

Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 00-000

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: <i>International Isotope Idaho</i>	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>John Miller, RSO 208-524-5300</i>
The Applicant Is (check one):	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
<input type="checkbox"/> Custom User	
<input type="checkbox"/> Manufacturer	
<input type="checkbox"/> Distributor	
<input checked="" type="checkbox"/> Manufacturer and Distributor	
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:
Model Number: <i>BMO6 Series</i>	Principal Use Code (see Appendix C): <input checked="" type="checkbox"/>
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:	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): <i>Part 35</i>
<input type="checkbox"/> Periodic Leak-Testing Is Not Required	Radionuclides and Maximum Activities (including loading tolerance): <i>Various activities</i> <i>Ba-133, Cs-137, Co-57, Na-22, Co-60, Ge-68</i>
<input checked="" type="checkbox"/> 6 Months	
<input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	
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: <i>Nima Ashkeboussi</i> Date: <i>5/25/05</i>	

CHECKLIST

Registration Certificate Holder:

Model:

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)	ok	✓	Plastic
Assembly methods (screw, welds, etc.); verify integrity	ok	✓	any welds
Source mounting (size and integrity) and security	ok	✓	any epoxy
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):			
Radiography - Unprotected 43515			
Radiography - In Device 43313			
Medical - Radiography 32312			
Medical - γ Teletherapy 53524			
Medical - Brachytherapy 53211			
Medical - Source Applicators 43312			
γ Gauges - Unprotected 43333			
γ Gauges - In Device 43232			
β Gauges, Low Energy γ Gauges, or			
X-ray fluorescence 33222			
Oil Well Logging 56522			
Portable Moist/Density 43333	ok	↓	22212
Neutron Applications 43323			
Calibration source activity > 30 μ Ci (1 MBq) <u>22212</u>			
γ Irradiators (I) 43323			
γ Irradiators (II, III) 43424			
γ Irradiators (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	NA	
On-Off indicators (description, qty., location)	N/A	NA	
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	N/A	NA	
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	ok	✓	
Shielding efficiency and integrity	ok	✓	

* Transfer of TX-1153-5-102-5 to NRL.
 Review is based on documentation that NRC received from Texas in letter dated April 27, 2005.

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<p>For medical devices:</p> <p>Type of FDA approval:</p> <ul style="list-style-type: none"> • Premarket notification (501(k)) • Premarket approval (PMA) • Investigational Device Exemption (IDE) • Humanitarian Device Exemption (HDE) <p>Type of Medical Use:</p> <ul style="list-style-type: none"> • manual brachytherapy, 35.400 • medical diagnosis, 35.500 • photon-emitting remote afterloader, 35.600 • photon-emitting teletherapy unit, 35.600 • gamma stereotactic radiosurgery unit, 35.600 • other medical, 35.1000 (intervascular brachytherapy, beta-emitting remote afterloaders, etc) <p>List of FDA limitations of use provided</p>	N/A	NA	
<p>Well logging (10 CFR 39.41) and Irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble as practical.</p>	N/A	NA	
<p>See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)</p>	N/A	NA	

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LABELING			
Complete and final copy of label attached	ok	✓	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	ok	✓	
Attachment and location(s) - visible to users?	ok	✓	exterior of vial + storage pig
Method of attachment is durable and permanent under normal conditions of use	ok	✓	laminated
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	ok	✓	NRC registration; by product materials only
Is label in compliance with regulatory requirements?	ok	✓	
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	ok	✓	range 2 to 5 yrs
Actions to be taken when product reaches end of its working life.	ok	✓	return to manufacturer
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	ok	✓	use in lab environment
How the device will be used	ok	✓	calibration source
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A	MA	
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	ok	✓	
Tests results	ok	✓	Actual testing
Years of use (incidents, failures, etc.)	ok	✓	historical use
Similarities to other sources/devices if they are used as basis.	N/A	W/S	
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, calibration dates, etc.)	ok	✓	
Conditions: including environments, scatter (product in beam), and use of guards and shields	ok	✓	
RADIATION PROFILES (CONTINUED)			

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Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)	ok	✓	
Shutter Open and Closed/Source Shielded	N/A	NA	
Verify radiation surveys for γ radiation meet inv ² law.	ok	✓	
Verify radiation surveys for non-γ radiation have not been calculated using inv ² law.	ok	NA	
QUALITY ASSURANCE			
Materials, subassemblies, services	ok	}	
Assembly methods (screws, welding, etc.)	ok		
Dimensions and tolerances	ok		
Activity, radiation levels, leak tests	ok		
Final inspection	ok		✓
QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)	ok		
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used	ok		
INSTALLATION	N/A		
Fixed, portable, movable, fixed installation but portable source housing	↓	}	
Inherent shielding, inaccessibility	↓		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	↓		NA
Mounting integrity			
ACCOMPANYING DOCUMENTATION	N/A		
Leak tests results and radiation surveys	↓	}	
Operation safety instructions, 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	↓		

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SERVICING						
The following activities may be performed by the persons indicated:				ok ↓	NA	provide disposal
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				↓	NA	
Leak test and radiation surveys				↓		
QA in the U.S.						

1st Reviewer Signature: *Nina Arkhlov* **Date:** 5/20/05

2nd Reviewer Signature: *John Pfeiffer* **Date:** 5/23/05