



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 1, 2018

Mr. Joseph DeFilippo Jr.
Quality Control/Safety Manager/
Radiation Safety Officer
Lambda Research Optics Inc.
1695 West MacArthur Blvd.
Costa Mesa, CA 92626

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. DeFilippo:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated November 29, 2017, and letter dated December 15, 2017, requesting an exempt distribution license.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application. An application for an exempt distribution license should not contain information concerning the possession and use of radioactive material because that information is covered in a separate possession license (where required).

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Control Number 602114.

J. DeFilippo

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If you have any questions, please contact me at (301) 415-5477, or by e-mail at Richard.Struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 040-38400

Enclosure:
Request for Additional Information

J. DeFilippo

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LAMBDA RESEARCH OPTICS INC., REQUEST FOR ADDITIONAL INFORMATION

Date: February 1, 2018

Certified Mailing No.: 7015 0640 0003 2910 1993

ML18010A208 (pkg.)

ML18031A499 (Letter)

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Richard Struckmeyer	Deborah Weaver	Richard Struckmeyer
DATE	02/1/2018	01/31/2018	02/1/2018

OFFICIAL RECORD COPY

Lambda Research Optics Inc., Application dated November 29, 2017
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Lambda Research Optics Inc., application dated November 29, 2017, and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, Chapter 40 (10 CFR 40), Section 40.52. Please be advised that an application for an exempt distribution license should not contain information concerning the possession of radioactive material because that is covered in your separate possession license (where required).

For applicants in some Agreement States and for those in NRC jurisdiction (Non-Agreement States), a separate possession license is required for use and manufacturing of products containing some forms of source material. You provided an address for your company in the State of California. Please determine from the state radiological materials licensing authority whether you are required to have a possession license. The contact information for this is:

Gonzalo Perez, Branch Chief
CA Dept. of Health Services
Radiologic Health Branch
P.O. Box 997414, MS7610
Sacramento, CA 95899-7414
PH (916)440-7942 FX (916)341-7224
gonzalo.perez@cdph.ca.gov

Also, if you intend to conduct the activities described in your application in other States, you should determine whether a possession license is required in each such jurisdiction. Additional contact information, if needed, can be found at <https://scp.nrc.gov/>.

Please provide a copy of any possession license(s) that are required. The NRC will not issue an exempt-distribution license until you provide any required possession license(s).

Please provide the information required by each of the following regulations. If any of the required information was provided in your application, please indicate where it can be found.

1. 10 CFR 40.52(b)(1) requires the applicant to submit detailed information regarding the maximum quantity of source material in each product. Your application stated the maximum amount which will be possessed at any one time, but apparently did not state the maximum quantity of source material in each product.
2. 10 CFR 40.52(b)(2) requires the applicant to submit details of construction and design of each product, if applicable. For coated lenses, this must include a description of manufacturing methods that will ensure that the coatings are unlikely to be removed under the conditions expected to be encountered during handling and use.

Enclosure

3. 10 CFR 40.52(b)(3) requires, for products with applicable quantity or concentration limits, the applicant to submit 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 provide a copy of your quality control procedures and describe your quality assurance program which will ensure the products meet the required standards.
4. 10 CFR 40.52(b)(4) requires labeling or marking its container with the identification of the initial transferor of the product and the source material in the product. In your application, a description of labelling is provided in the Radiation Safety Program Manual, page 49 of 70; however, this description does not appear to include the identification of the initial transferor of the product. Please describe how your labelling will identify initial transferor. A copy or copies of applicable label(s) would be helpful.
5. Please identify additional locations, if any, from which distribution of your product will take place.
6. The following paragraph does not require a specific response; however, you should confirm that you understand the requirement contained in the cited regulation:

10 CFR 40.53(c)(1) requires each person licensed under Section 40.52 to maintain and report records of all transfers of byproduct material.