



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

September 13, 2011

Mail Control No. 575400

Light Sources, Inc.
ATTN: Mr. Eugene Czako
Sr. Development Engineer
37 Robinson Boulevard
Orange, CT 06477

SUBJECT: DISCONTINUED REVIEW OF APPLICATION FOR NEW EXEMPT
DISTRIBUTION LICENSE

Dear Mr. Czako:

This refers to your Application for Material License, Nuclear Regulatory Commission (NRC) Form 313, dated June 7, 2011 attached to letter dated May 20, 2011, to a September 7th telephone conversation with your consultant, Ms. Barlow, regarding the application, and to a August 30, 2011, letter signed by Janos Kovacs.

As discussed with Ms. Barlow, your letter and application raises confusion regarding how your application affects the activities of two current NRC licensees and does not completely address the information that is required pursuant to NRC's regulations regarding your product(s). As explained, your application must address each regulatory requirement, as appropriate, that is specified in 10 CFR 30.15 (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/>), 10 CFR 32.14 (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0014.html>) and 10 CFR 32.15 (<http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/part032-0015.html>) and as further explained in NUREG-1556, Vol. 8 (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>).

With regard to your August 30 letter, Please note that the footnote provided at 10 CFR 30.15(a)(8) defines electron tubes to include, "spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents." NRC has long considered lamps to fall into this category as they are designed to "conduct or control electrical currents." Persons who receive the lamps are exempt from the radioactive material disposal requirements found in 10 CFR Part 20 and may dispose of the lamps without regard to its radioactivity, and are not required return the lamps. Nor is there any requirement that you should inform or suggest that the lamps be returned because of their radioactivity. However, other jurisdictions may impose disposal restrictions due to other hazardous characteristics. Should lamps be returned, how you handle the lamps may be a possession license issue, but it is not an exempt distribution license issue.

We find that the following requirements need to be addressed:

1. Your letter indicates that you will be the direct importer of products that will then be transferred to two current NRC exempt distribution licensees who also hold active possession licenses for the products. Given that an exempt distribution license is only required for person (company) who initially transfers or distributes a product to an unlicensed person, this creates a confusing situation as there will be multiple exempt distribution licenses for the products after initial importation. You should be aware that you could import and transfer the product to the other two licensees without you needing an exempt distribution licensee, as a transfer between specific licensees pursuant to 10 CFR 30.41 (providing your possession license doesn't specifically prohibit such transfers).

We would appreciate clarification regarding your transfer to these two licensees and your need for an NRC exempt distribution license. We would also appreciate any information you may have regarding the licensees intent with regard to maintaining their licenses.

2. While your application primarily only includes information regarding the two companies and the products they import and distribute under their E-licenses, there is some information suggesting that you may be considering importing and distributing lamps other than those the two companies are currently authorized to distribute, or lamps that labeled for different vendors. Please clarify if this is your intent.

Even if you only plan to import and transfer to the two existing licensees the products they are currently authorized for, each applicant needs to address all of the regulatory requirements independently so just including their previous submissions is generally not considered adequate. Note that applicants still need to address these requirements even when importing and distributing finished products. As explained in the note to item 6.1 of NUREG-1556, Vol. 8, this applies even when the product is an item that may be currently or previously distributed by another NRC licensee.

We further note that your application cover letter dated May 20, 2011, indicates that , in the future, you plan to import "additional brands and lamp models," therefore, it is important that all regulatory requirements are addressed. (Please clarify if this implies only other lamp manufactured by Radium Lampenwek or, perhaps, other manufacturers.) We also note that the lists attached to your August 30 letter appeared to include lamps that may not have been authorized for the other two licensed distributors. While your application did provide some general information regarding the lamps in item 5 as required in 10 CFR 32.14(a)(1), most other required items were not addressed.

3. 10 CFR 32.14(b)(2) requires the details of construction and design of each product. Please note that products may be grouped by design.
4. 10 CFR 32.14(b)(3) requires a description of the method of containment or binding of the byproduct material in the product.
5. 10 CFR 32.14(b)(4) requires the application to address, "Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product."
6. 10 CFR 32.14(b)(5) requires the application to address, "Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet." Please note, that even when importing a finished product, the applicant's QC should include procedures for verifying the product, and its labeling, upon receipt.
7. 10 CFR 32.14(b)(6) requires the applicant to submit information concerning "The proposed method of labeling or marking each unit ... and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product."

In the paragraph following item 11 of the attachment to your application, you indicate that you plan to develop labeling that includes a "part/specification number, however, it is unclear how this would meet the regulatory requirement that the manufacturer or initial distributor (transferor) be identified.

Your August 30th letter provides information describing why it may be difficult to label the individual lamps which we find acceptable; however, as specified in item 9.3 of NUREG-1556, Vol. 8, the label should be placed as close as possible to the product. Please address these issues.

8. 10 CFR 32.14(b)(7) requires, for products for which limits on levels of radiation are specified in 10 CFR 30.15 of this chapter, the radiation level and the method of measurement. 10 CFR 30.15 specifies that radiation levels not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

Without this information, we are unable to complete the review of your application and, as discussed with Ms. Barlow, we are discontinuing our review. If you provide the additional information within a year, we generally will not require resubmission of fees. Refer to Mail

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In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

J. Bruce Carrico
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs
Washington, DC 20555

ML_____

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