

Application and Review Checklist for SSD Case -

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: Name: <i>International Isotopes Inc</i> Address: <i>4137 Commerce Circle, Idaho Falls, Idaho 83401</i>	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Name: <i>John S. Miller</i> Title: <i>RSO</i> Phone: <i>202-524-5300</i>
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: <i>BMD06V5, BMD06V10, BMD06N20</i>	Principal Use Code (see Appendix E): <i>Calibration Sources</i>
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): Radionuclides and Maximum Activities (including loading tolerance): <i>Na-22, 0.5µCi Co-60, 0.10µCi Ge-68, 1.2µCi</i> <i>Cs-137, 0.5µCi Ba-133, 0.5µCi</i>
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 Number:		
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?	✓	✓	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	def.	def	Clarity dimensions - missing from drawing
Assembly methods (screw, welds, etc.); verify integrity	def.	✓	Clarity
Source mounting (size and integrity) and security	N/A	NA	
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919): Choose the ANSI/ISO Classification Calibration Source	def.	def	Discrepancy between tested classification vs. designation for all sources.
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	N/A	NA	
On-Off indicators (description, qty., location)	N/A	NA	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	N/A	NA	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	N/A	NA	
Shielding efficiency and integrity	def.	def	Clarity shielded storage pig
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	N/A	NA	
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	NA	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	N/A	NA	
LABELING			
Copy of label	def.	def	Request label drawing (all sources)
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	def.	def	need to be verified, not included
Permanent attachment and location(s) - visible to users?	def.	def	need to be verified, not included
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	def.	def	Need to be verified, not included
CONDITIONS OF USE			
Expected working life of the source/device (years, operations)	def	def	Need clarification
Actions to be taken when product reaches end of its working life.	def	def	Need clarification
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	N/A	def	
How the device will be used	N/A		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A		

CHECKLIST

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Model Number:

DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	✓	✓	
Tests results	def	def	clarify measurements vs. Microshield
Years of use (incidents, failures, etc.)	def	def	working life for each source confirm conditions specified for the BMQd
Similarities to other sources/devices if they are used as basis.	✓	✓	
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, etc.)	def	✓	Provide instrumentation and calibration
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A	—	
Distance from source/surface (per ANSI 538-1979)	N/A	—	
Shutter Open and Closed/Source Shielded	N/A	—	
Verify radiation surveys for γ radiation meet inv^2 law.	def	✓	} need calculations and prototype measurements
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	def	✓	
QUALITY ASSURANCE			
Materials, subassemblies, services	def	} ✓	Classifier
Assembly methods (screws, welding, etc.)	def		Classifier
Dimensions and tolerances	def		Classifier
Activity, radiation levels, leak tests	✓		
QA Manual and comparison of manual to Regulatory Guide 6.9	def.		Confirm that the current quality assurance is the one listed on the reg notice
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	N/A	} 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		
SAFETY INSTRUCTIONS			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	N/A	NR	
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	N/A	NR	
Transportation documents	N/A	NR	

E and S series

CHECKLIST

Registration Certificate Holder:
Model Number:

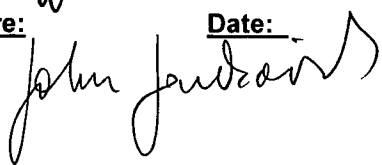
DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	N/A	—	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and 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"/>
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			
Who and where is source installed			
Leak test and radiation surveys			
QA in the U.S.			

1st Reviewer Signature: 

Date: 12/10/12

Date:

2nd Reviewer Signature:



Date: 12/11/2012