

April 14, 2014

Heraeus Noblelight Fusion UV Inc.  
ATTN: Darrin Leonhardt, RSO  
910 Clopper Road  
Gaithersburg, MD 20878

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION  
FOR RENEWAL OF EXEMPT-DISTRIBUTION LICENSE

Dear Mr. Leonhardt:

This refers to your application for Materials License, NRC Form 313 dated May 28, 2013, regarding renewal of your Exempt Distribution License No. 19-23798-01E. We do not have sufficient information to complete the review of your application. The documents listed in License Condition 13 are very old and should be replaced by an up-to-date description of your program. If you previously provided information to the U.S. Nuclear Regulatory Commission (NRC) in documents that are listed in License Condition 13, please resubmit the pertinent information in a new document. If you provided information to the NRC in your renewal application that responds to one of the requirements listed below, you may either restate the information or specify where in the application that information was provided.

A. Specific items concerning regulatory requirements:

In accordance with the requirements of 10 CFR 32.14, please provide the following information:

1. Details of chemical and physical form of, and maximum quantity in each product, as required by 10 CFR 32.14(b)(1).
2. Details of construction and design of each product, as required by 10 CFR 32.14(b)(2).
3. The method of containment or binding of the radioactive byproduct material in the product, as required by 10 CFR 32.14(b)(3).
4. Procedures for and results of prototype testing are required by 10 CFR 32.14(b)(4) to demonstrate that the byproduct 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 to be encountered in normal use of the product. Please provide these procedures and describe the prototype testing performed on the product.
5. Describe the quality control procedures to be followed in the fabrication of production lots of the product and provide a description of the quality standards the product will be required to meet, as required by 10 CFR 32.14(b)(5).

6. Describe the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product, as required by 10 CFR 32.14(b)(6).
7. Describe the radiation level and the method of measurement as required by 10 CFR 32.14(b)(7). Limits on levels of radiation are specified in Section 30.15 as follows: the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.
8. As stated in 10 CFR 32.14(c), each product will contain no more than the quantity of byproduct material specified for that product in §30.15. Please provide the quantity of byproduct material in your product. (Note: Although your application states "...the volumes and maximum activities of the HNFN products are trade secrets and have been provided in the required yearly material transfer reports to the NRC," this information must be provided in the application. You may request to withhold certain information that is deemed confidential or proprietary by following the guidance in Section B, below.)
9. As required by 10 CFR 32.14(d), describe how the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.
10. Describe your quality assurance practices in the manufacture of the part or product, or the installation of the part into the product as required by 10 CFR 32.15(a)(1).
11. As stated in 10 CFR 32.15(a)(3), each person licensed under §32.14 shall visually inspect each unit in inspection lots. Any unit that has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit. Describe how you shall visually inspect each unit in inspection lots for defects.
12. Describe how you shall prevent transfer to other persons for use under §30.15 of this chapter or equivalent regulations of an Agreement State any defective part or product, as required by 10 CFR 32.15(c).

B. Request to withhold the contents of your application from public view:

The attachments to your application contain the following statement: "Information contained herein is SAIC proprietary information and is made available to you as required for our Material License renewal. This information is submitted in confidence and its disclosure to you is not intended to constitute public disclosure or authorization for disclosure to other parties." Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public

domain, and therefore may be viewed by any member of the public who requests to see them.

In order to request that NRC withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 10 CFR 2.390. The applicant should submit all of the following:

- A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
- A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
- An affidavit that:
  - Is notarized.
  - Clearly identifies (such as by name or title and date) the document to be withheld.
  - Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and who has been authorized to apply for withholding on behalf of the company.
  - States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
  - Provides a rational basis for holding the information in confidence.
  - Fully addresses the following issues:
    - Is the information submitted to and received by NRC in confidence? Provide details.
    - To the best of the applicant's knowledge, is the information currently available in public sources?
    - Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
    - Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant: If so, explain why in detail. The explanation should include the value of the information to your company, the amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the 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.

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>.

Any correspondence regarding your amendment application should reference Control Number 581000.

If you have any questions, please feel free to contact me at (301) 415-5477 or by electronic mail: [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov).

Sincerely,

**/RA/**

Richard K. Struckmeyer, Health Physicist  
Licensing Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Docket No. 030-32547  
License No. 19-23798-01E

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If you have any questions, please feel free to contact me at (301) 415-5477 or by electronic mail: [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov).

Sincerely,

Richard K. Struckmeyer, Health Physicist  
Licensing Branch  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Docket No. 030-32547  
License No. 19-23798-01E

DISTRIBUTION: SSD\_ELicense RI/DNMS MSSA r/f  
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**ML14100A589**

<b>OFC</b>	MSSA	MSSA	MSSA
<b>NAME</b>	RStruckmeyer	MKotzalas	RStruckmeyer
<b>DATE</b>	4/14/14	4/14/14	4/14/14

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