

January 5, 2017

II-VI Optical Systems, Inc.
ATTN: Andrew Riser
General Manager
36570 Briggs Road
Murrieta, CA 92563

SUBJECT: II-VI OPTICAL SYSTEMS, INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR A NEW LICENSE

Dear Mr. Riser:

This letter refers to your application dated November 11, 2016, and received on December 7, 2016, for an Exempt Distribution License. In reviewing your applications, we found that additional information is required.

Title 10 of the *Code of Federal Regulations* (10 CFR) 40.52 requires the applicant to submit sufficient information regarding the product pertinent to evaluation of the potential radiation exposure. Your application did not contain all required information. Please submit to us the following information:

1. In your application, you stated that the optical components are manufactured in Murrieta or Trinity, California. Please provide the specific location of your facility in Trinity California. Additionally, provide the specific location of your facility in New Port Richey, Florida.
2. Provide a copy of your California and Florida material licenses. Please note, in accordance with 10 CFR 40.13(c)(10), a possession and use license is required for distribution under 10 CFR 40.52.
3. Initial transfer is the transfer that first puts a product or material into use under a particular regulatory provision, in this case an exemption from licensing. Transfers to international customers do not constitute initial distribution and reimport is considered an initial transfer, thus requiring such transfer to be completed under a specific license issued under 10 CFR 40.52. In order for international customer products to be imported into the U.S. without a separate license under 10 CFR 40.52, such distributions would be considered to occur under the requirements of any license issued to II-VI Optical Systems.
 - a. The foreign distributor must be able to indicate that the product meets the initial distribution requirements prior to import into the U.S. (e.g., include proper labeling and documentation verifying that the lenses or mirrors were manufactured by II-VI Optical System with the products). Please describe how you will ensure that proper labeling will be kept through reimport in order to identify the products were originated from your company.

- b. How will you ensure that the products will not be modified by your foreign customers before they re-distribute them into the U.S.?
- c. How will you ensure that the foreign distributor does not include lenses (or other products) not manufactured by you in the product? The foreign distributor should be notified that if it does include products requiring an initial distribution license that are not covered by your license (or a license issued to other companies with similar provisions), that they (or their U.S. customer) would need to obtain a license authorizing initial distribution under 10 CFR 40.52 for those other products.
- d. The regulations do not require you to report distributions for products not being initially distributed into the U.S. (i.e., international distributions). However, in order for international customer products to be imported into the U.S. without a separate license under 10 CFR 40.52, II-VI Optical Systems must be able to account for the transfers into the U.S. for use under the exemption. Please describe how you plan to identify and report these initial transfers back into the U.S. (e.g., is there a system that you can develop to receive reports from your customers on the number and types of lenses that are distributed back to the U.S., or can you suggest a different method for the U.S. Nuclear Regulatory Commission (NRC) to understand how much of the materials are reimported into the U.S. so that we may more accurately project impact to public health and safety rather than reporting all foreign distributions?).

We will continue our review upon receipt of this information. 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.

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

A. Riser

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If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

Shirley S. Xu
Materials Safety License Branch
Division of Material Safety, States, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 040-38394
Mail Control No. 592464

A. Riser

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If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA/

Shirley S. Xu
Materials Safety License Branch
Division of Material Safety, States, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 040-38394
Mail Control No. 592464

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