Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 10-38

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):

☐	Custom User
☐	Manufacturer
☐	Distributor
☒	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: BMCY68-DDHH-YY, 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:

☒	Specific Licensees Only
☐	General Licensees Only
☐	Both Specific and General Licensees
☐	Persons Exempt from Licensing

Leak-Test Frequency:

☐	Periodic Leak-Testing is Not Required
☒	6 Months
☐	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 10 CFR 32.74

Radionuclides and Maximum Activities (including loading tolerance):
Ge-68, 12 mCi
Co-57, 12 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**
	1st Reviewer	**2nd 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)	OK	def	Source size changes provided in request and on drawing — drawing is not legible
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	DEF	def	Request label drawing example
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)	DEF	def	Mfg & Mode need to be verified on Label
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	✓	Can continue if leak test and labels OK

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Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	✓	
How the device will be used	OK	✓	Lab or medical environment
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	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.)	DEF	def	Provide assumptions and calculations supporting the modeling of the radiation profile for 0.5 mCi Ge-68
Conditions: including environments, scatter (product in beam), and use of guards and shields	DEF	def	Request refers to activity limit for active matrix less than 2.36 inches in diameter, but SSD has 2.6 inches, clarify the discrepancy
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
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	✓	No change
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	—	

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Mounting integrity	N/A	—	
SAFETY INSTRUCTIONS			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	✓	No change
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:	N/A	—	

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			
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:** 8/25/2010

2nd Reviewer Signature: John Jandovitz **Date:** 9/9/2010