From:

kjbonawitz@aol.com

Sent:

Tuesday, November 04, 2008 10:44 AM

To:

Elizabeth Ullrich

Subject:

Re: SLi Lighting NRC license

**Attachments:** 

NRC ltr01revised.doc; nrc Training.doc

Take a look at the attached, I'll then send you two copies, by mail, for your files. Key

----Original Message-----

From: Elizabeth Ullrich < Elizabeth. Ullrich @nrc.gov > To: kjbonawitz@aol.com < kjbonawitz@aol.com >

Sent: Mon, 3 Nov 2008 8:38 am

Subject: RE: SLi Lighting NRC license

Kevin,

I need the letter I hard copy with a real signature. A couple of comments:

Q3: re-read the question, and confirm that you understand that, as the initial importer, you are considered by the NRC to be the "manufacturer" of record for purposes of the NRC.

Q6 - who is your RSO???

Q7 - did not find an attachment describing training.

Q8 - was not asnwered

Q9a - describe your audits

Q9e - was not answered

Q9f - was not answered

Q9g - describe the surveys

Q11 - no training info provided, no references to DOT training in resume's

As for meeting to see your facilities, let's meet in New Jersey. I am not available Nov 6, Nov 11-12-13 or Nov 17. Other dates are still open.

thanks,

**Betsy** 

Betsy Ullrich, MS, CHP

Senior Health Physicist

Commercial and R&D Branch

Division of Nuclear Material Safety

Region I

**Nuclear Regulatory Commission** 

(610) 337-5040

Elizabeth.Ullrich@nrc.gov

39-3/336-01

From: kjbonawitz@aol.com [mailto:kjbonawitz@aol.com]

Sent: Thursday, October 30, 2008 6:01 PM

To: Elizabeth Ullrich

Cc: Chris.Barton@sliinc.com; rlessy@pattonboggs.com

Subject: SLi Lighting NRC license

Eleizabeth, I've attached the original files, for your records and have added the following;

- 1) NRC label
- 2) quality report(s)
- 3) test procedures
- 4) Notice to be installed at warehouse locations.

Let me know if we need anything else,

Thank you for your help,

Kevin

McCain or Obama? Stay up to date on the latest from the campaign trail with AOL News.

McCain or Obama? Stay up to date on the latest from the campaign trail with AOL News.

#### E-mail Properties

Mail Envelope Properties (8CB0CAB52A09511-B88-7F)

Subject:

Re: SLi Lighting NRC license

Sent Date:

11/4/2008 10:44:34 AM

Received Date:

11/4/2008 10:44:34 AM

From:

kjbonawitz@aol.com

Created By:

kjbonawitz@aol.com

Recipients:

Elizabeth.Ullrich@nrc.gov (Elizabeth Ullrich)

Tracking Status: None

Post Office:

webmail-me17.sysops.aol.com

Files

Size Date & Time

MESSAGE

140001

11/4/2008

NRC ltr01revised.doc 86940 nrc Training.doc 39308

olImportanceNormal

Options
Expiration Date:
Priority:
ReplyRequested:
Return Notification:

False

False

olNormal

Sensitivity: olNe Recipients received:

October 8, 2008

Ms. Betsy Ullrich Senior Health Physicist Commercial and R & D Branch Division of Nuclear Materials Safety

Re: SLI Lighting Products

Research for Additional Information

Control No. 142837

Dear Ms. Ullrich:

The following are answers to questions posed in the NRC letter of October 2, 2008. Our responses are in **bold** type.

- 1. We understand that you plan to distribute certain items (lamps containing krypton-85 gas) to persons who are exempt from the requirements of a license pursuant to 10 CFR 30.15. Confirm that you currently are not distributing lamps containing krypton-85, and will not distribute these items until you are authorized to do so in compliance with the regulations of the NRC. If our understanding is incorrect, please inform us in writing. SLI is not currently distributing lamps containing Krypton 85 and will not distribute these items until we have been authorized by the NRC.
- 2. In order to distribute lamps containing krypton-85 gas to person who are exempt from the requirements of a license, you must obtain 1) a license for distribution of the devices to persons exempted from licensing, pursuant to 10 CFR 30.15. That application must be submitted as described in MUREG-1556, "Consolidated Guidance About Materials Licensees", Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses" (NUREG-1556, VO. 8). This document can be found at the NCRS's web site as described below; and 2) license(s) to cover all activities associated with the possession and use of licensed materials (such as receiving, storing, shipping etcetera) at your warehouse locations.
  - a. Confirm that you will apply for the required exempt distribution license, as described in MUREG 1556, Vol. 8. As described in Section 7.3 of NUREG-1556, Vol. 8, that currently the Division of Materials Safety and State Agreements. Office of Federal and State Materials and Environmental Management Programs (FSME), U.S. Nuclear Regulatory Commission, Washington, DC 2055-0001. We are applying for the required exempt distribution license.
  - b. The application currently under review will authorize possession and use only at those warehouse locations in states under NRC jurisdiction. Based on the

list of warehouse locations submitted with his application, only the SLI Midwest facility in Indianapolis and the Genesis Services location in Blackwood, New Jersey, are currently under the NRC jurisdiction; all other warehouses listed are located in Agreement States. Confirm that, for any warehouse locations in Agreement States, you will apply for a license in the appropriate Agreement State for possession and use of the materials. Alternately, you may choose to limit the warehouses that receive krypton-85 lamps prior to initial distribution, and therefore require fewer licenses for possessions and use.

- 3. Confirm that you understand that, as the initial importer and distributor of devices containing radioactive materials in the United States, this company is considered by the NRC to be the initial manufacturer/distributor of the devices, and is responsible for ensuring that the imported devices meet the requirements as described in NRC regulations, license, and the Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device (SSD Registry). A description of this can be found Section 8.6 of NUREG-1556. "Consolidated Guidance About Materials Licensees." Volume 12, "Program-Specific guidance About Possession Licenses for Manufacturing and Distribution" (NUREG-1556, Vo. 12). This document can be found at the NRC web site as described below. As the manufacturer, you must comply with the requirements in 10 CFR Parts 19, 20, and 30. The lamps in question are sold for distribution to persons exempt from licensing. SLi is the manufacturer of these products.
- 4. Because you are a new applicant for a new license, we need to meet with you at one or more of the NRC locations and/or at your business office in South Carolina prior to issuing the new license. An individual from our office will contact you within the next several weeks (or has contacted you) to schedule an appointment for this meeting. We are available to meet, please choose a place and time.
- 5. Please provide the following information to supplement Item 5 of your application:
  - a. In accordance with Section 8.6 of NUREG-1556, Vol. 12, identify each device that you intend to distribute by the manufacturer name and model number. See attached addendum A-B-C.
  - b. State the maximum activity of krypton-85 per source to be possessed under this license. Based on the application, it appears that the maximum activity may be 0.0005 microcuries; however, column 5A also refers to "see hidden page below" for certain items but the hidden pages were not provided. Same as above.
  - c. State the maximum quantity of krypton-85 to be authorized on your license. This amount should include the total activity you expect to possess at any one time in all locations under NRC jurisdiction, in all devices and/or sources in storage, use, ready for shipment, waste, etc. See page one.

- 6. Item 7 of the application states that Ingrid Lohrengel, Patrick Beerten and John Stockswill be responsible for the radiation safety program. See page 2 attached.
  - a. In accordance with Section 8.7.1 of NUREG-1556, Vol. 12, specify the individual who will be named as the Radiation Safety Officer (RSO) for the manufacturer distributor possession license, and provide information demonstrating that the proposed RSO is qualified by training and experience to perform the duties of the RSO for the materials to be authorized by your license. If that individual is not located at your NRC main office or warehouse locations and/or is not a SLI Lighting employee:
    - i. Describe: how control over the radiation safety program that will be delegated to the consultant-RSO; the relationship that will exist between the consultant-RSO and your institutional management for funding the radiation safety program and related regulatory requirements; the consultant-RSO's minimum amount of on-site time (hours per week/month/quarter, as applicable) performing RSO duties; and the availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. See safety training personnel.
    - ii. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence. At each of our manufacturing facilities we have trained employees to handle these situations. We also employ URS out of Greenville SC as an environmental consultant.
    - iii. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant-RSO with limited authority. Sammy Smith
  - b. In accordance with Section 8.7.2, name all other persons who will be authorized to handle, or supervise the handling of, licensed materials and will be listed on the license. Provide information for each individual that demonstrates that he/she is qualified by training and experience to possess and use the licensed material.
- 7. In accordance with section 8.8 of NUREG-1556, Vol. 12, describe the radiation safety training that will be provided to all individuals who will handle the lamps containing krypton-85 at your facilities. Although the risks from the sources are low, individuals who are present in the area and/or handle the license materials should know such information as: how to recognize the sources/devices containing radioactive materials; limitations for activities with the sources/devices (can they remove sources from the device?); regulatory requirements for transfers, posting, labeling, disposal, Department of Transportation (DOT) shipping requirements etc; and any other appropriate topics. Confirm that any ancillary personnel working in areas such as shipping/receiving, maintenance, etcetera will be appropriately

- instructed in recognizing and handling the devices, and their limitations for working with or around the devices. See attached Sylvania training method.
- 8. In accordance with Section 8.9 of NUREG-1556, Vol. 12, describe the facilities and equipment to be available at each location under NRC jurisdiction where licensed material will be used and possessed. For the lamps containing krypton-85, you should, as a minimum, describe the areas assigned for receiving, storage, preparation, shipping, security and any measurement of radioactive materials. This is a stocking warehouse for all SLi products. Forklifts and hand trucks are used to move the lamps to their stocking and shipping locations. No preparation is done since the items are received in shippable inner and outer cartons. All facilities are secure and locked every night.
- 9. Item 10 of your provided training documents in languages other than English. However, this item should describe your radiation safety program, commensurate with you actual activities with krpton-85 lamps in the warehouses. In addition, as the initial manufacturer/importer, you are responsible to ensure that the lamps you import meet the design requirements. We import products designed and specified by our company, Sylvania Lighting. These lamps meet all design requirements by the IEC, ANSI and Sylvania Lighting.
  - a. In accordance with Section 8.10.1 of NUREG-1556, Vol. 12, describe your audit program for ensuring radiation safety and compliance with NRC regulations and requirements, including quality assurance for the products containing krypton-85. Audits. We've submitted quality examples of our lamps. All of our lamps are tested before they are released for shipment from the factory. These tests confirm that the products meet ANSI/IEC/Sylvania specifications.
  - b. In accordance with Section 8.10.2 of NUREG-1556, Vol. 12, describe the monitoring instruments that you have (or would have access to) for routine and/or emergency monitoring of radiation or radioactive contamination. **Geiger counter**
  - c. In accordance with Section 8.10.3 of NUREG-1556, Vol. 12, provide your procedures for ensuring material accountability; OR state "physical inventories will be conducted at intervals nor to exceed 6 months, to account for all sealed sources or devices received or possessed under the license;" OR provide an alternate procedure for ensuring that devices have not been lost, stolen, or misplaced. Please note that 10 CFR 32.17 required that an annual report of transfers be submitted to the NRC, and specifies the information that must be included in the report. Sylvania takes 2 physical inventories per year.
  - d. In accordance with Section 8.10.3 or NUREG-15456, Vol. 12, you do not have to submit procedures for package receipt and safe package opening and handling. Please note, however, that you are required to have such procedures and they will be reviewed during inspection. Cartons are not

- opened. They ship from our warehouse directly to our customers. We only have warehouse facilities in the US.
- e. In accordance with Section 8.10.4 or NUREG-1556, Vol. 12, describe how you will assess (or have assessed) occupational doe from your activities. We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, radiation dose in excess of 10% of the allowable limits.
- f. In accordance with Section 8.10.4 of NUREG-1556, Vol. 12, confirm that you will develop, document, implement, and maintain operating procedures and emergency procedures, commensurate with the radiation safety requirements for your licensed materials. Confirmed
- g. In accordance with Section 8.10.4 of NUREG-1556, Vol. 12, describe the radiation surveys you will perform, commensurate with the radiation safety requirements for your licensed materials. We understand that leak tests are not required for sealed sources of kypton-85. Radiation surveys. We have purchased equipment to measure the levels of kr 85. If material is damaged we will measure to see if there has been any leakage. If so the area will be quarantined and "cleaned" up meeting all NRC guidelines.
- 10. In the application, you enclosed a description of the outer carton label. Please note that lamps must be marked and/or labeled as described in 10 CFR 32.15(d)(1). The labeling and marking of the lamps will be reviewed in your application to distribute the lamps to persons who do not require a license but will possess them pursuant to 10 CFR 30.15. See attached.
- 11. Confirm that you will transport, or offer for transport licensed devices in accordance with the requirements of the Department of Transportation (DOT). Please note that DOT regulations require that all persons who will prepare packages for transportation be trained in the applicable requirements at 3-year intervals (49 CFR 172.704). Training –All shipments are made through 3<sup>rd</sup> party companies. (transportation companies) We meet all DOT requirements when transporting all of our products.
- 12. Item 11 states that you would follow all hazardous waste rules and regulations for waste disposal. Please note that the sources in the devices may be considered radioactive waste, in addition to hazardous waste due to mercury or other hazardous component. Also. Radioactive waste may not be exported, in accordance with 10 CFR 110.23(a)(1). Confirm that if any of the sources or devices become radioactive waste, that such radioactive waste will be transferred to an authorized radioactive waste broker for appropriate disposal. Disposal will be handled appropriately through authorized radio active waste facilities.

SYLVANIA	MANUAL DE PROCEDIMIENTOS DE RADIOLOGICAL PROTECTION	Hoja: 1/103
Chapter III.	RADIOLOGICAL PROTECTION	Sección 3.1.

### **3.1.9. TRAINING**

Training	Trainers/ Facilitators	Trainees	Frequency
Introduction to Radiological Protection	Responsible for Radiological Security;	Production, Maintenance and	Yearly
Program general	Production,	Process Control	
information	Maintenance, and	Supervisors;	
	Process Control	Mechanics; Process	
	Supervisors.	Inspectors,	
1		Miscellaneous	
		Production Personnel	
Security Standards	Supervisors of Dept. 13	Production Personnel of Dept. 13	Yearly
Responsibilities of	Responsible for	Superintendents and	Yearly
radiological protection	Radiological Security	Supervisors of Dept. 13	•
Operational	Resp. of Radiological	Production,	Yearly
Radiological Protection	Protection, Production,	maintenance and	
1	Maintenance and	process control	
	Process Control	supervisors of Dept. 13;	
	Supervisors	Mechanics; Process	
		Inspectors;	
		Miscellaneous &	·
		Production personnel	
Emergency Procedures	Resp. of Radiological	Production,	Yearly
	Protection, Production,	maintenance and	
	Maintenance and	process control	
	Process Control	supervisors of Dept. 13;	
	Supervisors	Mechanics; Process	
		Inspectors;	
		Miscellaneous &	
		Production personnel;	
Management of	Resp. of Radiological	Emergency Brigade Superintendents and	Yearly
disposal of radioactive	Security	miscellaneous of Dept.	l
material	Security	13.	
Monitoring and	Resp. of Radiological	Production,	Yearly
measuring Radiation	Security	Maintenance and	· Carry
sadaring radiation		Process Control	
		Supervisors of Dept. 13,	
		Warehouse Supervisors	:
Storage and	Resp. of Radiological	Production,	Yearly
transportation of	Security	Maintenance and	
cylinders containing	· · · · ·	Process Control	
Kr85		Supervisors of Dept. 13,	
		Warehouse	
		Supervisors,	
		Responsible of raw	
	<u> </u>	materials warehouse	<u> </u>

SYLVANIA	MANUAL DE PROCEDIMIENTOS DE RADIOLOGICAL PROTECTION	Hoja: 2/103
Chapter III.	RADIOLOGICAL PROTECTION	Sección 3.1.

Security standards for the sue of Krypton	Resp. of Radiological Security	Production, Maintenance and Process Control Supervisors of Dept. 13, Warehouse Supervisors	Yearly
Management of disposal of material with Kr85	Resp. of Radiological Security	Production Supervisors of Dept. 13	Yearly
Basic course in Radiological Protection	Resp. of Radiological Security	Personnel occasionally exposed to radiation	Every 2 years for new workers and refresher
Advanced course in Radiological Protection	Corresponding agency	Resp. for Radiological Security	Every 5 years