

August 18, 2009

MSIB-A P&GD 006

FOLDER CONTENTS FOR SSD CASE:

Document Description	Document Date	1st Reviewer Folder Check	LA ADAMS Input
SSD Application	2/24/2009		✓
Acceptance review letter	2/24		✓
NRC RAI	5/27		✓
NRC review checklist	7/31		✓
RAI response	5/21		✓
Sealed Source and Device Certificate NR- 1235-S-109-S			✓
Completion letter for SSD Case	7/31		✓
Additional documents			
NRC RAI No. 2			
RAI No. 2 response			
Note to File for SSD Case			
NRC email			
Email from licensee	5/27, 28 6/1, 9, 24, 30	7/15, 17	✓
Letter to	regarding proprietary information		
Telephone Record			

Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 09-015

SUMMARY DATA	
<b>Name and Complete Mailing Address of the Applicant:</b> International Isotopes Inc. 4137 Commerce Circle Idaho Falls, ID 83401	<b>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:</b> Mr. John J. Miller Radiation Safety Officer 208-524-5300
<b>The Applicant is (check one):</b> <input type="checkbox"/> Custom User <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor <input checked="" type="checkbox"/> Manufacturer and Distributor	<b>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</b>
<b>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</b>	<b>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</b> RadQual, LLC 114 Barrington Town Square #124 Aurora, OH 44202
<b>Model Number:</b> BM10-33 BM10-37 BM10-57 BM10-68	<b>Principal Use Code (see Appendix E):</b> X Medical Reference Source
<b>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</b>	<b>For Use by:</b> <input checked="" type="checkbox"/> Specific Licensees Only <input type="checkbox"/> General Licensees Only <input type="checkbox"/> Both Specific and General Licensees <input type="checkbox"/> Persons Exempt from Licensing
<b>Leak-Test Frequency:</b> <input type="checkbox"/> Periodic Leak-Testing is Not Required <input checked="" type="checkbox"/> 6 Months <input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	<b>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</b>  <b>Radionuclides and Maximum Activities (including loading tolerance):</b> BM10-57, Co-57, 1.0 mCi BM10-68, Ge-68/Ga-68, 0.5 mCi BM10-37, Cs-137, 0.20 mCi BM10-33, Ba-133, 0.20 mCi

**CERTIFICATION:**

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

**Certifying Officer — Typed Name and Title**

**Signature:**

**Date:**

**CHECKLIST**

**Registration Certificate Holder:**

**Model:BM10-33, BM10-37, BM10-57, and BM10-68**

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
DESCRIPTION/CONSTRUCTION			
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	✓	✓	<i>Similar</i>
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	✓	✓	
Assembly methods (screw, welds, etc.); verify integrity	✓	✓	
Source mounting (size and integrity) and security	✓	✓	
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919):	✓	✓	97C22212 Medical reference source <i>q/s</i>
Radiography - Unprotected . . . . . 43515			
Radiography - In Device . . . . . 43313			
Medical - Radiography . . . . . 32312			
Medical - $\gamma$ Teletherapy . . . . . 53524			
Medical - Brachytherapy . . . . . 53211			
Medical - Source Applicators . . . . . 43312			
$\gamma$ Gauges - Unprotected . . . . . 43333			
$\gamma$ Gauges - In Device . . . . . 43232			
$\beta$ Gauges, Low Energy $\gamma$ Gauges, or			
X-ray fluorescence . . . . . 33222			
Oil Well Logging . . . . . 56522			
Portable Moist/Density . . . . . 43333			
Neutron Applications . . . . . 43323			
Calibration source activity > 30 $\mu$ Ci (1 MBq) . . . . . 22212			
$\gamma$ Irradiators (I) . . . . . 43323			
$\gamma$ Irradiators (II, III) . . . . . 43424			
$\gamma$ Irradiators (II, III, IV) . . . . . 53424			
Chromatography . . . . . 32211			
Static Eliminators . . . . . 22222			
Smoke Detectors . . . . . 32222			
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	n/a		

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DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
On-Off indicators (description, qty., location)	n/a	N/A	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	n/a	N/A	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	n/a	N/A	
Shielding efficiency and integrity	n/a	N/A	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	n/a	N/A	Source
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	n/a	N/A	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	n/a	N/A	

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DESCRIPTION	OK/DEF		COMMENTS
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<b>LABELING</b>			
Copy of label	✓	✓	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	✓	✓	
Permanent attachment and location(s) - visible to users?	✓	✓	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	✓	OK.	
<b>CONDITIONS OF USE</b>			
Expected working life of the source/device (years, operations)	✓	✓	
Actions to be taken when product reaches end of its working life.	✓	✓	
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	✓	✓	
How the device will be used	✓	✓	<i>&lt;Not a device&gt;</i>
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	n/a	N/A.	
<b>PROTOTYPE TESTING/HISTORICAL USE</b>			
Tests methods and conditions (for source and device)	✓	✓	
Tests results	✓	✓	
Years of use (incidents, failures, etc.)	n/a	N/A	<i>Not available.</i>
Similarities to other sources/devices if they are used as basis.	n/a	N/A.	
<b>RADIATION PROFILES</b>			
		✓	Microshield 7.0 used to calculate radiation profiles. I used Microshield 5.05 to obtain similar results with numbers or relatively same order of magnitude.
Survey instrument used (type, window thickness, sensitivity, etc.)	n/a	N/A	
Conditions: including environments, scatter (product in beam), and use of guards and shields		/	
Distance from source/surface (per ANSI 538-1979)		/	
Shutter Open and Closed/Source Shielded		- N/A	

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DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
Verify radiation surveys for $\gamma$ radiation meet $inv^2$ law.			
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.			

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DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>QUALITY ASSURANCE</b>			
Materials, subassemblies, services	✓	✓	
Assembly methods (screws, welding, etc.)	✓	✓	
Dimensions and tolerances	✓	✓	
Activity, radiation levels, leak tests	✓	✓	
QA Manual and comparison of manual to Regulatory Guide 6.9	n/a	N/A	
<b>INSTALLATION</b>			
Fixed, portable, movable, fixed installation but portable source housing	✓	✓	
Inherent shielding, inaccessibility	n/a	N/A	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	n/a	N/A	
Mounting integrity	n/a	N/A	
<b>SAFETY INSTRUCTIONS</b>			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		—	
<b>ACCOMPANYING DOCUMENTATION</b>			
Leak tests results and radiation surveys	✓	✓	
Transportation documents	n/a	—	<i>Regulatory bodies &amp; Agency in licensing.</i>
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	✓		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	n/a	N/A	

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DESCRIPTION				OK/DEF		COMMENTS
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SERVICING				n/a	✓	
The following activities may be performed by the persons indicated:						
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant			
Installation						
Relocation						
Maintenance						
Repair						
Source Exchange						
Calibration						
Leak Testing		✓				
Radiation Survey						
Training						
FOREIGN VENDORS				n/a	N/A	
Drop ship				n/a	N/A	
Who and where is source installed				n/a	N/A	
Leak test and radiation surveys				n/a	N/A	
QA in the U.S.				n/a	N/A	

**1<sup>st</sup> Reviewer Signature:**

*W. B. Huel*

**Date:** 08/04/2009.

**2<sup>nd</sup> Reviewer Signature:**

*W. B. Huel*

**Date:**