

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>SABIA, Inc 10901 Technology Place San Diego, CA 92127</i>	
Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>James F. Miller, RSO. (858) 217-2000</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:	
/	
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>X1-XP</i>	
Principal Use Code (see Appendix C): <i>H</i>	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	
<i>Materials Analyzer</i>	
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 checked="" type="checkbox"/>	Persons Exempt from Licensing
Leak-Test Frequency:	
<input checked="" 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): <i>31.5</i>	
Radionuclides and Maximum Activities (including loading tolerance):	
<i>Cf-252 27mCi</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: <i>Anna Amos</i>	Date:

*No After 31.5
License*

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?	Def. ✓	✓	Not clear. Inconsistent to analyze comp. of mat on a conv. belt or is to analyze the comp. of mat going through a pipe?
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	Def.	Def.	All eng. drawing are missing.
Assembly methods (screw, welds, etc.); verify integrity	Def.	Def.	
Source mounting (size and integrity) and security	Def.	Def.	
Is source ANSI classification sufficient (from ANSI N43.6-1997 and ISO 2919):			The design and use of the device is not the name or number.
Radiography - Unprotected 43515			
Radiography - In Device 43313			
Medical - Radiography 32312			
Medical - γ Teletherapy 53524			
Medical - Brachytherapy 53211			
Medical - Source Applicators 43312	OK	✓	
γ Gauges - Unprotected 43333			
γ Gauges - In Device 43232		OK	
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 (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	Def.	N/A	N/A
On-Off indicators (description, qty., location)	Def.	N/A	N/A
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	Def.	N/A	N/A
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	Def.	✓	Def: HDPE / use not addressed.
Shielding efficiency and integrity	Def.	Def.	Def: HDPE / Pb may meet. Not addressed. File.

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Model:

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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	
Well logging (10 CFR 39.41) and irradiator (10 CFR 36.21) sources must be as nondispersible and nonsoluble as practical.	N/A	N/A	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	N/A	N/A	

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Model:

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LABELING			
Complete and final copy of label attached	OK	def.	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	N/A	
Attachment and location(s) - visible to users?	Def.	Def.	Need confirmation
Method of attachment is durable and permanent under normal conditions of use	Def.	Def.	Info not included
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	Def.	Def.	Inconsistent manufacturer info
Is label in compliance with regulatory requirements?	OK	Def.	Need Confirmation
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	Def.	Def.	Not specified
Actions to be taken when product reaches end of its working life.	Def.	Def.	info on what they would do w/ the device is missing
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	Def.	Def.	Information missing the info in the app is regarding the X-1 model
How the device will be used	Def.	Def.	Info is inconsistent
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A	N/A	"FREE" impact not addressed - HDPE or Lead Shields
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	Def.	Def.	Not included
Tests results	Def.	Def.	Not included
Years of use (incidents, failures, etc.)	Def.	Def.	Need clarification
Similarities to other sources/devices if they are used as basis.	Def.	Def.	Need info
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, calibration dates, etc.)	Def.	Def.	Not included
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A	N/A	

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Model:

DESCRIPTION	OK/DEF		COMMENTS
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RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 (2001) 2009	N/A	Def	
Shutter Open and Closed/Source Shielded	N/A	N/A	
Verify radiation surveys for γ radiation meet inv^2 law.	N/A	N/A	Info not included
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	Def.	Def	Info not included
QUALITY ASSURANCE			
Materials, subassemblies, services	Def.	Def	Need clarification
Assembly methods (screws, welding, etc.)	Def.	Def	Need clarification
Dimensions and tolerances	Def.	Def.	Need clarification
Activity, radiation levels, leak tests	Def.	Def	Not provided
Final inspection	Def.	Def	Not provided
QA Manual and comparison of other (generally) accepted guidance (e.g., ANSI/ISO/ASQ 9001-2001)	Def.	Def	Not provided
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used	N/A	N/A	
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	OK	Def	fixed device but portable source housing
Inherent shielding, inaccessibility	Def.	Def	No details provided for floor mounting
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	Def.	N/A	
Mounting integrity	Def.	Def.	
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	Def.	Def	
Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	Def.	Def.	Op manual provided does not include these areas
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	N/A	

CHECKLIST

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Model:

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DESCRIPTION				OK/DEF		COMMENTS
				1 st Reviewer	2 nd Reviewer	
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	Def ✓		Supporting documentation was not provided.
Installation			X			
Relocation			X			
Maintenance		X	X			
Repair			X			
Source Exchange			X			
Calibration		X	X			
Leak Testing			X			
Radiation Survey			X			
Training			X			
FOREIGN VENDORS						
Drop ship				N/A	N/A	
Who and where is source installed				N/A	N/A	
Leak test and radiation surveys				N/A	N/A	
QA in the U.S.				N/A	N/A	

1st Reviewer Signature:

[Handwritten Signature]
John P. [unclear]

Date:

6/2/13

6/3/13

2nd Reviewer Signature:

[Handwritten Signature]

Date:

06/05/2013