

Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 12 -12

SUMMARY DATA			
Name and Complete Mailing Address of the Applicant:		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:	
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:		Principal Use Code (see Appendix C): A (D)	
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):	
<input type="checkbox"/>	Periodic Leak-Testing is Not Required		
<input checked="" type="checkbox"/>	6 Months	Radionuclides and Maximum Activities (including loading tolerance):	
<input type="checkbox"/>	Attached is justification for a leak test frequency of greater than 6 months		
<p>CERTIFICATION:</p> <p>THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>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.</p> <p>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.</p>			
Certifying Officer — Typed Name and Title			
Signature:			Date:

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?	no	no	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	det	complete w/ RAJ	
Assembly methods (screw, welds, etc.); verify integrity	ok	✓	
Source mounting (size and integrity) and security	ok	✓	
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):			
Radiography - Unprotected43515	ok	✓	
Radiography - In Device43313			
Medical - Radiography32312			
Medical - γ Teletherapy53524			
Medical - Brachytherapy53211			
Medical - Source Applicators43312			
γ Gauges - Unprotected43333			
γ Gauges - In Device43232			
β Gauges, Low Energy γ Gauges, or X-ray fluorescence33222			
Oil Well Logging56522			
Portable Moist/Density43333			
Neutron Applications43323			
Calibration source activity > 30μCi (1 MBq)22212			
γ Irradiators (I)43323			
γ Irradiators (II, III)43424			
γ Irradiators (IV)53424			
Chromatography32211			
Static Eliminators22222			
Smoke Detectors32222			
Definition of shutter operation (locked in "off" position, not locked in "on" position), Fail safe, spacing and tolerances	n/a	n/a	
On-Off indicators (description, qty., location)	n/a	n/a	
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	n/a	n/a	
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	n/a	n/a	
Shielding efficiency and integrity	n/a	n/a	

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
<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	n/a	
<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	n/a	
<p>See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)</p>	ok	✓	

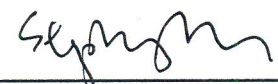
LABELING			
Complete and final copy of label attached	n/a	n/a	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	n/a	n/a	
Attachment and location(s) - visible to users?	n/a	n/a	
Method of attachment is durable and permanent under normal conditions of use	n/a	n/a	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	n/a	n/a	no change
Is label in compliance with regulatory requirements?			
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	n/a	✓	no change
Actions to be taken when product reaches end of its working life.	}	n/a	
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		n/a	
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	
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	ok	✓	
Tests results	ok	✓	
Years of use (incidents, failures, etc.)	n/a	n/a	
Similarities to other sources/devices if they are used as basis.	n/a	n/a	
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	n/a	n/a	
RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)	ok	✓	
Shutter Open and Closed/Source Shielded	n/a	n/a	
Verify radiation surveys for γ radiation meet inv^2 law.	✓	✓	

Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.			
QUALITY ASSURANCE			
Materials, subassemblies, services		✓	
Assembly methods (screws, welding, etc.)	} n/a	n/a	} same
Dimensions and tolerances		n/a	
Activity, radiation levels, leak tests		n/a	
Final inspection		n/a	
QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)		n/a	
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used		n/a	
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	
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	} n/a	n/a	
Operation safety instructions, 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			/	N/A		Source
Relocation			/			
Maintenance			/			
Repair			/			
Source Exchange			/			
Calibration			/			
Leak Testing			/			
Radiation Survey			/			
Training						
FOREIGN VENDORS						
Drop ship				N/A		
Who and where is source installed				↓		
Leak test and radiation surveys						
QA in the U.S.						

1st Reviewer Signature: 

Date:

2nd Reviewer Signature: 

Date:

April 20, 2012