

Appendix C: Application and Review Checklist

Application and Review Checklist SSD 01-37
 new device: NR-xxxx-D-1xx-S

"DISCONTINUE REVIEW"

SUMMARY DATA									
Name and Complete Mailing Address of the Applicant: Scan Technologies, Inc. 303 Jacobsen Drive Rock Branch Industrial Park Poca, WV 25159 800-955-8321	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Carl Baldwin, RSO 800-955-8321								
The Applicant is (check one): <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td> <td>Custom User</td> </tr> <tr> <td></td> <td>Manufacturer</td> </tr> <tr> <td style="text-align: center;">x</td> <td>Distributor</td> </tr> <tr> <td></td> <td>Manufacturer and Distributor</td> </tr> </table>		Custom User		Manufacturer	x	Distributor		Manufacturer and Distributor	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: Scantech International Party Ltd. 40 Maple Avenue Forestville, South Australia 5035 +61(8)82976144
	Custom User								
	Manufacturer								
x	Distributor								
	Manufacturer and Distributor								
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: NA	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: Kanawha Scales & Systems, Inc. (shares same facilities with Scan Technologies) DEF-1.1								
Model Number: CM-100	Principal Use Code (see Appendix F): D, H								
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Conductive Materials Moisture Monitor	For Use by: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">x</td> <td>Specific Licensees Only</td> </tr> <tr> <td></td> <td>General Licensees Only</td> </tr> <tr> <td></td> <td>Both Specific and General Licensees</td> </tr> <tr> <td></td> <td>Persons Exempt from Licensing</td> </tr> </table>	x	Specific Licensees Only		General Licensees Only		Both Specific and General Licensees		Persons Exempt from Licensing
x	Specific Licensees Only								
	General Licensees Only								
	Both Specific and General Licensees								
	Persons Exempt from Licensing								
Leak-Test Frequency: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td> <td>Periodic Leak-Testing is Not Required</td> </tr> <tr> <td style="text-align: center;">x</td> <td>6 Months</td> </tr> <tr> <td></td> <td>Attached is justification for a leak test frequency of greater than 6 months</td> </tr> </table>		Periodic Leak-Testing is Not Required	x	6 Months		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): 30.32 Radionuclides and Maximum Activities (including loading tolerance): FROM FORM Cf-252, 100 micrograms nominal FROM 1.5 75 micrograms max per capsule 1-4 capsules per device. loading tolerance +/- 2.0%, therefore max activity 102 micrograms. DEF-5		
	Periodic Leak-Testing is Not Required								
x	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 N/A									
Signature: N/A	Date:								

CHECKLIST

Registration Certificate Holder:

Model:

2nd review J.S.

DESCRIPTION	OK/DEF	COMMENTS
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?	NA	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	DEF-3	<i>def</i>
Assembly methods (screw, welds, etc.); verify integrity		<i>def</i>
Source mounting (size and integrity) and security		<i>def</i>
Is source ANSI classification sufficient (from ANSI N542-1977):	43323	
Radiography - Unprotected	43515	both sources
Radiography - In Device	43313	already
Medical - Radiography	32312	registered
Medical - γ Teletherapy	53524	
γ Gauges - Unprotected	43333	DEF-5
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	
γ Irradiators (II, III, IV)	43424	
γ Irradiators (I)	43323	
Static Eliminators	22222	
Smoke Detectors	32222	
Definition of shutter operation (locked in Off position OK , not locked in On position OK), Fail safe DEF , spacing and tolerances	DEF-13.6	<i>def</i>
On-Off indicators (description, qty., location) both electric and mechanical -	OK	<i>✓</i>
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	OK	<i>may need guards</i>
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	OK	<i>clarify dose rate</i>
Shielding efficiency and integrity		<i>Need more information</i>
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	NA	<i>NA</i>
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	NA	<i>NA</i>
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.) ANSI N43.8-1979 (was ANSI N538-1979)	OK	<i>✓</i>
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	N/A	<i>clarify dimensions text</i>
Permanent attachment and location(s) - visible to users?	DEF-11	<i>def</i> Location /Rivetting
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	DEF-11	ANSI Classificatio Dimensions
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	10-15 Years	<i>✓</i>
Actions to be taken when product reaches end of its working life.	OK	<i>Return to distributor</i>
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	<i>data to -50C only</i>
How the device/source will be used	OK	<i>✓</i>

CHECKLIST

Registration Certificate Holder:

Model:

2nd reviewer T. Janakovich

DESCRIPTION	OK/DEF	COMMENTS
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A	<i>NA</i>
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device) <i>fire test - OK</i> <i>corrosion - OK</i>	DEF	✓ DROP, FIRE and Vibration
Tests results	DEF	✓ Incorrect calibration of survey meters
Years of use (incidents, failures, etc.) <i>not sufficient b/c does not provide leak test results, only lack of shutter failure</i>		✓ Need clarification of data
Similarities to other sources/devices if they are used as basis.	N/A	
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	DEF-13	<i>needs calibration</i> 6 month calibration required on S. meters
Conditions: including environments, scatter (product in beam), and use of guards and shields		→ Clarification required
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.	N/A	✓
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	OK	✓
QUALITY ASSURANCE		
Materials, subassemblies, services	OK	✓
Assembly methods (screws, welding, etc.)	DEF-4	✓
Dimensions and tolerances	DEF-4	✓
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	X	<i>fixed</i>
Inherent shielding, inaccessibility		<i>may need guards</i>
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	DEF	<i>def</i> Needs clarification
Mounting integrity	DEF	✓ Needs more specific direction
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	✓
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys section 4 says copy of profile as in N538 (Fig 5) given	DEF	✓ Needs clarification
Transportation documents	Not provided	<i>NA</i>

CHECKLIST

Registration Certificate Holder:

Model:

2nd reviewer

DESCRIPTION	OK/DEF	COMMENTS
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	DEF-13	
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		X	x
Relocation		X	x
Maintenance		X	X
Repair		x	?
Source Exchange		x	x
Calibration		x	?
Leak Testing		x	X
Radiation Survey		x	X
Training			?

✓

FOREIGN VENDORS

Drop ship			Sources supplied by USA manufacturers
Who and where is source installed			<i>clarify company role IN USA</i>
Leak test and radiation surveys	OK	✓	
QA in the U.S.			Needs clarification.

OTHER:

Reviewers:

Ujagar S. Bahchu.....(R/A)

Ujagar S. Bahchu

John Jankovich

JPJ 2/21/02