

Application and Review Checklist

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

SUMMARY DATA										
Name and Complete Mailing Address of the Applicant: MEPROLIGHT, Inc. 1 Lawton Street Yonkers, NY 10705		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Bradley D. Fisher, Operations Manager (972) - 6-6395060 (Israel)								
The Applicant is (check one): <table border="1"> <tr> <td></td> <td>Custom User</td> </tr> <tr> <td></td> <td>Manufacturer</td> </tr> <tr> <td>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: MEPROLIGHT, LTD. (Scopus Light (1990) Ltd.) Kibbutz Maayan Zvi Hof HaCarmel 30805 Israel
	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: N/A		Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:								
Model Number: See Attached Lists		Principal Use Code (see Appendix F): W								
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): 1. Weapon (Gun) Sights 2. Watches and Altimeters		For Use by: <table border="1"> <tr> <td></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>X</td> <td>Persons Exempt from Licensing</td> </tr> </table>		Specific Licensees Only		General Licensees Only		Both Specific and General Licensees	X	Persons Exempt from Licensing
	Specific Licensees Only									
	General Licensees Only									
	Both Specific and General Licensees									
X	Persons Exempt from Licensing									
Leak-Test Frequency: <table border="1"> <tr> <td>X</td> <td>Periodic Leak-Testing is Not Required</td> </tr> <tr> <td></td> <td>6 Months</td> </tr> <tr> <td></td> <td>Attached is justification for a leak test frequency of greater than 6 months Tritium-Exempt</td> </tr> </table>		X	Periodic Leak-Testing is Not Required		6 Months		Attached is justification for a leak test frequency of greater than 6 months Tritium-Exempt	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 30.19		
X	Periodic Leak-Testing is Not Required									
	6 Months									
	Attached is justification for a leak test frequency of greater than 6 months Tritium-Exempt									
		Radionuclides and Maximum Activities (including loading tolerance): Hydrogen-3 (tritium) gas 120 mCi maximum (see attached)								
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		Bradley D. Fisher, Operations Manager								
Signature: /RA/		Date: 27 June 2000								

CHECKLIST
Registration Certificate Holder: MEPROLIGHT, Inc.


Model: Sights, Watches and Altimeters - various models

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?	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 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	N/A	Sources are Tritium and must meet ANSI N540 standards. The certificates of registration for both sources listed state that they meet the standards.
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, etc. to prevent access to beam or high radiation levels	N/A	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	N/A	
Shielding efficiency and integrity	N/A	Worst case scenarios allow tritium gas to escape.
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	N/A	
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	N/A	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	OK	Sources meet ANSI N540.

CHECKLIST

Registration Certificate Holder: MEPROLIGHT, Inc.

Model: Sights, Watches and Altimeters - various models

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label	OK	stamped or painted
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	exempt
Permanent attachment and location(s) - visible to users?	OK	H-3 & 
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	OK	exempt
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	OK	6 yrs for most
Actions to be taken when product reaches end of its working life.	OK	normal trash ok
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	
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)	OK	
Tests results	OK	
Years of use (incidents, failures, etc.)	OK	all models currently in distribution in US
Similarities to other sources/devices if they are used as basis.	OK	
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	N/A	not a gauge
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A	not a gauge
Distance from source/surface (per ANSI 538-1979)	N/A	not a gauge
Shutter Open and Closed/Source Shielded	N/A	not a gauge
Verify radiation surveys for γ radiation meet inv^2 law.	N/A	not a gauge
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	N/A	not a gauge

CHECKLIST**Registration Certificate Holder:** MEPROLIGHT, Inc.**Model:** Sights, Watches and Altimeters - various models

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services	OK	
Assembly methods (screws, welding, etc.)	OK	
Dimensions and tolerances	OK	
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	OK	
Inherent shielding, inaccessibility	OK	tamper-proof
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	N/A	
Mounting integrity	OK	
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	OK	none for user
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	OK	none for user
Transportation documents	OK	
Operation, 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	OK	

CHECKLIST

Registration Certificate Holder: MEPROLIGHT, Inc.

Model: Sights, Watches and Altimeters - various models

DESCRIPTION				OK/DEF	COMMENTS
SERVICING					
The following activities may be performed by the persons indicated:				OK	Included instructions tell the user to return damage or defective items to the distributor. Unit replacement would occur rather than repair or maintenance on the sources.
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
Installation			see comment		
Relocation			see comment		
Maintenance			see comment		
Repair			see comment		
Source Exchange			see comment		
Calibration	N/A	N/A	N/A		
Leak Testing	N/A	N/A	N/A		
Radiation Survey	N/A	N/A	N/A		
Training	N/A	N/A	N/A		
FOREIGN VENDORS					
Drop ship				N/A	
Who and where is source installed				N/A	
Leak test and radiation surveys				N/A	
QA in the U.S.				N/A	