

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

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: RAM Services 510 County Highway V Two Rivers, WI 54241	
Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Mr. Jordan 1-920-686-3889 or Jerry Wiza (President) donjordan@ramservicesinc.com	
The Applicant is (check one):	
<input type="checkbox"/>	Custom User
<input type="checkbox"/>	Manufacturer
<input checked="" type="checkbox"/>	Distributor
<input type="checkbox"/>	Manufacturer and Distributor
If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: Real Time Instruments Pty. Ltd. Lot 5 Mackay Marina Village Mackay, Queensland Australia 4740	
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: N/A	
Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:	
Model Number:	
Principal Use Code (see Appendix C): H	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): RTI Allscan	
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): Cf-252 12.4 MBq [3 capsules total 12.4 MBq or 3 capsules each 12.4 MBq]	
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	✓	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	def	def	need drawing of source holder identifying the parts, and an overall drawing of the device with overall dimensions in units
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):			Frontier Tech. Corp.
Radiography - Unprotected 43515			FTC-100 series - 04-298-S-101-J
Radiography - In Device 43313			Classification C6X644
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	ok		QSA Global
Oil Well Logging 56522			CVU.CYn - MA-1059-S-271-J
Portable Moist/Density 43333			Classification C6VS45
Neutron Applications 43323			
Calibration source activity > 30μCi (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	ok	✓	
On-Off indicators (description, qty., location)	ok	✓	Attachment 10 and 14
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	ok	✓	
Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium & steel, and so forth)	ok	✓	
Shielding efficiency and integrity	ok	✓	

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

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?		def	location is not specified
Method of attachment is durable and permanent under normal conditions of use	OK	✓	
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	def	def	Activity 6 mCi white Request ask for 12.4 nCi mcr?
Is label in compliance with regulatory requirements?	def	def	
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	OK	✓	Working life 30 years
Actions to be taken when product reaches end of its working life.	OK	✓	Device will be refurbished
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		✓	- 30 to 50°C See Attachment 17, 18
How the device will be used	OK	✓	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing		NA	
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)		def	Attachment 16 drop test + vib. test results not provided
Tests results	def	def	prototype system currently in operation for months
Years of use (incidents, failures, etc.)	def	NA	
Similarities to other sources/devices if they are used as basis.		NA	
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, calibration dates, etc.)	✓	✓	Attachment 8
Conditions: including environments, scatter (product in beam), and use of guards and shields	✓	✓	
RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)	b/c ✓	✓	
Shutter Open and Closed/Source Shielded	b/c ✓	def	profile w/shutter open is not provided
Verify radiation surveys for γ radiation meet inv ² law.	✓	NA	

Verify radiation surveys for non-γ radiation have not been calculated using inv ² law.		✓	
QUALITY ASSURANCE			
Materials, subassemblies, services	OK	✓	} QA checklist
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)		} def	No QA program manufacturer
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used			US audit: independence of auditor is needed
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	OK	✓	20% above rad profile was stated
Inherent shielding, inaccessibility	OK	def	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	OK	✓	
Mounting integrity	OK	✓	
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys		✓	
Operation safety instructions, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		def	Op. Manual is not provide
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A	NA	

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

1st Reviewer Signature: Ly. Seck **Date:** July 3, 2012
2nd Reviewer Signature: John P. Anderson **Date:** 8/22/12