

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

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: Smiths Detection 30 Technology Dr. Warren, NJ 07059 Canada	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Georgia Ranger, RSO
The Applicant is (check one):	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: Smiths Detection 1730 Aimco Blvd Mississauga, Ontario L4W 1V1 Canada
<input type="checkbox"/> Custom User	
<input type="checkbox"/> Manufacturer	
XXX <input type="checkbox"/> Distributor	
<input 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: Distributor Smiths Detection Or Smiths Detection 35 Melanie Lane 30 Technology Dr Whippany, NJ 07981 Warren, NJ 07059
Model Number:	Principal Use Code (see Appendix C):
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Gas Chromotography	For Use by:
	<input type="checkbox"/> Specific Licensees Only
	XXX <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): General Licensees - 10 CFR 31.5
<input type="checkbox"/> Periodic Leak-Testing is Not Required	Radionuclides and Maximum Activities (including loading tolerance): Ni - 15 mCi (0.56 GBq)
XXX <input type="checkbox"/> 6 Months	
<input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	
CERTIFICATION:	
<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?	OK		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	OK		
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 - Unprotected 43515 Radiography - In Device 43313 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 Oil Well Logging 56522 Portable Moist/Density 43333 Neutron Applications 43323 Calibration source activity > 30FCi (1 MBq) 22212 γ Irradiators (I) 43323 γ Irradiators (II, III) 43424 γ Irradiators (IV) 53424 Chromatography 32211 Static Eliminators 22222 Smoke Detectors 32222	32211 Chromatography		
Definition of shutter operation (locked in "off" position, not locked in "on" position), Fail safe, spacing and tolerances	N/A		
On-Off indicators (description, qty., location)	N/A		
Safety interlocks, guards, and so forth to prevent access to beam or high radiation levels	N/A		
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: C Premarket notification (501(k)) C Premarket approval (PMA) C Investigational Device Exemption (IDE) C Humanitarian Device Exemption (HDE)</p> <p>Type of Medical Use: C manual brachytherapy, 35.400 C medical diagnosis, 35.500 C photon-emitting remote afterloader, 35.600 C photon-emitting teletherapy unit, 35.600 C gamma stereotactic radiosurgery unit, 35.600 C other medical, 35.1000 (intervascular brachytherapy, beta-emitting remote afterloaders, etc)</p> <p>List of FDA limitations of use provided</p>	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		
<p>See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)</p>	N/A		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
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?	OK		
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)	OK		
Is label in compliance with regulatory requirements?	OK		
CONDITIONS OF USE			
Estimated working life of the source/device (years, operational cycles)	OK		
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)	?		Do we just go by the actual temperatures that there tested
How the device will be used	OK		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	OK		
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	Def		quesiton on the rationale for the type of base plate used for the hammer test and temperature test only up to 400EC, cert says 500 should we only allow up to 400?
Tests results	OK		
Years of use (incidents, failures, etc.)	OK		
Similarities to other sources/devices if they are used as basis.	OK		
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, calibration dates , etc.)	Def		Need calibration dates for the devices used for measurements

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 st Reviewer	2 nd Reviewer	
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A		
RADIATION PROFILES (CONTINUED)			
Distance from source/surface (per ANSI 538-1979, N43.8 - 2001)	N/A		
Shutter Open and Closed/Source Shielded	N/A		
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.	N/A		
QUALITY ASSURANCE			
Materials, subassemblies, services	OK		
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)	OK		
Additional measures for SSDs if ANSI/ISO/ASQ 9001-2001 is used	OK		
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	OK		
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	Def		Need to verify instrument calibration
Operation safety instructions, 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	?		
SERVICING			

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF		COMMENTS
				1 st Reviewer	2 nd Reviewer	
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			xxxx			
Relocation			xxxx			
Maintenance			xxxx			
Repair			xxxx			
Source Exchange			xxxx			
Calibration			xxxx			
Leak Testing	xxxx	xxxx	xxxx			
Radiation Survey			xxxx			
Training			xxxx			
FOREIGN VENDORS						
Drop ship				N/A		
Who and where is source installed				OK		
Leak test and radiation surveys				Def		need confirmation on instrument calibration
QA in the U.S.				OK		

1st Reviewer Signature: Tomas Herrera */RA/* John Jankovich */RA/* **Date:** 07/13/04

2nd Reviewer Signature: _____ **Date:** _____