

Application and Review Checklist

SSD 01-06 and 01-07

NR-0155-S-101-S	NR-0155-S-102-S	NR-0155-S-103-S	NR-0155-S-104-S
NR-0155-S-105-S	NR-0155-S-106-S	NR-0155-S-107-S	NR-0155-S-108-S
NR-0155-S-109-S	NR-0155-S-110-S	NR-0155-S-111-S	NR-0155-S-112-S
NR-0155-S-113-S	NR-0155-S-114-S	NR-0155-S-115-S	NR-0155-S-116-S
NR-0155-S-117-S	NR-0155-D-120-S	NR-0155-D-124-S	NR-0155-D-126-S
NR-0155-D-801-S	NR-0155-D-802-S	NR-0155-D-803-S	

The Application and Review Checklist are shown on the following pages.

SUMMARY DATA									
<p>Name and Complete Mailing Address of the Applicant:</p> <p>NAME/ADDRESS CORRECTION TO: OK</p> <p>Department of the Army Director, Tank-Automotive and Armaments Command, Rock Island ATTN: AMSTA-LC-SF Rock Island, IL 61299-7630</p>	<p>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:</p> <p>response letters to: Vernon E. Vondera technical contact: Jeff Havener 309-782-2965</p>								
<p>The Applicant is (check one):</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 10%;"></td> <td>Custom User</td> </tr> <tr> <td></td> <td>Manufacturer</td> </tr> <tr> <td></td> <td>Distributor</td> </tr> <tr> <td style="text-align: center;">x</td> <td>Manufacturer and Distributor</td> </tr> </table>		Custom User		Manufacturer		Distributor	x	Manufacturer and Distributor	<p>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</p>
	Custom User								
	Manufacturer								
	Distributor								
x	Manufacturer and Distributor								
<p>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</p>	<p>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: on some SSDs, custom user is Department of Defense</p>								
<p>Model Number: various</p>	<p>Principal Use Code (see Appendix F): various</p>								
<p>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</p> <p>various</p>	<p>For Use by:</p> <table border="1" style="width: 100%;"> <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								
<p>Leak-Test Frequency:</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;">x</td> <td>Periodic Leak-Testing is Not Required</td> </tr> </table> <p>REQUEST TO CHANGE WORDING FOR AREA CONTAMINATION WIPE TESTS - ok</p>	x	Periodic Leak-Testing is Not Required	<p>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</p> <p>30.32</p>						
x	Periodic Leak-Testing is Not Required								

	6 Months	Radionuclides and Maximum Activities (including loading tolerance):
	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
DESCRIPTION/CONSTRUCTION	N/A	
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected 43515 Radiography - In Device 43313 Medical - Radiography. 32312 Medical - γ Teletherapy 53524 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 γ Irradiators (II, III, IV) 43424 γ Irradiators (I) 43323 Static Eliminators 22222 Smoke Detectors 32222		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances		
On-Off indicators (description, qty., location)		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		
Shielding efficiency and integrity		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label	N/A	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)		
Actions to be taken when product reaches end of its working life.		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		
How the device will be used		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing		
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)	N/A	
Tests results	N/A	
Years of use (incidents, failures, etc.)	OK	reported additional information regarding use history and failures
Similarities to other sources/devices if they are used as basis.	OK	SEE ITEM ABOVE
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	N/A	
Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

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

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING				N/A	
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				N/A	
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

OTHER:

- provided copies of documents that had been missing from background file IDed during an earlier SSD review. OK

Reviewers:

Michele Burgess /RA/ 06/25/01

Seung Lee /RA/ 06/25/01