



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 23, 2011

Docket No. 03038458
Control No. 575319

License No. 06-31445-01

Eugene Czako
Senior Development Engineer
Light Sources, Inc.
37 Robinson Boulevard
Orange, CT 06477

SUBJECT: LIGHT SOURCES, INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 575319

Dear Mr. Czako:

This is in reference to your application dated June 7, 2011, applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Please confirm that you are a management representative. If you are not a management representative, then please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.
2. 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, Vol. 12). This document can be found at the NRC's web site as described below. Specifically, 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. As the manufacturer, you must comply with the requirements in 10 CFR 32.14, 32.15, and 32.16 for these items, in addition to the requirements in 10 CFR Parts 19, 20 and 30.

3. Because you are an applicant for a new license, we will meet with you at your site in Shelton, Connecticut, 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.
4. Item 5 of the application states that the individual lamps will contain krypton-85 gas, not to exceed 0.120 microcuries per lamp, and that you do not expect to possess more than 40,000 lamps (4,800 microcuries krypton-85 total). Confirm if the authorized quantity on your license should be "not to exceed 0.120 microcuries per lamp and 5,000 microcuries total." This amount should include the total activity you expect to possess at any one time, in all devices and/or sources possessed at the Orange, Connecticut location in storage, use, ready for shipment, waste, etc. You may propose alternate maximum quantities to be possessed.
5. The cover letter dated May 20, 2011, to your application indicates that you have included documentation on other companies that distribute lamps containing krypton-85 from the same supplier you propose to use. However, 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. If the device must be included in the SSD registry, that information will be requested as part of the review of your request for a distribution license.
6. Item 7 of the application states that Earl Digioia, Environmental and Safety Engineer, oversees all of your safety and waste handling procedures. Item 8 of the application states that Eugene Czako has received two days of training from the manufacturer in the handling of the lamps.
 - 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 in Orange, Connecticut, and/or is not a Light Sources, Inc. 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.

- (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.
 - (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.
 - 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 Eugene Czabo and Earl Digioia and any other individuals who will handle the lamps containing krypton-85 at your facility. 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.
- 8. Item 10 of your application states that you do not currently have a radiation safety program. However, a minimal radiation safety program is required, commensurate with your actual activities in Orange, Connecticut. In addition, as the initial manufacturer/importer, you are responsible to ensure that the lamps you import meet the design requirements specified in the SSD Registry.
 - 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.
 - 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.

- c. Item 9 of your application states that a full inventory count is done at least twice yearly. 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 not 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 requires that an annual report of transfers be submitted to the NRC, and specifies the information that must be included in the report.
 - d. In accordance with Section 8.10.3 of NUREG-1556, 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.
 - e. In accordance with Section 8.10.4 of NUREG-1556, Vol. 12, describe how you will assess (or have assessed) occupational dose from your activities.
 - f. In accordance with Section 8.10.6 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.
 - g. In accordance with Section 8.10.1 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 krypton-85.
9. Item 9 of your application states that a caged area in the plant is used to control and limit the access to quality controlled and special inventoried products. The above implies that individuals not authorized to handle the licensed material have access to the caged area where the lamps will be stored. Confirm that only individuals authorized to handle the lamps will enter the cage or provide procedures which ensure that only authorized individuals handle the lamps.
10. 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).

11. Item 11 states that, "Any lamps still intact are all handled by 100% recycling through Northeast Lamp recycling. Lamp bodies that may have been broken are handled as separate waste through Veolia Environmental Services." However, if damaged devices are received by Light Sources, Inc. or an event such as a building fire occurs, the sources in the devices may be considered radioactive waste. Radioactive waste may not be exported, in accordance with 10 CFR 110.23(a)(1). Also, intact lamps cannot be recycled but may be returned to the manufacturer or they may be treated as radioactive waste. 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.

We understand that you have applied for a license for distribution of the devices to persons exempted from licensing, pursuant to 10 CFR 30.15. Review of that application will include review of the labeling of the devices and instructions to users of the lamps.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; then Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 575319. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Steve Courtemanche

Steve Courtemanche
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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