

Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 10-37

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: Name: International Isotopes, Inc. Address: 4137 Commerce Circle Idaho Falls, ID 83401	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Name: John J. Miller Title: RSO Phone: 208-524-5300 jjmiller@intisoid.com
The Applicant is (check one): <input type="checkbox"/> Custom User <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor <input checked="" type="checkbox"/> Manufacturer and Distributor	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: Manufacturer: Address:
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: Distributor: Address:	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: Name: Address:
Model Number: BM06E, BMO6S	Principal Use Code (see Appendix E): (X) Medical Reference
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	For Use by: <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
Leak-Test Frequency: <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	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 35.65 Radionuclides and Maximum Activities (including loading tolerance): Ge-68, 1.2 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	John J. Miller, RSO
Signature:	Date: 8/9/10

First Reviewer: John O'Donnell Ujagar Bhachu

Second Reviewer:

John Jankovich

CHECKLIST

Applicant: International Isotopes		Case No.: 10-37	
SSD Registration No.: NR-1235-S-102-S		Model Number: BMO6E, BMO6S	
DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd 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?	OK	✓	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	N/A	✓	No change from previous approval
Assembly methods (screw, welds, etc.); verify integrity	N/A	✓	No change
Source mounting (size and integrity) and security	N/A	✓	
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919): Calibration source > 30µCi (1 MBq) 22212	OK	✓	Previously addressed in Prototype Testing as 97C22312
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	N/A	—	
On-Off indicators (description, qty., location)	N/A	—	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	N/A	—	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	N/A	—	
Shielding efficiency and integrity	N/A	—	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	N/A	—	
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	—	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	N/A	—	
LABELING			
Copy of label	OK	✓	In current SSD
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	✓	Previously approved
Permanent attachment and location(s) - visible to users?	OK	✓	No changes
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	OK	✓	No changes
CONDITIONS OF USE			
Expected working life of the source/device (years, operations)	OK	✓	No change, but the activity increase potentially extends the useful life from 2 to 3 years
Actions to be taken when product reaches end of its working life.	OK	✓	Information provided by distributor
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	DEF	✓	Safety Analysis states combustion above 20 degrees C, verify and correct, as appropriate

Rated as 97C22312
Temp. test is -40°C to 150°C

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DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
How the device will be used	OK	✓	No Change
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A	—	Specific licensees only
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	N/A	✓	No change
Tests results	N/A	✓	Previously provided
Years of use (incidents, failures, etc.)	N/A	✓	No change
Similarities to other sources/devices if they are used as basis.	N/A	✓	No change
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, etc.)	OK	✓	Calculations previously approved. Factor 2.4 applied to previous radiation profile for 0.5 mCi Ge-68 to get readings for 1.2 mCi Ge-68
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A	—	
Distance from source/surface (per ANSI 538-1979)	OK	✓	Contact, 5, 30 & 100 cm distance levels provided
Shutter Open and Closed/Source Shielded	N/A	—	
Verify radiation surveys for γ radiation meet inv^2 law.	N/A	—	
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	OK	✓	Ge-68 is EC, but Ga-68 emits e+
QUALITY ASSURANCE			
Materials, subassemblies, services	OK	No Change	No change
Assembly methods (screws, welding, etc.)	OK		No change
Dimensions and tolerances	OK		No change
Activity, radiation levels, leak tests	OK		No change
QA Manual and comparison of manual to Regulatory Guide 6.9	OK		Previously approved
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	N/A	—	
Inherent shielding, inaccessibility	N/A	—	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	N/A	—	
Mounting integrity	N/A	—	

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SAFETY INSTRUCTIONS				
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	✓	Previously approved	
ACCOMPANYING DOCUMENTATION				
Leak tests results and radiation surveys	OK	✓	Table of external radiation levels provided	
Transportation documents	N/A	—		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	N/A	—		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	—		
SERVICING				
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N/A
Relocation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Maintenance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Repair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Source Exchange	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Leak Testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Radiation Survey	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
FOREIGN VENDORS				
Drop ship	N/A	—		
Who and where is source installed	N/A	—		
Leak test and radiation surveys	N/A	—		
QA in the U.S.	N/A	—		

1st Reviewer Signature:

John O'Donnell

Date: 8/23/2010

2nd Reviewer Signature:

John P. J. J. J.

Date: 9/9/2010