1.85 MBq)

## Co-57 Point Source

- The BMSY-057 is a Co-57 point source intended for use in the Siemens Symbia SPECT/CT systems with Auto Quality Control (AQC) option.



Model No.	Nuclide	Activity
BM06S-57	Co-57	5.0 mCi
BM06S-157	Co-57	10.0 mCi
BM06S-60	Co-60	0.05 mCi
BM06S-33	Ba-133	0.25 mCi
BM06S-37	Cs-137	0.2 mCi
BM06S-22	Na-22	0.2 mCi

SS&D NR-1235-S-102-S (activity levels above are nominal values) Other activity levels available upon request.

- A patented design unique to RadQual, the S-Vial allows for use in either the syringe or vial positions on your dose calibrator dipper. It enables accurate measurement by minimizing the physical geometry and position geometry effects, thereby maximizing your ion chamber accuracy.

- All dose calibrator sources are calibrated against a traceable National Institute of Standards (NIST) solution in a similar geometry, using a pressurized ion chamber. They contain approximately 5cc's of total volume with 3cc's of active epoxy.
- Sources are packaged in an individual lead shield that is color coded to the source.
- All sources are shipped with a certificate of calibration, leak test certification, radiation safety handling instructions, and a custom decay calendar.
- Dimensions: total source Height 3.0", Major Diameter 1.125", Minor Diameter 0.625", Activity Height 1.5", and Activity Diameter 0.445".



Model No.	Nuclide	Activity
BM06E-57	Co-57	5.0 mCi
BM06E-157	Co-57	10.0 mCi
BM06E-60	Co-60	0.05 mCi
BM06E-33	Ba-133	0.25 mCi
BM06E-37	Cs-137	0.2 mCi
BM06E-22	Na-22	0.2 mCi

SS&D NR-1235-S-102-S (activity levels above are nominal values)  
Other activity levels available upon request.

- All Dose calibrator sources are calibrated against a traceable National Institute of Standards (NIST) solution in a similar geometry, using a pressurized ion chamber. RadQual “E” vials contain approximately 23 cc’s of total volume with 20cc’s of active epoxy.
- Each source is packaged in an individual lead shield that is color coded to the source.
- All sources are shipped with a certificate of calibration, leak test certification, radiation safety handling instructions, and a custom decay calendar.



Model No.	Nuclide	Activity
BM06V-XX-57	Co-57	5.0 mCi
BM06V-XX-157	Co-57	10.0 mCi
BM06V-XX-60	Co-60	0.05 mCi
BM06V-XX-33	Ba-133	0.25 mCi
BM06V-XX-37	Cs-137	0.2 mCi
BM06V-XX-22	Na-22	0.2 mCi

XX denote the vial size needed - 05 for 5cc, 10 for 10cc, 20 for 20cc  
 SS&D NR-1235-S-102-S (activity levels above are nominal values)  
 Other activity levels available upon request.

- Dose calibrator sources are available in 5cc, 10cc, or 20cc sizes.
- All Dose calibrator sources are calibrated against a traceable National Institute of Standards (NIST) solution in a similar geometry, using a pressurized ion chamber.
- Each source is packaged in an individual lead shield that is color coded to the source.
- All sources are shipped with a certificate of calibration, leak test certification, radiation safety handling instructions, and a custom decay calendar.



## Introducing Simulated I-131 Capsule & Syringe Sources

Patent Pending

- The first ever simulated I-131 source using NIST traceable Ba-133.
- RadQual Simulated I-131 sources allow the user to accurately calibrate their dose calibrators for direct measurement of I-131. By utilizing an NIST traceable calibrated amount of Ba-133 and our patented source technology, the reading on the I-131 setting is equal to the Ba-133 activity level.
- Available in two source configurations; 1) Our patented dual geometry "S" vial which allows for accurate calibration in both the syringe and vial dose calibrator positions. 2) Our new capsule design which allows for calibration of individual doses.

Model No.	Nuclide	Activity
NS06S-133 (Syringe Standard)	Ba-133	200 $\mu$ Ci
NS06SQ-133 (Capsule Standard)	Ba-133	200 $\mu$ Ci

- All sources are shipped with a certificate of calibration, leak test certification, radiation safety handling instructions, and a custom decay calendar.



- RadQual’s calibrated rod sources typically have a calibration accuracy of  $\pm 3\% - 5\%$  at a 95% confidence level.
- The calibrated rod sources are manufactured by gravimetric transference of NIST traceable solutions and calibration is confirmed using a Sodium Iodide detector or Dose Calibrator.
- Sources are available in 3" (76 mm) or 5" (127 mm) lengths with a diameter of 0.47" (11.9 mm).

Model No.	Nuclide	Activity
BM08-57	Co-57	0.1 - 1 $\mu$ Ci
BM08-60	Co-60	0.1 - 0.5 $\mu$ Ci
BM08-37	Cs-137	0.1 - 1 $\mu$ Ci
BM08-33	Ba-133	0.1 - 2 $\mu$ Ci
BM08-22	Na-22	0.1 - 5 $\mu$ Ci
BM08-68	Ge-68	0.1 $\mu$ Ci
BM08-152	Eu-152	0.1 - 0.5 $\mu$ Ci

- Activity end is color coded to provide easier identification.
- All sources are shipped with a certificate of calibration, leak test certification, radiation safety handling instructions, and a custom decay calendar.



Model No.	Nuclide	Activity
BM03-57L-50	Co-57	50 $\mu$ Ci
BM03-57L-100	Co-57	100 $\mu$ Ci
BM03-68L-100	Ge-68	100 $\mu$ Ci max*
BM03-57L-XXX	Co-57	1.0 mCi max*
BM03-57A-XXX	Co-57	5.0 mCi max*
BM03-22A-XXX	Na-22	0.5 mCi max*
BM03-68A-XXX	Ge-68	0.5 mCi max*
Left & Right Markers		
BM03-57-LR	Co-57	100 $\mu$ Ci

\*Lower activity levels available. SS&D NR-1235-S-106-S

### Spot Markers

RadQual's Spot Markers are reference sources manufactured by gravimetric transfer of a Co-57/epoxy mixture and checked by ion chamber for content.

There are two designs available. The traditional Lucite marker with a total diameter of 1.0 inches

(2.54 cm), an active area of 0.125 inches (3 mm) and a total thickness of 0.25 inches (6.4 mm). The Aluminum marker has the same dimensions, but is designed and approved by regulatory authorities for activity content up to 12.0 mCi (444 MBq) of Co-57.

### Left & Right Markers

Right and Left Markers aid in patient orientation for both SPECT and Planar Imaging.

- Nominal activity is 33  $\mu$ Ci left marker and 66  $\mu$ Ci Right marker.
- Activity concentration in  $\mu$ Ci per mm is equivalent in both markers.
- Disc dimensions are 2 inch diameter (2.54 cm) and 0.25 inch thick (0.63 cm).
- Disc is backfilled with epoxy to seal in activity.
- Sources shipped with technical data sheet that includes radiation safety recommendations and leak test results.



Model No.	Nuclide	Activity
BM10-057-100	Co-57	100 $\mu$ Ci (3.7 MBq)
BM10-057-200	Co-57	200 $\mu$ Ci (7.4 MBq)
BM10-057-250	Co-57	250 $\mu$ Ci (9.25 MBq)

*Pen point markers containing Co-57 are available up to 1.0 mCi (37 MBq). Additional models are available manufactured using Cs-137 or Ba-133 with maximum activities of 0.2 mCi (7.4 MBq) or Ge-68/Ga-68 with a maximum activity of 0.5 mCi (18.5 MBq).*

RadQual's pen point marker is designed for highlighting or tracing the outlines of a particular anatomical region or feature on a patient during imaging.

Our pen point markers are constructed using 300 series stainless steel. Each source is supplied with a 0.5" wall thickness threaded cap to shield the active point when the source is not being used. The overall length of the source with shield in place is 10.1" (25.6 cm), with the shield removed the length decreases to 9.26" (23.5 cm). The pen point marker has a diameter of 0.25" (6.3 mm).





Aids in indicating anatomical location for SPECT Imaging and in indicating organ size or region of interest by counting the number of visible "hot and cold" segments. Custom sources can be made containing a maximum activity of 1.2 millicuries (44.4 MBq).

### **Co-57 Flexible Ruler (BM83-20)**

- Sources contain 460 microcuries of Co-57 (20 microcuries per segment).
- Each source contains 23 "hot" 1 cm segments and 24 "cold" 1 cm stainless steel segments. Total length is 18.5"(47 cm).

*SS&D NR-1235-S-107-S*

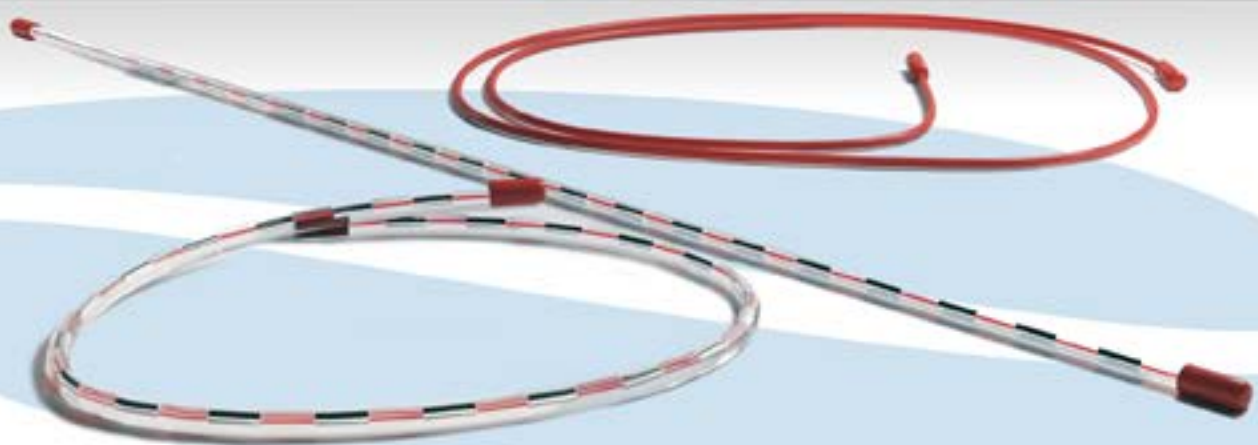
### **Co-57 Rigid Ruler (BM83-30)**

- Sources contain 160 microcuries of Co-57 (20 microcuries per segment).
- Each source contains 8 "hot" 1 cm segments and 9 "cold" 1 cm segments, total length is 6.7 inches (17 cm).

*SS&D NR-1235-S-107-S*

### **Flexible Line Source (BM83-10)**

- Extremely flexible and easily shaped into configurations necessary for outlining areas of interest.
- Sources contain 150  $\mu$ Ci of Co-57 evenly distributed throughout the epoxy over the 19.7" (50 cm) active length. (<5  $\mu$ Ci/in).
- The activity is uniformly dispersed in an epoxy matrix and encapsulated in a thin "poly" tube with an 0.032" (0.8mm) inside diameter and a 0.094" (2.4mm) outside diameter. *SS&D NR-1235-S-107-S*



- 20cm diameter PET phantoms containing Ge-68.
- Available in active lengths of 19cm, 27cm and 30cm.
- Each source is PET scanned and verified for uniformity.
- Complete with quality documentation and leak test certificate.
- Typical Calibration Uncertainty is +/- 3% at the 95% Confidence Level.
- 100% satisfaction guarantee.

Model No.	Size	Activity
BMCY68-2019-01	19 cm	1.2 mCi
BMCY68-2019-02	19 cm	2 mCi
BMCY68-2019-22	19 cm	2.2 mCi
BMCY68-2019-03	19 cm	3 mCi
BMCY68-2027-02	27 cm	2 mCi
BMCY68-2030-03	30 cm	3 mCi



- Custom molded hard plastic ATA 300 Category 1 case made from high impact HDPE with high density foam inserts and a hinged lid for ease of use.
- Rugged case can be used for depleted source returns. Free one-for-one expended source return with each purchase.
- Cases can be purchased for an additional cost. Consult with your distributor for pricing.



Model No.	Nuclide	Activity
BM68-01-010	Ge-68	1.0 mCi (Pair - 1.0 mCi each)
BM68-01-012	Ge-68	1.2 mCi (Pair - 1.2 mCi each)
BM68-01-022	Ge-68	2.2 mCi (Pair - 2.2 mCi each)
BM68-01-030	Ge-68	3.0 mCi (Set of 3 - 3.0 mCi each)
BM68-01-040	Ge-68	4.0 mCi (Set of 3 - 4.0 mCi each)
BM68-01-050	Ge-68	5.0 mCi (Set of 3 - 5.0 mCi each)

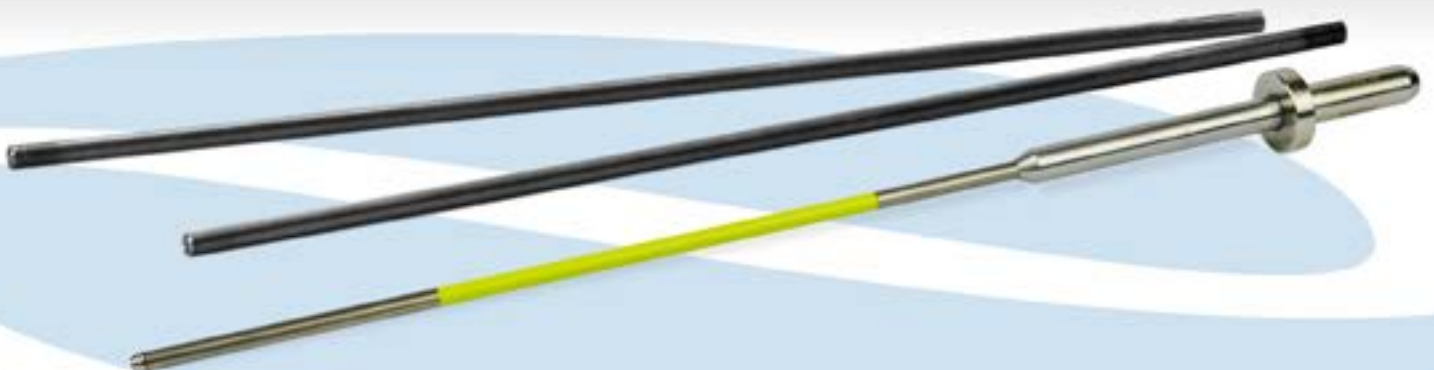
## Ge-68 Transmission Rods

- Detector setup rod sources for Siemens PET scanners.
- Contains uniformly dispersed Ge-68 in an epoxy matrix.
- Line source has overall length of 192 mm and active dimensions of 183 mm length by 1.5 mm diameter in a doubly encapsulated stainless steel housing.

Model No.	Nuclide	Activity	Used In
BM68-02-150	Ge-68	1.5 mCi	Discovery STE & ST PET/CT
BM68-02-050	Ge-68	500 µCi	Discovery 690 PET/CT
BM68-02-027	Ge-68	270 µCi	Discovery 600 PET/CT

## Ge-68 Normalization Pins

- Normalization pins for GE Discovery PET/CT scanners.
- Contains uniformly dispersed Ge-68 in an epoxy matrix.
- Line source has active dimensions of 159 mm length by 1.5 mm diameter in a doubly encapsulated stainless steel housing.



Model No.	Nuclide	Activity
BM22-01-100	Na-22	100 $\mu$ Ci (3.7 MBq)
BM22-01-400	Na-22	400 $\mu$ Ci (14.8 MBq)



## Na-22 Rod Source

- The BM22-01 is a Na-22 line source made for use with Philips Medical PET/CT scanners, GeminiTF/LXL, Ingenuity TF, and Vereos.
- Overall dimensions of 3.00" ( 76 mm) length by 0.134" (3.4 mm) diameter and an active volume of 0.59" (15 mm) length by 0.072" (1.8 mm) diameter in a stainless steel housing.

## Multi-Modality Markers

- Our BM03-XXL Multi-Modal Spot Markers have a Lucite housing that contains a Teflon CT marker with an active diameter of 0.125" (3 mm) and overall dimensions of 1.0" (2.54 cm) diameter by 0.25" (6.4 mm) thick.
- Our BM03-XXT Multi-Modal Spot Markers have a Teflon housing with overall dimensions of 1.0" (2.54 cm) diameter by 0.25" (6.4 mm) thick and a 3 mm active element. Available with either Na-22 or Ge-68 in standard nominal activities of 10  $\mu$ Ci (0.37 MBq) or 100  $\mu$ Ci (3.7 MBq).
- Na-22, 10  $\mu$ Ci sources are also available as a set of 6 sources, BM03-22T-PET-10-SET, for use in Philips Gemini PET/CT scanners.



Model No.	Nuclide	Activity
BM03-22L-PET-10	Na-22	10 $\mu$ Ci (0.37 MBq)
BM03-22L-PET-100	Na-22	100 $\mu$ Ci (3.7 MBq)
BM03-22L-PET-10-SET	Na-22	6 x 10 $\mu$ Ci (0.37 MBq)
BM03-68L-PET-10	Ge-68	10 $\mu$ Ci (0.37 MBq)
BM03-68L-PET-100	Ge-68	100 $\mu$ Ci (3.7 MBq)
BM03-22T-PET-10	Na-22	10 $\mu$ Ci (0.37 MBq)
BM03-22T-PET-10-SET*	Na-22	6 x 10 $\mu$ Ci (0.37 MBq)
BM03-22T-PET-100	Na-22	100 $\mu$ Ci (3.7 MBq)

\* Compatible with Philips Gemini TF, LXL, GXL, Vereos PET/CT, and Ingenuity TF.

Model No.	Nuclide	Activity
BM06S-6805	Ge-68	0.5 mCi
BM06S-681	Ge-68	1.0 mCi
BM06S-681XS	Ge-68	1.0 mCi w/extra shielding

SS&D NR-1235-S-102-S (activity levels above are nominal values)

### PET Imaging Simulated F-18 Dose Calibrator (Ge-68)

- Available in S, E & V dose calibrator vial configurations.
- Dose calibrator standards are calibrated for Ge-68 activity against a traceable National Institute of Standards (NIST) source, using a pressurized ion chamber and cross calibrated for F-18 and Cu-64 calibration.
- All sources are shipped with a certificate of calibration, leak test certification, radiation safety and handling instructions and a custom decay calendar showing both the F-18 and Cu-64 equivalent activity.
- Each source is packaged in an individual lead shield.



Series	Nuclide	Activity
BM08-68	Ge-68	0.1 $\mu$ Ci to 0.3 $\mu$ Ci

*Special order sizes available up to a maximum of 1.5 uCi*

## PET Imaging Rod Source (Ge-68)

RadQual's calibrated rod sources typically have a calibration accuracy of  $\pm 3\%$  -  $5\%$  at a 99% confidence level. Physical dimensions are 2.96 inches (75 mm) total length by 0.47 inches (11.9 mm) diameter.

- RadQual's calibrated rod sources are manufactured by gravimetric transference of NIST traceable solutions.
- Calibration is confirmed using a sodium iodide detector.



This patented product allows for cross calibration of your PET scanner, dose calibrator, and well detector for Ga-68 and F-18, and is useful in multi-center imaging trials to both assess bias and enable correction of biases due to instrumentation factors for serial PET studies.

- Cylinder contains a 0.5 mCi (18.5 MBq) of Ge-68/Ga-68 (in secular equilibrium) cylinder which is implicitly traceable to NIST this is supplied with a base mount for the Data Spectrum ECT Phantom.
- The dose calibrator for this series contains approximately 25  $\mu$ Ci (0.90 MBq) of F-18 equivalent activity and is directly traceable to NIST.
- The rod source contains approximately 0.14  $\mu$ Ci (3.85 kBq) and is implicitly traceable to NIST. A custom decay chart for Ge-68/Ga-68 and F-18 are provided with this source series.

## Why Radqual Pet F-18 X-Cal System?

All of the sources in this set are manufactured from the same Ge68/Ga-68 epoxy process using NIST traceable balances to ensure accurate measurement of weight. Our proprietary process allows for extremely uniform activity distribution within the cylinder. The content of the cylinder and rod source are determined by the concentration of the directly traceable dose calibrator standard. So the activity contents of all of the sources are known at the 95% confidence level within +/- 2.5%.

Model No.: BMCY68-0404	
Cylinder Dimensions	Height 3.68 (in) - 9.37 (cm)
	Diameter 2.77 (in) - 7.04 (cm)
Cylinder Active Matrix	Height 1.77 (in) - 4.50 (cm)
Base Mount Dimensions	Diameter 1.77 (in) - 4.50 (cm)
	Diameter 7.08 (in) - 18 (cm)







RadQual is the U.S. distributor for LEA Premium Calibration Standards in the United States and Canada. LEA's calibration and reference sources are measured according to ISO 17025:2017 under COFRAC accreditation, which provides the same traceability as the National Institute of Standards and Technology (NIST).

For a list of available products, download the catalog [\[here\]](#) or visit [lea-sources.com](http://lea-sources.com).

Philips - ADAC, Marconi, Picker					
Camera Model	Configuration	UFOV (in)	Active Dimensions (in)	Recommended Nominal Activity	RadQual Model No.
ARC 3000	Circular	15	18.5	10 mCi	BM02-10
Argus	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Brightview	Rectangular	20.25 x 16	23.8 x 16.4	10 mCi	BM01L-10
Cardio 60	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Cardio MD	Rectangular	9.2 x 15.4	15.5 x 9.3	10 mCi	BM07-10
Cirrus	Circular	15	18.5	10 mCi	BM02-10
Forte	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Genesys	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Precedence	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Solus	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Cardial	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Vertex	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Skylight	Rectangular	20 x 14	23.8 x 16.4	10 mCi	BM01L-10
Axis/Irix	Rectangular	21 x 15.5	23.8 x 16.4	10 mCi	BM01L-10
Prism 1000 (single head)	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Prism 2000 (2 head)	Rectangular	20 x 15	23.8 x 16.4	10 mCi	BM01L-10
Prism 3000 (3 head)	Rectangular	15.7 x 9.4	18 x 14	10 mCi	BM04-10
SX300	Square	14 x 14	18 x 14	10 mCi	BM04-10

Siemens Medical Systems					
Camera Model	Configuration	UFOV (in)	Active Dimensions (in)	Recommended Nominal Activity	RadQual Model No.
3700, 7500 Orbiter Series	Circular	15.25	18.5	10 mCi	BM02-10
3700, 7500 Orbiter Series	Rectangular	21.25 x 15	16 x 24	10 mCi	BM02-10
Body Scan	Rectangular	23.5 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
c.cam	Rectangular	14 x 8.4	15.5 x 9.3	10 mCi	BM07-10
Diacam	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10
e.cam (dual head)	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10
Intevo	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10
Multispect (dual head)	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10
Multispect 3 (3 heads)	Rectangular	16 x 12	18 x 14	10 mCi	BM04-10
Symbia	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10
EVO Excel	Rectangular	21.25 x 15	23.8 x 16.4	10 mCi	BM01L-10

GE Medical - Elscint, SMV, Sopha					
Camera Model	Configuration	UFOV (in)	Active Dimensions (in)	Recommended Nominal Activity	RadQual Model No.
Brivio NM 615	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Discovery VH	Rectangular	20 x 14	23.8 x 16.4	10 mCi	BM01L-10
Discovery 530C	Square	9 x 9	10 x 10	20 mCi	BM55-20
Discovery NM 630	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Discovery NM/CT 670	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Discovery NM 750b	Square	9 x 9	10 x 10	20 mCi	BM05-20
Discovery NM /CT 850	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Discovery NM/CT 860	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
DST/Dsi	Rectangular	12.99 x 14	18 x 14	10 mCi	BM04-10
DSTXLi	Rectangular	21.3 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
DS7	Round	15.75	18.5	10 mCi	BM02-10
Hawkeye	Rectangular	20 x 14	23.8 x 16.4	10 mCi	BM01L-10
Infinia	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Maxi 2 and Maxi 37	Circular	15	18.5	5 mCi	BM02-05
Millennium MG	Rectangular	14 x 20	23.8 x 16.4	10 mCi	BM01L-10
Millennium MPR, VG	Rectangular	15.75 x 21.75	23.8 x 16.4	10 mCi	BM01L-10
Millennium MPS	Square	14.5 x 14.5	23.8 x 16.4	10 mCi	BM01L-10
Maxxus	Rectangular	21 x 16	23.8 x 16.4	10 mCi	BM01L-10
Myosite	Rectangular	20 x 14	23.8 x 16.4	10 mCi	BM01L-10
MyoSPECT	Square	9 x 9	10 x 10	20 mCi	BM55-20
Optima	Rectangular	14 x 9	15.5 x 9.3	10 mCi (7.5 mCi)	BM07-10
Starcam ACT	Circular	15.4	18.5	10 mCi	BM02-10
Starcam XCT	Circular	15.4	18.5	10 mCi	BM02-10
Starcam XRT	Rectangular	21 x 16	23.8 x 16.4	10 mCi	BM01L-10
Ventri	Rectangular	14.6 x 7.4	15.5 x 9.3	10 mCi	BM07-10
Varicam	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10
Helix	Rectangular	21.25 x 15.75	23.8 x 16.4	10 mCi	BM01L-10

Other Manufacturers					
Camera Model	Configuration	UFOV (in)	Active Dimensions (in)	Recommended Nominal Activity	RadQual Model No.
<b>gviMD</b>					
mSPECT	Rectangular	14.8 x 9.5	15.5 x 9.3	10 mCi	BM07-10
One Pass	Square	8.5 x 8.5	10 x 10	10 mCi	BM05-10
Clear Vision	Square	8.5 x 8.5	10 x 10	10 mCi	BM05-10
<b>IS<sup>2</sup></b>					
SR (Single Head)	Rectangular	20.8 x 15.3	23.8 x 16.4	10 mCi	BM01L-10
Pulse CDC	Rectangular	15 x 10.2	18 x 14	10 mCi	BM01L-10
DCC	Rectangular	15 x 10.2	15.5 x 9.3	10 mCi	BM07-10
SC	Circular	15	18.5	10 mCi	BM02-10
<b>Mediso Medical Imaging Systems</b>					
CardioSpect SC	Rectangular	20.8 x 15.3	23.8 x 16.4	10 mCi	BM01L-10
CardioCam	Square		15.5 x 9.3	10 mCi	BM07-10
CardioSpect SR	Rectangular	20.8 x 15.3	23.8 x 16.4	10 mCi	BM01L-10
CardioSpect D90	Rectangular	14.5 x 9	15.5 x 9.3	10 mCi	BM07-10
CardioSpectVMAX	Rectangular	20.8 x 15.3	23.8 x 16.4	10 mCi	BM01L-10
AnyScan	Rectangular	20.8 x 15.3	23.8 x 16.4	10 mCi	BM01L-10
<b>Digirad</b>					
2020tc	Square	8 x 8	10 x 10	10 mCi	BM05-10
Ergo	Rectangular	15.6 x 12.2	18 x 14	10 mCi	BM04-10
Cardius Series	Square	8 x 8	10 x 10	10 mCi	BM05-10
<b>Dilon</b>					
6800 Acella	Rectangular	15 x 10.2	15.5 x 9.3	15 mCi	BM07-15
6800 BSG	Square		10 x 10	0.5 mCi	BM05-99D
6800 BSG <small>Attenuation Plates</small>	Square		10 x 10	3 mCi	BM05-99D3
<b>Gamma Medica</b>					
Luma GEM	Square	8 x 8	10 x 10	10 mCi	BM05-10
<b>Mid Atlantic Imaging</b>					
MiaCam	Rectangular	15.6 x 12.2	18 x 14	10 mCi	BM04-10
<b>Universal Medical Resources</b>					
CorCam	Rectangular	15 x 10.2	15.5 x 9.3	10 mCi	BM07-10

# General Information

## Licensing Requirements for Non-Exempt Sources

It is RadQual's policy to require verification of the customer's Agreement State or NRC radioactive materials license. No orders will be shipped or processed without a copy of the customer's license on file at International Isotopes Idaho Inc (INIS).

In the event that the customer's license has expired, a copy of the expired license and a timely renewal letter must be submitted. If the timely renewal letter is more than six months old we will contact the applicable regulatory authorities and confirm that the timely renewal is still valid. Compliance with applicable local, state and federal regulations concerning procurement and possession of radioactive materials is the responsibility of the customer.

## Exempt Quantity Sources

Quantities of radioactive materials that do not exceed the applicable quantity set forth in 10 CFR §30.71, Schedule B may be purchased by individuals without a specific license issued by the US Nuclear Regulatory Commission (NRC) or an Agreement State. RadQual will accept orders for exempt quantity sources from customers that do not possess a specific license. Exempt quantity sources cannot be shipped to distributors or other licensees that intend to redistribute sources unless the distributor or licensee possess an exempt distribution license.

## Quality Control and Quality Assurance

INIS has a well developed Quality Assurance program that has been verified to meet the standards of ANSI/AMSE, US FDA 21CFR 820 as well as ISO 13485 & 9001. All of our products are manufactured in accordance with cGMP and customer specifications. The Company is a participating member of the National Institute of Standards and Technology (NIST) Measurement Assurance Program for the radiopharmaceutical industry and is a registered manufacturer of class I medical devices with the U.S. Food and Drug Administration (FDA).

RadQual provides a wide range of nuclear medicine devices to which the CE Mark has been applied. This indicates our conformity to the provisions of EU Medical Device Regulation (MDR) 2017/745 (Annex II), which enables our representatives to distribute freely within the European Community.

RadQual and INIS's continued compliance to these quality related regulations is assured through regular audits performed by independent auditors.

## Product Changes

New product development and improvement is an ongoing process at RadQual. We reserve the right to change manufacturing methods, component materials and or fabrication techniques that will not affect the performance of the product, pending all necessary regulatory approvals.

## **Product Availability**

Most products can be shipped from inventory within two business days. In the event that we need to manufacture the product for shipment please allow two weeks after receipt of the order. Please contact the Sales and Marketing Department or your local RadQual distributor for more information regarding the availability of certain products. An expected ship date will be established for each order when accepted into our order entry system.

## **Return Policy**

Due to the nature of our products, all sales are final and no items can be returned for credit without prior approval from RadQual or RadQual's distributor. At RadQual we understand that mistakes can be made and will do everything possible to assist you in rectifying the problem. If a product does not meet your expectations, let us know. Our customer service team works closely with sales and quality assurance to address customer concerns promptly. Such a claim must be made, and the source returned to INIS, within 30 days after receipt of the shipment for full credit.

Before any return is made, RadQual must be notified so that a return authorization may be issued and necessary documents completed. Shipments returned without proper notification may be refused upon delivery and credit withheld.

Full credit will be given for sources that are found not to meet specifications as long as the source is returned to INIS within 30 days of receipt. RadQual will be responsible for inbound freight of the suspect source, and the outbound freight for the replacement source.

Sources reported and returned after the 30 day period, may not be given credit and all freight expense belongs to the customer.

In the case that the customer ordered the incorrect source model the following will apply: The customer must notify RadQual or their distributor and return the source within 15 days of shipment to request a replacement source. There will be a restocking fee charged for the original source. If the customer notifies RadQual or their distributor after 15 days but before 30 days a 50% credit will be offered for the original source.

After a 30 day period no credit will be given without agreement from RadQual. In all instances the customer will be expected to pay all freight charges.

In the event that the sources are being returned from an overseas location, the shipment must be sent with DDP (Delivery Duty Paid) terms so that the customer is billed for all fees.

## Source Disposal Policy

RadQual will take back all nuclear medicine sources for disposal on a one-to-one basis. A source may be returned for disposal as long as the equivalent replacement source is purchased from RadQual's distributors. The customer will be required to pay all shipping costs for the return of the sources unless prior arrangements have been made. In the event that the sources are being returned from an overseas location, the shipment must be sent with DDP (Delivery Duty Paid) terms so that the customer is billed for all fees.

A packet with return documents are sent with new product shipments. It is the responsibility of the customer to ensure compliance with all guidelines and regulations relative to the shipment of radioactive materials. Shipments returned without a proper authorization may be refused upon delivery. Please note that customers will be charged for any unauthorized returns.

Contact INIS directly at 208.524.5300 for source returns outside of the one-for-one basis policy.

## Methods of Calibration

INIS participates in the Radioactivity Measurements Assurance Program (MAP) conducted by the National Institute of Standards and Technology (NIST) in cooperation with the NRMMap, Inc.

In this program NIST provides blind samples which are assayed by INIS, with the results sent to NIST. NIST then reports back to INIS the difference between the NIST calibrated value and INIS's calibrated value. In addition, INIS can send finished products to NIST for product verification and calibration. Over the years INIS has maintained a high degree of precision and accuracy with NIST. Traceability is established and maintained through this cross-calibration process.

A Certificate of Calibration is provided for each NIST traceable source purchased from RadQual, The Certificate provides a statement of traceability, a description of the physical and nuclear characteristics of the source, a description of the method of calibration, and quantitative identification of detected impurities. Activities are given in the Curie and SI systems.

Unless otherwise specified, all sources are manufactured to a precision of +20% / -10% with respect to the customer's requested activity. NIST traceable sources have an accuracy of  $\pm 5\%$  or better with respect to the certified measured value. Non-traceable (nominal) sources have an accuracy of +20%/ -10% with respect to the measured value and are supplied with a Nominal Data Sheet which characterizes the source.

The total uncertainty associated with a traceable source, is an estimate of the possible variance between the certified activity and the true activity, includes weighing uncertainty, random uncertainty, and systematic uncertainty. The quadratic combination of these uncertainties is generally less than  $\pm 5\%$  at the 99% confidence level.

INIS maintains a variety of current nuclear detector/assay systems to calibrate sources and to check for impurities. The calibration equipment is checked daily using NIST traceable standards. Stability is further insured by maintaining the instrumentation in a carefully controlled environment. All assay equipment and techniques are verified through MAP on a regularly scheduled basis. Sources are either calibrated directly against NIST standards or by using NIST traceable assay equipment and techniques.

## **Flood Source Uniformity Verification**

RadQual was the first in the industry to perform Quality Control of all flood sources using a gamma camera. It became apparent during our process validation that claiming an exact value for CV, INL and DNL would only lead to confusion as our protocols for testing and your procedures for daily performance might be different, which will result in different values. In addition as we use a unit cell (0.48 cm<sup>2</sup>) many times smaller than our competitors (6 cm<sup>2</sup>) comparing values between manufacturers would not be valid. That being said RadQual stands 100% behind our products. If you receive a source that does not meet specifications we will replace it immediately at no cost.

### **Coefficient of Variation (CV)**

A ratio of the standard deviation vs. the average count, expressed as a percent age. This factor expresses the overall scattering of values from the average.

### **Integral Uniformity (INL)**

Measurement of the difference between the maximum count and the minimum count, expressed as a percentage. This value is a measurement of the difference between the coldest and hottest points.

### **Differential Uniformity (DNL)**

Measurement of the largest extremes between two neighboring points on the flood source; all of the neighboring points are compared, and the highest value is reported. This value describes how fluid the transition is from one unit cell to the next unit cell.



## Ordering/Quotes

RadQual only sells our products through a network of carefully selected distributors and Radiopharmacies. We at RadQual are committed to our distributors and feel that ethics outweigh the dollar. Our distributors share their customer lists with us and we believe that to use this information to compete directly with them is a violation of trust.

RadQual distributors can be found throughout the United States and the world. A list of our distributors is posted on our website. If you are having trouble finding a distributor or radiopharmacy that represents RadQual Products please contact:

Customer Service at 208.524.5300 or sales@radqual.com

We will direct you to one of our distributors or have them contact you immediately.

## Product Shipping

Packaging and shipment of RadQual products by International Isotopes Inc. (INIS) adhere to the US Department of Transportation regulations, 49CFR and the International Air Transportation Association (IATA).

INIS utilizes two types of packaging for shipment of radioactive source products: excepted packaging and type A packaging. Certificates of compliance can be found on the RadQual website.

Excepted Packaging "Limited Quantity" is used when the activity limits do not exceed those defined in 49 CFR 173.425 and IATA regulations table 10.5.A and the radiation level at any point on the package does not exceed 0.5 millirem per hour. All products shipped from INIS as "excepted packages" meet the requirements of 49 CFR 173.421 and IATA Dangerous Goods Regulation 10.5.9.4.

The quantity of radioactive material shipped in a Type A package is limited to the A1 and A2 values for special and normal form respectively. The A1 and A2 values are listed 49 CFR 173.435 and Table 10.4.A. of the IATA Dangerous Goods Regulations.

Labeling of Type A packages is based on the maximum external surface radiation level and the Transport Index (T.I.); a unit-less number equivalent to the maximum radiation level in millirem/hour at a distance of one meter from the external surface of the package. Labeling criteria is prescribed in 49 CFR 172.403 and Paragraph 10.5.17.4 of the IATA Dangerous Goods Regulations. All radiation level measurements are made with a calibrated survey meter with appropriate detection capabilities.

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