



International
Isotopes
INCORPORATED

February 10, 2023

Mr. Tomas Herrera

U.S. NRC

NMSS/MSST/MSTB/SSDT

11545 Rockville Pike, MS TWFN B60

Rockville, MD 20852

Subject: Request to Amend Sealed Source and Device Registrations NR-1235-S-102-S, NR-1235-S-104-S, NR-1235-S-106-S, NR-1235-S-107-S, NR-1235-S-108-S, and NR-1235-S-109-S

Dear Mr. Herrera,

International Isotopes Inc. (INIS) is revising the logo for RadQual LLC, a wholly owned subsidiary of INIS, and intends to incorporate a new logo on sealed sources covered under Sealed Source and Device Registrations NR-1235-S-102-S, NR-1235-S-104-S, NR-1235-S-106-S, NR-1235-S-107-S, NR-1235-S-108-S, and NR-1235-S-109-S.


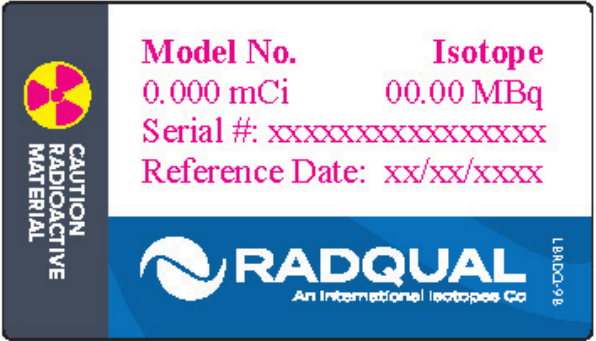
In addition, and to comply with US, EU, and UK medical device labeling requirements, the source or source packaging will include a unique identifier label (UDI), also referred to as a barcode, the Conformité Européenne Mark (CE), the UK Conformity Assessed Mark (UKCA), and the names and addresses of our authorized representatives for the European Union.

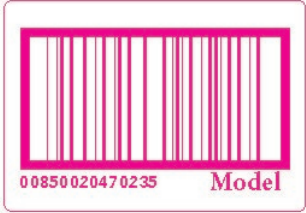
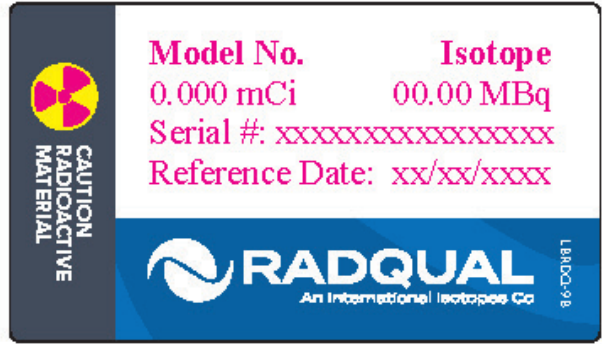
The revised labels, and associated SSDR and Source Models are provided in the attached Label Revision table.

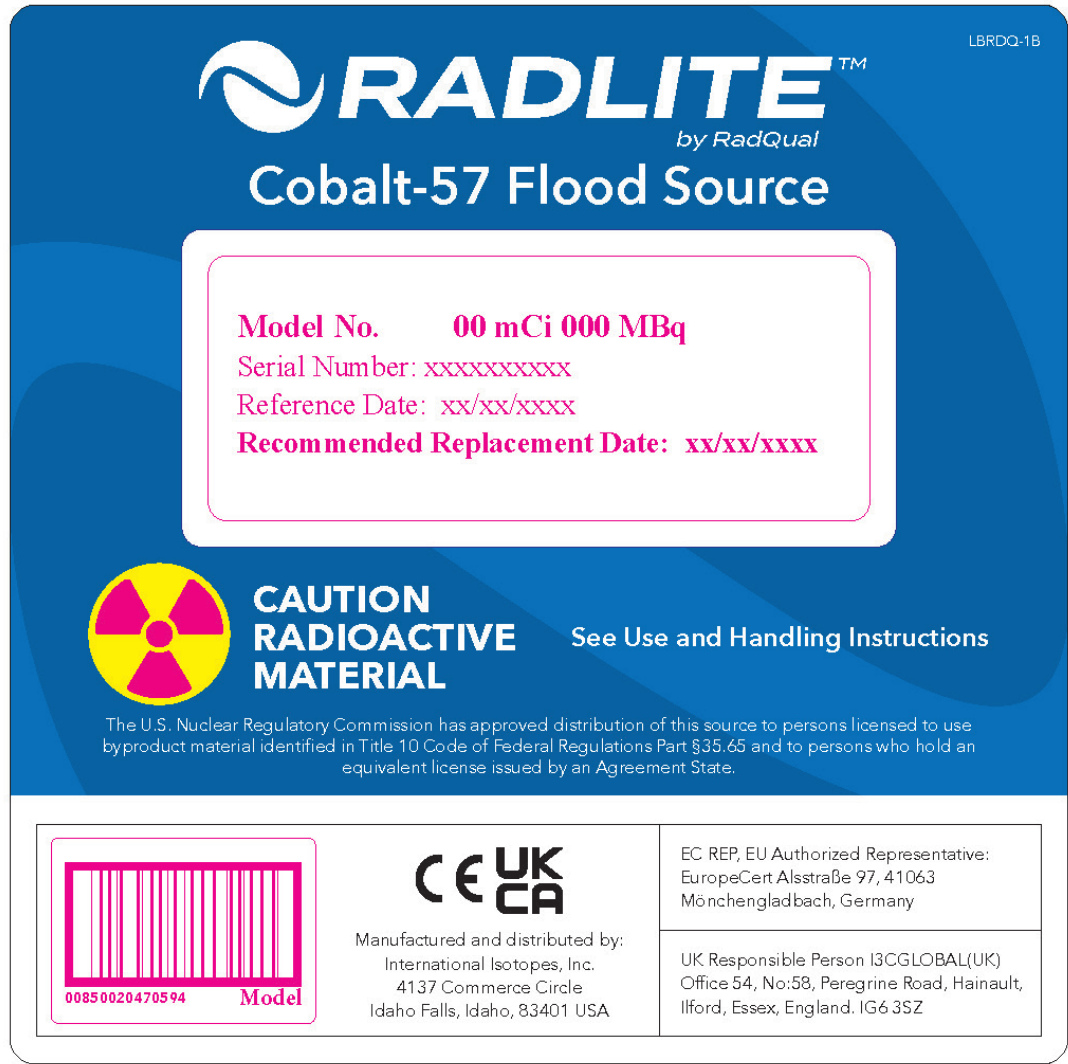
Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com.





Sincerely,

John J. Miller, CHP
Radiation Safety Officer
JJM-2023-04

SSDR	Source Model(s)	Label
NR-1235-S-102-S (E-vial, Syringe, and Serum Vial sources)	BM06E	 <p>Lable: LBRDQ-8B, 3.5 in. x 1.5 in.</p>
	BM06S BM06V5 BM06V10 BM06V20	 <p>Lable: LBRDQ-9B, 1.75 in. x 1 in.</p>

NR-1235-S-102-S (E-vial, Syringe, and Serum Vial sources)	Source Shield	<div data-bbox="747 228 1772 500">  <div data-bbox="1104 261 1373 472"> <p>CE UK CA</p> <p>Manufactured and distributed by: International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401 USA</p> </div> <div data-bbox="1394 261 1761 472"> <p>EC REP, EU Authorized Representative: EuropeCert Alstraße 97, 41063 Mönchengladbach, Germany</p> <p>UK Responsible Person I3CGLOBAL(UK) Office 54, No:58, Peregrine Road, Hainault, Ilford, Essex, England. IG6 3SZ</p> </div> </div> <p data-bbox="632 524 1440 602">Lable: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p> <div data-bbox="968 618 1566 959">  </div> <p data-bbox="632 976 1083 1008">Lable: LBRDQ-9B, 1.75 in. x 1 in.</p>
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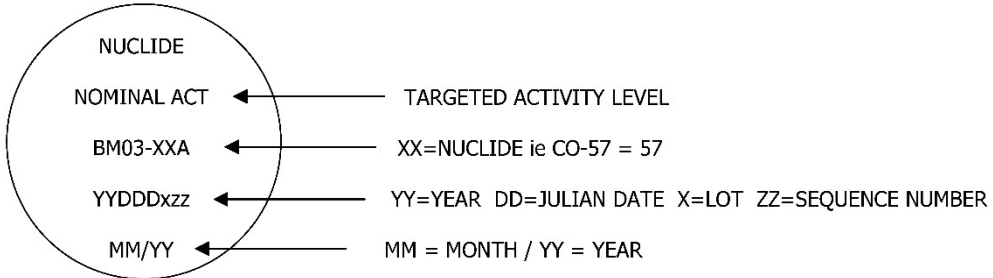



<p>NR-1235-S-104-S (Co57 Flood sources)</p>	<p>BM01L</p>	<div data-bbox="730 228 1791 1286"><p>The label is for a RADLITE Cobalt-57 Flood Source. It features the RADLITE logo with 'by RadQual' underneath. The model number is 00 mCi 000 MBq, and the serial number is xxxxxxxxxxxx. The reference date is xx/xx/xxxx, and the recommended replacement date is xx/xx/xxxx. A cautionary note states that the U.S. Nuclear Regulatory Commission has approved distribution of this source to persons licensed to use byproduct material identified in Title 10 Code of Federal Regulations Part §35.65 and to persons who hold an equivalent license issued by an Agreement State. The label also includes a barcode with the number 00850020470594, the CE UK CA mark, and contact information for the manufacturer, International Isotopes, Inc., and the EC REP, EuropeCert.</p></div> <p>Label: LBRDQ-1B, 5 in. x 5 in. (Note: EC REP and UK Responsible Person subject to change)</p>
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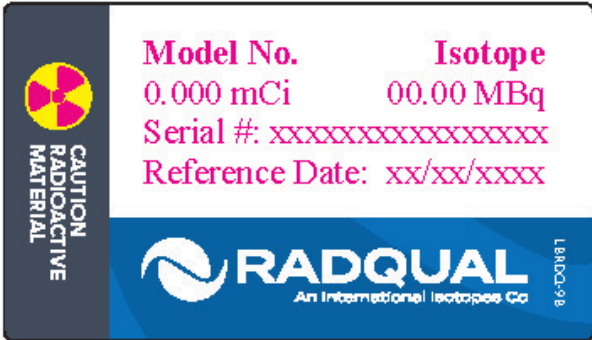
NR-1235-S-104-S (Co57 Flood sources)	BM01L (Jubilant)	<div data-bbox="764 224 1766 1227">   <p>Cobalt-57 Flood Source</p> <p>LBRDQ-12B</p> <div data-bbox="926 488 1604 786"> <p>Model No. 00 mCi 000 MBq</p> <p>Serial Number: xxxxxxxxxxxx</p> <p>Reference Date: xx/xx/xxxx</p> <p>Recommended Replacement Date: xx/xx/xxxx</p> </div> <div data-bbox="848 797 961 915">  </div> <p>CAUTION RADIOACTIVE MATERIAL</p> <p>See Use and Handling Instructions</p> <p><small>The U.S. Nuclear Regulatory Commission has approved distribution of this source to persons licensed to use byproduct material identified in Title 10 Code of Federal Regulations Part §35.65 and to persons who hold an equivalent license issued by an Agreement State.</small></p> <div data-bbox="789 1003 1745 1203"> <div data-bbox="806 1016 1052 1190">  <p>00850020470594 Model</p> </div> <div data-bbox="1087 1016 1346 1190"> <p>CE UK CA</p> <p>Manufactured and distributed by: International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401 USA for Jubilant Radiopharma.</p> </div> <div data-bbox="1381 1016 1738 1190"> <p>EC REP, EU Authorized Representative: EuropeCert Alstraße 97, 41063 Mönchengladbach, Germany</p> <p>UK Responsible Person I3CGLOBAL(UK) Office 54, No:58, Peregrine Road, Hainault, Ilford, Essex, England. IG6 3SZ</p> </div> </div> </div>
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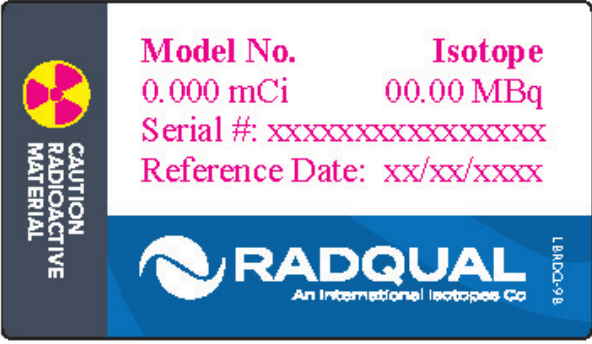
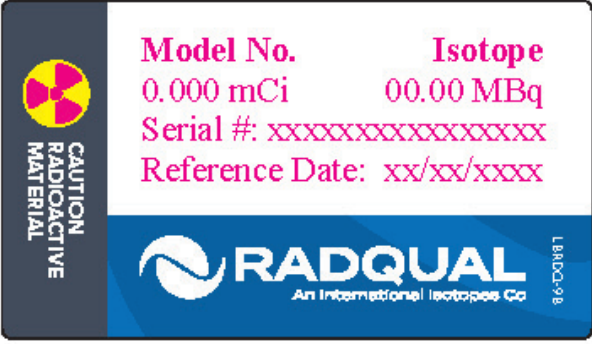
Label: LBRDQ-12B, 5 in. x 5 in.

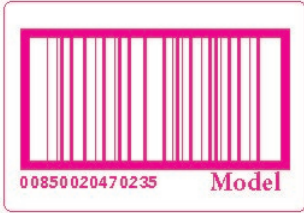

(Note: EC REP and UK Responsible Person subject to change)

NR-1235-S-104-S (Co57 Flood sources)	BM01 BM02 BM04 BM05 BM55 BM07	<div data-bbox="735 225 1791 1276"> <p>RADQUAL An International Isotopes Co</p> <p>Cobalt-57 Flood Source</p> <p>Model No. 00 mCi 000 MBq Serial Number: xxxxxxxxxx Reference Date: xx/xx/xxxx Recommended Replacement Date: xx/xx/xxxx</p> <p>CAUTION RADIOACTIVE MATERIAL See Use and Handling Instructions</p> <p>The U.S. Nuclear Regulatory Commission has approved distribution of this source to persons licensed to use byproduct material identified in Title 10 Code of Federal Regulations Part 35.65 and to persons who hold an equivalent license issued by an Agreement State.</p> <p>00850020470594 Model</p> <p>CE UK CA</p> <p>Manufactured and distributed by: International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401 USA</p> <p>EC REP, EU Authorized Representative: EuropeCert Alstraße 97, 41063 Mönchengladbach, Germany</p> <p>UK Responsible Person I3CGLOBAL(UK) Office 54, No:58, Peregrine Road, Hainault, Ilford, Essex, England. IG6 3SZ</p> </div> <p>Label: LBRDQ-13A, 5 in. x 5 in. (Note: EC REP and UK Responsible Person subject to change)</p>
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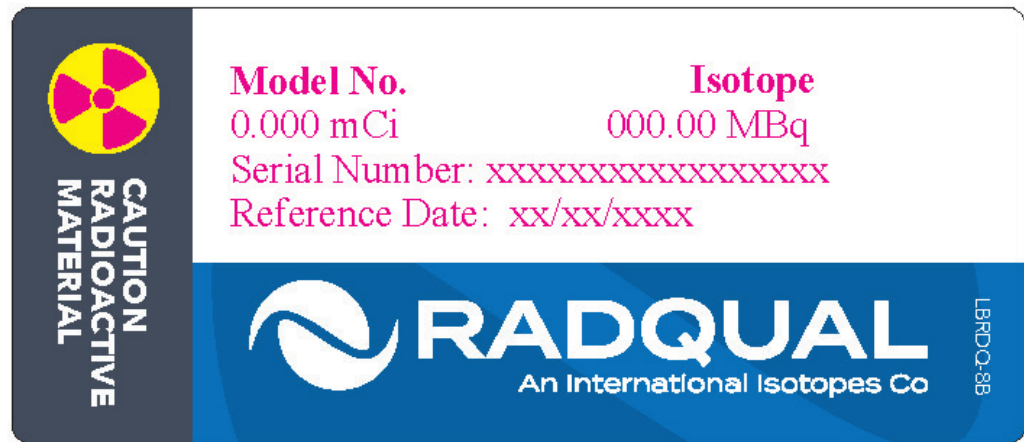

NR-1235-S-106-S (Lucite and Aluminum Spot Marker sources)	BM03-XXA (Top)	 <p>Laser Etching per drawing DWG-NUC-008</p>	
	BM03-XXA (Bottom)		
	BM03-XXL (Top)	 <p>Label: LBRDQ-4, 1 in. diameter round (May include logo if space permits, reference date may be trimmed to mm/yyyy.)</p>	



NR-1235-S-106-S (Lucite and Aluminum Spot Marker sources)	BM03-XXL (Bottom)		
		Label: 1 in. diameter round trifoil – Black on White or White on Black	
	Shield or Packaging	 <p>Label: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p>	
		 <p>Label: LBRDQ-9B, 1.75 in. x 1 in.</p>	

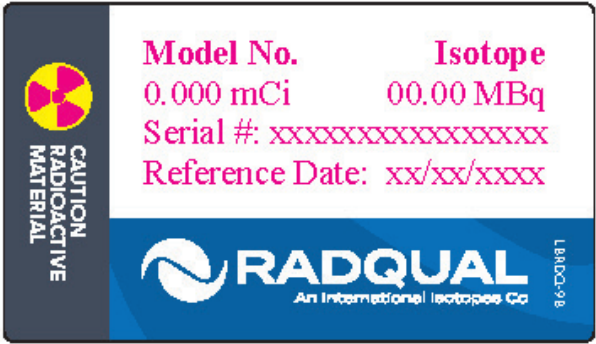

NR-1235-S-107-S (Rigid and Flexible, Line and Ruler sources)	BM83-10 BM83-20 BM83-30	<p>Sources with flexible tubing or rigid Acrylic as outer encapsulation</p>  <p>Lable: LBRDQ-9B, 1.75 in. x 1 in.</p>
	BM83-12 BMXX-YY	<p>Sources with stainless steel as outer encapsulation:</p> <p>Option 1: Laser etch with: Trifoil, Model Number, Isotope, Activity, Serial Number, and Reference Date (as size permits).</p>
		<p>Option 2:</p>  <p>Lable: LBRDQ-9B, 1.75 in. x 1 in. (Note this lable may be included on steel sources with partial etchings)</p>

NR-1235-S-107-S (Rigid and Flexible, Line and Ruler sources)	Shield or Packaging	<div data-bbox="751 224 1774 495">  <div data-bbox="1102 256 1375 467"> <p>CE UK CA</p> <p>Manufactured and distributed by: International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401 USA</p> </div> <div data-bbox="1396 256 1753 467"> <p>EC REP, EU Authorized Representative: EuropeCert Alstraße 97, 41063 Mönchengladbach, Germany</p> <p>UK Responsible Person I3CGLOBAL(UK) Office 54, No:58, Peregrine Road, Hainault, Ilford, Essex, England. IG6 3SZ</p> </div> </div> <p data-bbox="634 522 1438 604">Lable: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p> <div data-bbox="976 636 1564 974">  <div data-bbox="1102 669 1543 820"> <p>Model No. Isotope 0.000 mCi 00.00 MBq Serial #: xxxxxxxxxxxxxxxxx Reference Date: xx/xx/xxxx</p> </div> <div data-bbox="1102 868 1543 966"> <p>RADQUAL An International Isotopes Co</p> </div> </div> <p data-bbox="634 993 1081 1026">Lable: LBRDQ-9B, 1.75 in. x 1 in.</p>
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<p>NR-1235-S-108-S (Cylindrical Phantom sources)</p>	<p>BMCY68- DDHH- YY</p>	<div data-bbox="741 212 1787 1256"><p>The label is for a RADQUAL Ge-68 Cylinder Phantom. It features the RADQUAL logo at the top, followed by 'An International Isotopes Co' and 'Ge-68 Cylinder Phantom'. A central white box contains the following information: Model No. 00 mCi 000 MBq, Serial Number: xxxxxxxxxxxx, Reference Date: xx/xx/xxxx, and Recommended Replacement Date: xx/xx/xxxx. Below this is a yellow radiation warning symbol with the text 'CAUTION RADIOACTIVE MATERIAL' and 'See Use and Handling Instructions'. A paragraph states: 'The U.S. Nuclear Regulatory Commission has approved distribution of this source to persons licensed to use byproduct material identified in Title 10 Code of Federal Regulations Part 35.65 and to persons who hold an equivalent license issued by an Agreement State.' At the bottom, there is a barcode with the number 00850020470594 and the word 'Model'. To the right of the barcode is the CE UK CA mark and the text 'Manufactured and distributed by: International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401 USA'. Further right, there are two sections for authorized representatives: 'EC REP, EU Authorized Representative: EuropeCert Alstraße 97, 41063 Mönchengladbach, Germany' and 'UK Responsible Person I3CGLOBAL(UK) Office 54, No:58, Peregrine Road, Hainault, Ilford, Essex, England. IG6 3SZ'.</p></div> <p>Lable: LBRDQ-5B, 5 in. x 5 in (Note: EC REP and UK Responsible Person subject to change)</p>
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NR-1235-S-108-S (Cylindrical Phantom sources)	BMCY68- DDHH- YY	<p>Option 2: When dimensions of the source do not permit Option 1:</p> <div data-bbox="751 256 1768 695">  </div> <p>Lable: LBRDQ-8B, 3.5 in. x 1.5 in.</p> <div data-bbox="751 808 1768 1079">  </div> <p>Lable: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p>
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NR-1235-S-108-S (Cylindrical Phantom sources)	BMNT57- DDHH- YY	 <p>Lable: LBRDQ-8B, 3.5 in. x 1.5 in.</p>
NR-1235-S-109-S (Penpoint Marker source)	BM10 (body)	 <p>Lable: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p>

NR-1235-S-109-S (Penpoint Marker source)	BM10 (body)	<p>Option 2</p>  <p>Lable: LBRDQ-9B, 1.75 in. x 1 in.</p>
	BM10 (shield)	 <p>Lable: LBRDQ-14A 4.25 in. x 1.125 in. (Note: EC REP and UK Responsible Person subject to change)</p>

Notes: Magenta coloring of text and barcodes represents location of the information on the label and not actual text or barcode.

Label LBRDQ-14A will be included on all source shields or packaging as indicated in the table, on all sources distributed.

Preferred marking of sources with stainless steel or aluminum encapsulations is through laser etching. When the size of the source does not accommodate all markings, and additional label may be applied to the source, shield or packaging.