

Application and Review Checklist for Acceptance Review for SSD 00-047

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:

eV Products, a Division of II-VI, Inc.
373 Saxonburg Boulevard
Saxonburg, PA 16056

Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:

J. Bruce Glock, Division Manager
(724) 352-5228

The Applicant is (check one):

Custom User

Manufacturer

Distributor

☒ Manufacturer and Distributor

If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:

N/A

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: CPC-48

Principal Use Code (see Appendix E): (D) Gamma Gauge

Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):

For Use by:

Specific Licensees Only

☒ General Licensees Only

Both Specific and General Licensees

Persons Exempt from Licensing

Leak-Test Frequency:

Periodic Leak-Testing is Not Required

☒ 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):
10 CFR 31.5, 32.51**

Radionuclides and Maximum Activities (including loading tolerance):

Cd-109, 55 mCi

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		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	Def	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	x	
Assembly methods (screw, welds, etc.); verify integrity	Def	
Source mounting (size and integrity) and security	Def	
Is source classification sufficient (ANSI N43.6 or 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 > 30 μ Ci (1 MBq) 22212 γ Irradiators (I) 43323 γ Irradiators (II, III) 43424 γ Irradiators (II, III, IV) 53424 Chromatography 32211 Static Eliminators 22222 Smoke Detectors 32222		Need clarification
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	Def	
On-Off indicators (description, qty., location)	x	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	x	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	Def	
Shielding efficiency and integrity	x	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	N/A	
Well logging sources must be nondispersible and nonsoluble. (see App. B for a list of approved well logging sources as of Nov. 1991)	N/A	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		
LABELING		
Copy of label		

CHECKLIST**Registration Certificate Holder:****Model:**

DESCRIPTION	OK/DEF	COMMENTS
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?	Def	
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)		20 yrs
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)	Def	
How the device will be used		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	Def	
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.		
RADIATION PROFILES	Def	
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 γ radiation meet inv^2 law.		
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.		
QUALITY ASSURANCE	Def	
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	Def	

CHECKLIST**Registration Certificate Holder:****Model:**

DESCRIPTION				OK/DEF	COMMENTS
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				✓	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys					
ACCOMPANYING DOCUMENTATION					
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				Def	
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					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

Signature:

/RA/

Date: 11/20/00

See RAI letter.