

Date mailed: 6/5/13

April 5, 2013



U.S. Nuclear Regulatory Commission
Commercial and R&D Branch, Region 1
Attn: Dennis Lawyer
Health Physicist
475 Allentown Road
King of Prussia, PA 19406-1415

J-6

MS-16

Ref: License No. 20-30024-03

03034371

Dear Mr. Lawyer:

This letter is in response to your letter to me dated May 6, 2013. I apologize for the delay in responding. Inclosed is Revision 2.4 of our Information Manual On Licensed Products Containing Radioactive Material. The Manual has been revised to address your concerns regarding the handling and eventual disposal of customer returned, damaged or unwanted lighting products, either previously distributed or undistributed. The policy is self explanatory and, I believe, addresses your stated concerns. I would certainly appreciate any suggestions you might make to improve it, before we implement it.

If there are any questions on the above or if additional information is required please contact me at the address below or directly by telephone at (845) 635-8698 or fax at (845) 635-5016.

Sincerely,

Alan H. Jones
Corporate Radiation Safety Officer

cc: Albert P Lelis, Danvers
Peter van Breda, Danvers
Chris LaRusso, Danvers
Miguel Morales, RSO, Catano, PR

Enclosed: OSRAM SYLVANIA INC
INFORMATION MANUAL ON LICENSED PRODUCTS
CONTAINING RADIOACTIVE MATERIAL, REV 2.4

OSRAM SYLVANIA
100 Endicott Street
Danvers, MA 01923
(978) 777-1900
www.sylvania.com

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NMSS/RGN1 MATERIALS-002

OSRAM SYLVANIA INC.

INFORMATION MANUAL ON LICENSED PRODUCTS CONTAINING RADIOACTIVE MATERIAL

**** Technical Information
**** Requirements
**** Responsibilities

Revision 2.4
June 3, 2013

Issued By: _____



Alan H. Jones
Corporate Radiation Safety Officer
OSRAM SYLVANIA, INC.

1.OVERVIEW

OSRAM SYLVANIA, INC. is currently licensed by the federal government to manufacture, import and distribute certain lamps and starters containing small quantities of radioactive material. Radioactive Krypton-85 (Kr-85) gas is a constituent of the fill gas of certain models of imported metal halide lamps and the glow switches that are used in some types of compact fluorescent lamps. Radioactive Promethium-147 (Pm-147) is plated on the electrode of the glow starter bottle used in one formerly imported compact fluorescent lamp model. The following are the starter and lamp types containing radioactive material currently manufactured or imported by OSRAM SYLVANIA, INC. and licensed for distribution:

<u>PRODUCT</u>	<u>TYPE</u>	<u>RADIOACTIVE CONTENT</u>
Compact Fluorescent Lamps	Dulux S	Kr-85
	Dulux D	Kr-85
	Dulux DD	Kr-85
	Dulux T	Kr-85
	BFT-15 ¹	Pm-147
Metal Halide Lamps	HMD	Kr-85
	HQI	Kr-85
	HSD	Kr-85
	HSR	Kr-85
	HTI	Kr-85
	MC	Kr-85
	MCP	Kr-85
Starters	ST	Kr-85
Sun Lamps	COSMEDICO	Kr-85
	JK-RUSA	Kr-85
¹ This lamp is no longer stocked		

- ▶ Possession of any radioactive material above certain quantities requires authorization by a federal or state regulatory agency. The authorization is in the form of a Radioactive Materials License issued either by the federal Nuclear Regulatory Commission in "Non-Agreement States" or by state regulatory agencies in "Agreement States".
- ▶ Radioactive material cannot be introduced into a consumer product without a special Radioactive Materials License, called an "E" license, issued **only** by the Nuclear Regulatory Commission. The license authorizes distribution of the specified product to end-users (consumers), who are then **exempt** from the requirement for a radioactive materials license to possess it. Stipulations (conditions) in the license address such matters as maximum amount of radioactive material allowed per item, quality control and package labeling.
- ▶ Although the consumer is exempt from the requirement for a radioactive materials license to possess products manufactured and distributed under an "E" license, the initial distributor (transferor) is not. The manufacturer or importer that first transfers the product from its control to someone else is required to have a radioactive materials possession license, as well.

2. TECHNICAL INFORMATION

► Krypton-85

Kr-85 is a radioactive noble gas and as such does not react chemically with any substance nor is it absorbed by the body.

Kr-85 atoms, as with all radioactive material, emit radiation as they are transformed (disintegrate) into atoms of a different material. 99.6% of the time the radiation given off by a Kr-85 atom is a beta particle with a maximum energy of 0.67 MeV; 0.4% of the time a 0.51 MeV gamma ray is given off.

Kr-85 has a half-life of 10.7 years, that is, it takes 10.7 years for one half of a quantity of Kr-85 to disintegrate into non-radioactive material. After approximately 10 half-lives (107 years) essentially none of the original Kr-85 would remain.

► Promethium-147

Pm-147 is a radioactive rare earth metal commonly used in self-luminous dial watches and clocks.

Pm-147 atoms emit radiation as they are transformed (disintegrate) into a different material. 100% of the time the radiation given off is a beta particle with a maximum energy of 0.225 MeV.

Pm-147 has a half-life of 2.6 years, that is, it takes 2.6 years for one half of a quantity of Pm-147 to disintegrate into a very low specific activity radioactive material found in the earth's crust. After approximately 10 half-lives (26 years) essentially none of the original Pm-147 would remain.

- Radioactive material is used in starters and lamps, in small quantities, to aid in quick ignition by producing ionization which acts as a charge carrier. Not much material is needed to do the job. The maximum authorized activity in any OSRAM SYLVANIA lamp is 0.145 microcuries of Kr-85 and 0.5 microcuries of Pm-147. (A microcurie is a measure of radioactivity.) The average lamp contains 0.01 microcuries of Kr-85 and 0.5 microcuries of Pm-147. The federal government (USNRC) allows a maximum of 30.0 microcuries of Kr-85 or Pm-147 in a lamp for sale to the general public. This is over 200 times the amount of Kr-85 and 60 times the amount of Pm-147 authorized for use in OSRAM SYLVANIA lamps.
- Because of the small quantity of radioactive material contained in the products distributed by OSRAM SYLVANIA and the type of radiation emitted, most of the radiation is stopped (absorbed) by the walls of the lamps and starters. The maximum radiation level measured at one centimeter from any OSRAM SYLVANIA lamp is 0.002 mrem/hr (a measurement of radiation dose to the human body). Listed below are allowable or measured radiation levels from various sources for comparison purposes:

OSRAM SYLVANIA HQI lamp at 1 centimeter –	0.002 mrem/hr
OSRAM SYLVANIA BFT-15 lamp at 1 centimeter –	ND ²
Lamp at 1 centimeter (allowed by regulation) –	1.0 mrem/hr
Luminous watch at 10 centimeters (allowed by regulation) –	0.1 mrem/hr
Luminous clock at 10 centimeters (allowed by regulation) –	0.2 mrem/hr
Transcontinental flight	0.7 mrem/hr
Radiation from outer space (cosmic) in New York –	31.0 mrem/year

Radiation from outer space (cosmic) in Denver –

80.0 mrem/year

²ND = Not detectable above background radiation

- ▶ If the breakage of a lamp containing the Krypton results in releasing the gas, the very small quantity present would quickly dissipate to the surrounding atmosphere and as a noble gas the Krypton would not react with anything, therefore leaving no residual radioactive contamination. For any potential inhalation hazard to exist, a large number of lamps would have to be broken at the same time, in an occupied, small and unventilated space, a very unlikely occurrence.
- ▶ If the breakage of a lamp containing Promethium results in the breakage of the glow bottle containing the radioactive electrode, in all likelihood there would be no release of Pm-147, since it is electroplated on the wire and sealed with an electroplated nickel coating. In this form there would be no inhalation hazard.

Note: Although lamps containing Pm-147 have not been stocked for a number of years, the above information is retained in the Manual to cover customer returns. Any BFT-15 lamp returns should be handled as in the past.

3. OSRAM SYLVANIA INC. RADIOACTIVE MATERIAL LICENSES

Refer to Appendix A for a list of current licenses, facilities/operations licensed and radioactive material authorized.

4. REGULATORY & LICENSE REQUIREMENTS

- ▶ Distribution of OSRAM SYLVANIA lighting products containing radioactive material must be in accordance with Title 10 Part 32 of the Code of Federal Regulations and the terms and conditions of the Corporation's "E" license. The following requirements apply to all of the OSRAM SYLVANIA locations listed in Appendix A:
 - a. Kr-85 and Pm-147 are the only radioactive materials currently *licensed* for use in products distributed by OSRAM SYLVANIA, with maximum authorized quantities of 0.145 microcuries of Kr-85 per lamp or starter and 0.5 microcuries of Pm-147 per lamp.
 - b. Only the product types shown in Section 1 of this Manual are authorized for distribution. (The manual will be updated as changes are made.)
 - c. Every licensed product must be contained in a package (either individually or in bulk) which is marked with the OSRAM or OSRAM SYLVANIA name, (except for "private label" packages where our exempt distribution license number is used instead of our name), licensed type as a part of the overall model number and, for domestic distribution only, the following statement as to contents:
 - (1) Dulux - "Krypton-85" or "Kr-85" or "Glow switch contains Kr-85"
 - (2) BFT-15 - "Starter bottle within lamp base contains 50 nanocuries of Pm-147" or "Starter bottle contains Pm-147"
 - (3) Starters - "Glow switch contains Kr-85"
 - (4) Metal Halide Lamps - "Arc tube filling gas contains Kr-85"
 - d. Every year a report of licensed products transferred to persons exempt from licensing, during the preceding year, must be submitted to:

- (1) The report must include the following information:
 - (a) Description of each product transferred, by type;
 - (b) Total quantity of Kr-85 and/or Pm-147 transferred;
 - (c) The total number of units of each type transferred.

Note: The above reporting will normally be handled by the corporate office.

- The possession of licensed products for distribution by OSRAM SYLVANIA, prior to their *initial* distribution (transfer), must be in accordance with the applicable regulations of whichever agency has jurisdiction in the state in which the licensed OSRAM SYLVANIA facility is located and the terms and conditions of the license for the facility issued by that agency.
 - a. Each facility will be provided with a copy of its possession license and will be informed of any special requirements that apply to its facility either by license condition or state regulations.
 - b. One requirement that applies to **every** licensed facility is the one pertaining to the maximum quantity of Kr-85 and Pm-147 allowed on hand at any one time. The facility limits are specified on the license for that facility, in terms of millicuries (a measure of radioactivity 1000 times a microcurie). To demonstrate compliance, each facility is required to maintain on site either a monthly printout of the amount of Krypton-85/Pm-147 on hand or local access by computer to the amount of Krypton-85/Pm-147 on hand for any month. Each month a Krypton letter is sent to each DC by the Danvers office as a reminder that the previous month's inventory (Hazardous Materials Report) is available for downloading from SAP. This information must be retained on file or on the computer for possible future inspections by regulatory authorities. **THE AMOUNT OF KR-85 AND PM-147 ON HAND AT ANY TIME MUST NOT EXCEED THE LIMITS SHOWN ON THE FACILITY LICENSE.**
 - c. Refer to the appropriate facility license for specific information as to the quantities of Kr-85 and/or Pm-147 authorized. Contact the Corporate Radiation Safety Officer for any further necessary guidance.

5. WASTE DISPOSAL POLICY

A. Previously Distributed Lamps or Starters

- OSRAM SYLVANIA customers may legally dispose of previously distributed lamps and/or starters containing Kr-85 and Pm-147 without regard to their radioactive content by transfer to an approved Lamp Recycler for disposal as universal waste. The lamps should be packaged in accordance with the recycler's written procedure. *Note: the recycler is not required to possess a radioactive material license to receive these products.*
 - a. All such products are to be collected in sturdy containers and disposed of as universal waste through an approved lamp recycler³. (Contact Headquarters for the name of such a lamp recycler that can service your facility.)

³ A recycler that is aware that the lighting products received from OSI may contain certain radioactive materials and that for them such products are exempt from regulation with regard to the radioactive content

- **LAMPS OR STARTERS CONTAINING KR-85 OR PM-147 ARE NOT TO BE DISPOSED OF IN REGULAR FACILITY WASTE UNDER ANY CIRCUMSTANCES.**

B. Undistributed Lamps or Starters

- ▶ Lamps and/or starters that have never been distributed to end-users due to lamp damage or manufacturer's product recall.
 1. Damaged or broken lamps are to be collected in sturdy, lidded metal containers for eventual shipment to a licensed waste processor or burial site for disposal.
 2. Lamps recalled by the manufacturer will be packaged as specified for return shipment to the manufacturer.

6. EMERGENCIES

- ▶ Due to the form and quantity of the Kr-85 and Pm-147 contained in OSRAM SYLVANIA lighting products, there is no situation that can be reasonably theorized where there would be a hazard to employees resulting from any emergency involving these products. Therefore, the following procedure applies:
 - ▶▶ **IN THE EVENT OF ANY EMERGENCY INVOLVING PRODUCTS CONTAINING KRYPTON-85 or PROMETHIUM-147, EMPLOYEES SHOULD TAKE WHATEVER ACTIONS ARE APPROPRIATE FOR THE TYPE OF EMERGENCY INVOLVED, WITHOUT REGARD TO THE RADIOACTIVE CONTENT OF THE PRODUCT.**
- ▶ For the above reason, the breakage of any number of lamps is not considered an emergency. The only action necessary is the packaging of the broken lamps for shipment according to Section 5, above.
 - ▶▶ ***REFER TO APPENDIX B FOR ANY SPECIFIC EMERGENCY PROCEDURES AND/OR EMERGENCY PHONE NUMBERS REQUIRED BY YOUR REGULATORY AUTHORITY.***

7 DUTIES OF RESPONSIBLE INDIVIDUALS

- ▶ In order to obtain a license for OSRAM SYLVANIA Distribution Centers, a responsible individual at each had to be named, usually called the site Radiation Safety Officer (RSO). That individual is listed on each facility's license and has the following duties and responsibilities regarding OSRAM SYLVANIA's licensed use of Kr-85 and Pm-147:
 - a. Complying with all applicable regulations and license conditions;
 - b. Insuring that the facility license limits for Kr-85 and Pm-147 is not exceeded;
 - c. Notifying the Corporate Radiation Safety Officer and the appropriate regulatory agency if any loss or theft of product containing Kr-85 or Pm-147 is suspected;
 - d. Insuring that each immediate product container is marked as specified in 4.c, above;
 - e. Meeting and cooperating with USNRC and state regulatory inspectors and providing all requested information; (Note: Inspections can be anticipated as frequently as annually. Some agencies issue fines for certain violations.)
 - f. Forwarding copies of all communications from regulatory agencies concerning radioactive material to the Corporate Radiation Safety Officer;

- g. Keeping the Corporate Radiation Safety Officer informed, in advance, of any changes affecting the license, such as change of address or change of "on-site" responsible person;
 - (1) Any change in the licensed operations (as shown in the facility license), such as change of site RSO or any increase in the maximum amount of Kr-85 or Pm-147 allowed on hand, must be approved in advance by the appropriate regulatory agency **before** actually undertaking the change;
- h. Posting a "Notice to Employees", Form NRC-3 or equivalent state form in a location where it can be viewed by all employees.

8. INFORMATION THAT SHOULD BE MAINTAINED ON HAND:

- ▶ The latest revision of this manual
- ▶ Facility Radioactive Materials License for possession
- ▶ Supporting documentation for possession license
- ▶ OSRAM SYLVANIA's USNRC Exempt Distribution "E" License
- ▶ Facility-specific regulations and instructions (if any)
- ▶ Current and past inventory records (hard copies or viewable by computer)
- ▶ Latest version of the "Notice To Employees" (NRC Form 3 or the equivalent state form)
(Post on employee bulletin board when received and remove old version)

9. FOR ASSISTANCE OR MORE INFORMATION CONTACT:

- ▶ **CORPORATE RADIATION SAFETY OFFICER:**

Alan H. Jones
171 Traver Road
Pleasant Valley, NY 12569
(845) 635-8698
Fax: (845) 635-5016
Email: ahj@sctser.com

*****ANYTIME ON ANY SUBJECT*****

CERTIFICATION

THIS IS TO CERTIFY THAT I, _____, HAVE READ AND
(printed name of responsible person)
UNDERSTAND THE INFORMATION CONTAINED IN PAGES 1 OF 7 THROUGH 7 OF 7
OF THIS MANUAL PERTAINING TO OSRAM SYLVANIA LICENSED USE OF
RADIOACTIVE MATERIAL AT _____, AND THAT ALL OF MY
(facility address)
QUESTIONS ON THE SUBJECT HAVE BEEN SATISFACTORILY ANSWERED. I ALSO
UNDERSTAND MY RESPONSIBILITIES UNDER THE LICENSE AND THAT ANY QUESTIONS
THAT MAY ARISE PERTAINING TO COMPLIANCE WITH THE LICENSE AND OTHER
APPLICABLE REGULATIONS MAY BE ADDRESSED TO THE CORPORATE RADIATION
SAFETY OFFICER SHOWN IN SECTION 9, ABOVE.

Signed: _____

Title: _____

Date: _____

- *On assuming responsibilities as Site Radiation Safety Officer under the Radioactive Material License or upon receipt of the latest revision of this manual, please send a copy of this page, filled out & signed, to Alan Jones, Corporate Radiation Safety Officer by fax or email. Please retain the original on file.*

CURRENT LICENSES FOR RADIOACTIVE PRODUCTS

► **TO DISTRIBUTE SPECIFIED MANUFACTURED OR IMPORTED PRODUCTS CONTAINING KR-85 OR PM-147:**

USNRC License No. 20-30024-02E, expires: September 30, 2021

► **TO MANUFACTURE & POSSESS CERTAIN PRODUCTS CONTAINING KR-85 PRIOR TO INITIAL DISTRIBUTION:**

Manchester NH Plant:

New Hampshire License No. 430R, expires: September 30, 2013

Winchester KY Plant:

Kentucky License No.201-635-56, expired: March 31, 2013

(This license was terminated by the State of Kentucky on 1/28/13 at the request by the Site RSO. All work involving radioactive material had previously ceased with no plans for such work in the future..

► **TO POSSESS LICENSED PRODUCTS CONTAINING KR-85 OR PM-147 PRIOR TO INITIAL DISTRIBUTION:**

OSRAM SYLVANIA INC. Facility	Regulatory Authority	License Number	Expiration Date	Radioactive Material Authorized
1651 South Archibald Ave. Ontario, CA 91761	California	5873-36	3/26/10 ¹	Kr-85/Pm-147
1100 Tyrone Pike Versailles, KY 40383	Kentucky	201-423-91	5/31/14	Kr-85/Pm-147
2460 Broadhead Road Bethlehem, PA 18017	Pennsylvania	PA - 1395	5/31/23	Kr-85/Pm-147
Royal Industrial Park Building C Road No. 869 Barrio Palmas Catano, PR 00962	US Nuclear Regulatory Commission	20-300024-03	5/31/13 ¹	Kr-85

¹ Application for renewal submitted (Timely Renewal)

Note: Appendix A updated to 6/3/13

SITE-SPECIFIC EMERGENCY PROCEDURES

► **COMMONWEALTH OF KENTUCKY**

- a. For any serious emergency, such as fire or explosion involving products containing Kr-85 and/or Pm-147, the Kentucky Radiation Health Branch shall be notified as follows:

For normal working hours (8:AM - 5:00 PM): (502) 564-3700

After hours (toll free): (800) 255-2587

After hours (Duty Office): (502) 607-1637

- ### ► **IF REQUIRED, ADD YOUR STATE'S EMERGENCY PROCEDURES HERE** (Please send a copy to the Corporate Radiation Safety Officer)