

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

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: Sabia, 7946 Conway Ct San Diego, CA	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: James Miller, 858-279-4000
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 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 E):
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	Radionuclides and Maximum Activities (including loading tolerance): 27 mCi Cf-252
<input checked="" type="checkbox"/> 6 Months 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:	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?	OK	def	Name: Neutron Source Housing, Model S-3 S-3 5000 local and 5000 count	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	Def	Def	needs description/drawing for source drive mechanism, shielding.	
Assembly methods (screw, welds, etc.); verify integrity	Def	Def	Clarify which is S-3; source, source holder,	
Source mounting (size and integrity) and security	Def	Def	source housing	
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919):	Def	Log was source classified by NRC. N 542-1977-4323 reviewed (p. 3)?	Provide drawing of the "lockable source access"	
Radiography - Unprotected 43515				Provide drawing of beam and detector re. material to be tested
Radiography - In Device 43313				Device classification
Medical - Radiography 32312				used 8.9 mCi in stead of the max. activity
Medical - γ Teletherapy 53524				Describe the source design, provide drawing on how 4 sources are installed with a total of 27 mCi;
Medical - Brachytherapy 53211				What is the range of variations for one source
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				
Neutron Applications 43323				
Calibration source activity > 30 μ Ci (1 MBq) 22212				
γ Irradiators (I) 43323				
γ Irradiators (II, III) 43424				
γ Irradiators (II, III, 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	OK			
On-Off indicators (description, qty., location)	OK			
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	OK	def	needs description & drawing	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	OK	✓		
Shielding efficiency and integrity	Def.	✓		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	NA	NA		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	NA	NA		

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See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	GK	✓	

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LABELING			
Copy of label	OK	def	need realistic representation of physical drawing of label
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	✓	
Permanent attachment and location(s) - visible to users?	OK	def	location not specified
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	OK	✓	
CONDITIONS OF USE			
Expected working life of the source/device (years, operations)	OK	✓	10 years
Actions to be taken when product reaches end of its working life.	OK	✓	
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	def	✓	need info
How the device will be used	OK	✓	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	NA	NA	
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	}	def.	was tested with 8.9 μ Ci only are the profiles for this activity (Fig. 3), specify max.
Tests results			
Years of use (incidents, failures, etc.)		def.	
Similarities to other sources/devices if they are used as basis.			
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, etc.)	OK	✓	} however, overall radiation profile is a deficiency due to 8.9 μ Ci use etc.
Conditions: including environments, scatter (product in beam), and use of guards and shields	OK	✓	
Distance from source/surface (per ANSI 538-1979)	OK	✓	
Shutter Open and Closed/Source Shielded	OK	✓	
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	✓	

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QUALITY ASSURANCE			
Materials, subassemblies, services	OK	✓	
Assembly methods (screws, welding, etc.)	OK	✓	
Dimensions and tolerances	OK	✓	
Activity, radiation levels, leak tests	OK	✓	
QA Manual and comparison of manual to Regulatory Guide 6.9	OK	✓	
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	OK	def*	fixed, installed by the applicant
Inherent shielding, inaccessibility	OK		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	OK		
Mounting integrity			
SAFETY INSTRUCTIONS			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	def	delete code (p. 9) - insp. + maintenance - insp. of neutron shielding and port. source housing
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	OK	✓	
Transportation documents	OK	✓	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	OK	✓	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	NA	NA	

* Describe relevance of Procedures entitled "Source Installation, Radiation Gauge" and "Installation Removed... (Non-Routine Operations)", "Installation - Radiation Gauge", (pp 15-24)

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Model:

DESCRIPTION				OK/DEF		COMMENTS
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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			✓			
Relocation			✓			
Maintenance		✓				
Repair		✓			✓	
Source Exchange			✓			
Calibration			✓			
Leak Testing		✓				
Radiation Survey		✓				
Training			✓			
FOREIGN VENDORS						
Drop ship						
Who and where is source installed				NA	NA	
Leak test and radiation surveys						
QA in the U.S.						

1st Reviewer Signature:

[Handwritten Signature]

Date: 5/28/04

2nd Reviewer Signature:

[Handwritten Signature]

Date: 6/29/04