



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

April 2, 2018

Cultilux
ATTN: Zujia Xu
1013 Harimaw CT East
Metairie, LA 70001

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Xu:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated December 5, 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. These questions are based on our understanding that your products consist of gas electron tubes containing no greater than 10 Kilobecquerels for the 1000W lamps and 4.8 Kilobecquerels for the 315W lamps. If any of your products contain larger quantities of this, or contain other byproduct materials, we will ask additional questions.

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 is by the State of Louisiana.

Any correspondence regarding your amendment application should reference Control Number 602108.

Z. Wu

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If you have any questions, please contact me at (301) 415- 5452, or by e-mail at Donald.Lowman@nrc.gov.

Sincerely,

/RA by Shirley Xu for/

Don Lowman
Materials Safety Licensing Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39087
Mail Control No. 602108

Enclosure:
Request for Additional Information

Z. Wu

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CULTILUX, REQUEST FOR ADDITIONAL INFORMATION

Date: April 2, 2018

Certified Mailing No.: 7015 3010 0000 7901 7465

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NAME	DLowman	DWeaver	SXu	SXu for DLowman
DATE	04/2/2018	04/2/2018	04/2/2018	04/2/2018

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CULTILUX APPLICATION DATED DECEMBER 5, 2017 REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Cultilux application dated December 5, 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 32 (10 CFR 32), Sections 32.14 and 32.15, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public website (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>). Please be advised that an application for an exempt distribution license does not need information concerning the possession of radioactive material because that is covered in your separate State of Louisiana possession license. This includes Items 7 through 11 on Form 313.

Please provide the information required by each of the following regulations. You may need to obtain some of this information from your supplier(s). These regulations apply to companies that import products as well as those that manufacture products within the United States. Note that it is the applicant's responsibility to confirm the validity of all information.

1. 10 CFR 32.14(b)(2) requires the applicant to submit details of construction and design of each product. Applicants should provide a list of all models of each type of product they wish to distribute. The requested information should be provided for each type of tube.
2. 10 CFR 32.14(b)(3) requires the applicant to submit the method of containment or binding of the byproduct material in the product. Please describe the method by which Kr-85 gas is introduced and the glass tube is sealed.
3. 10 CFR 32.14(b)(6) requires the applicant to submit 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. Note: 10 CFR 32.15(d)(1) requires labeling or marking of each unit and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Please provide examples of your labels in the form of drawings, copies, or photographs. The guidance in NUREG-1556, Volume 8, Section 9.3, states: "For those products requiring labeling, NRC's policy is that the smallest item distributed must display the required label. If this is not possible, then the label should be placed as close as possible to the product. For example, if an electron tube is too small to label, then the label should be placed on the next smallest container, such as the bubble pack containing the electron tube."
4. 10 CFR 32.14(b)(7) requires that the applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including the radiation level and the method of measurement. In your application it is stated, "*The tube is within the glass of products specifically exempted from certain licensing requirements by operation of 330.40(c)(1)(G)(iii) because it contains 0.27 micro curies of Kr-85 and radiation levels do not exceed 1 millirad per hour at a distance of 1 centimeter when measured through 1 centimeter when measured through 1 milligrams per square centimeter of absorber*". Please provide reference for "330.40(c)(1)(G)(iii)". Also, provide evidence of

“radiation levels do not exceed 1 millirad per hour at a distance of 1 centimeter when measured through 1 centimeter when measured through 1 milligrams per square centimeter of absorber” and method of measurement.

5. 10 CFR 32.14(d) requires the applicant to provide information to show that 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. This requirement could be satisfied in by conducting your own testing or by acquiring information from the manufacturer or a third party. Whether you conduct your own testing, or rely on a description from the manufacturer or a third party of methods for testing samples of the product(s) and the results of these tests to satisfy this regulatory requirement, please provide this information in your response.
6. 10 CFR 32.15(b)(1) states that no person licensed under Section 32.14 shall transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.

Please describe how you will prevent the transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14.