

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

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: <i>Enviro-nics USA</i>	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: <i>Michael Phillips, 386 383 0386</i>
The Applicant Is (check one):	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
<input type="checkbox"/> Custom User	<i>Enviro-nics Oy Työmiehenkatu 2 Sola Mikkeli, Finland</i>
<input type="checkbox"/> Manufacturer	
<input checked="" type="checkbox"/> Distributor	
<input checked="" 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: <i>Amersham &amp; NRD, source manufacturers</i>
Model Number:	Principal Use Code (see Appendix E):
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): <i>Ion Generator chromatography</i>	For Use by:
	<input 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:	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): <i>32.26</i>
<input checked="" type="checkbox"/> Periodic Leak-Testing is Not Required	Radionuclides and Maximum Activities (including loading tolerance): <i>Am-241, 160 pCi</i>
<input type="checkbox"/> 6 Months	
<input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months	
<b>CERTIFICATION:</b> 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:

*Def: letter not signed. — OK, 11/5/63 response*

# CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> 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?	NA		
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 and ISO 2919):	No change.		<p>Auershaan: AMM &amp; NRD: Aool sources.</p> <p>A trimming will be done by Enironics, Finland. By looking into SSND regarding AMM &amp; Aool, the inactive parts were not specified. 4/11/5/03 response</p>
Radiography - Unprotected			
Radiography - In Device			
Medical - Radiography			
Medical - γ Teletherapy			
Medical - Brachytherapy			
Medical - Source Applicators			
γ Gauges - Unprotected			
γ Gauges - In Device			
β Gauges, Low Energy γ Gauges, or X-ray fluorescence			
Oil Well Logging			
Portable Moist/Density			
Neutron Applications			
Calibration source activity > 30μCi (1 MBq)			
γ Irradiators (I)			
γ Irradiators (II, III)			
γ Irradiators (II, III, IV)			
Chromatography			
Static Eliminators			
Smoke Detectors			
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	NA		
On-Off indicators (description, qty., location)	NA		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	NA		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	OK		
Shielding efficiency and integrity	OK		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	NA		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	NA		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	NA		

## CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>LABELING</b>			
Copy of label			
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	↑ OK ↓		
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)			this time, the label change was made only to inside cell, the outside labeling was made <del>from</del> last amendment. according
<b>CONDITIONS OF USE</b>			
Expected working life of the source/device (years, operations)			
Actions to be taken when product reaches end of its working life.	↑ No ↓		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	change		
How the device will be used			
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing			
<b>PROTOTYPE TESTING/HISTORICAL USE</b>			
Tests methods and conditions (for source and device)	OK		Same test as initial ones.
Tests results	Def.		the Radiation level did change
Years of use (incidents, failures, etc.)	NA		(1-50%) after vibration test.
Similarities to other sources/devices if they are used as basis.	NA		OK, 11/5/03 response
<b>RADIATION PROFILES</b>			
Survey instrument used (type, window thickness, sensitivity, etc.)			
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 $\gamma$ radiation meet $inv^2$ law.			
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.			

## CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>QUALITY ASSURANCE</b>			
Materials, subassemblies, services	<div style="display: flex; align-items: center; justify-content: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> ↑ ↓ </div> <div style="margin: 0 10px;"> <i>No</i>  <i>change</i> </div> </div>		
Assembly methods (screws, welding, etc.)			
Dimensions and tolerances			
Activity, radiation levels, leak tests			
QA Manual and comparison of manual to Regulatory Guide 6.9			
<b>INSTALLATION</b>			
Fixed, portable, movable, fixed installation but portable source housing	<div style="display: flex; align-items: center; justify-content: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> ↑ ↓ </div> <div style="margin: 0 10px;"> <i>No</i>  <i>change</i> </div> </div>		
Inherent shielding, inaccessibility			
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers			
Mounting integrity			
<b>SAFETY INSTRUCTIONS</b>			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys			
<b>ACCOMPANYING DOCUMENTATION</b>			
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
				1 <sup>st</sup> Reviewer	2 <sup>nd</sup> Reviewer	
<b>SERVICING</b>						
The following activities may be performed by the persons indicated:				NA		exempt products.
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						
<b>FOREIGN VENDORS</b>						
Drop ship				NA		
Who and where is source installed						
Leak test and radiation surveys						
QA in the U.S.						

**1<sup>st</sup> Reviewer Signature:**

*[Handwritten Signature]*

**Date:** 10/22/03

**2<sup>nd</sup> Reviewer Signature:**

*[Handwritten Signature]*

**Date:** 11/14/03