



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

May 22, 2018

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

SUBJECT: CULTILUX, SECOND REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR A NEW LICENSE

Dear Mr. Xu:

This letter refers to your letter dated April 9, 2018, responding to our questions for a new Exempt Distribution License. In reviewing your response, we have determined additional information is required to complete our review as found below:

1. In #4 of our letter dated April 2, 2018, we asked for a reference to 330.40(c)(1)(G)(iii). You stated the radiation measurements were conducted by the China factory which is certified by the Food and Drug Administration. Please provide the origin for 330.40(c)(1)(G)(iii); for example, provide the State regulation this section is from including a link or copy of the regulation. Additionally, please provide, as requested, evidence of radiation levels not exceeding 1 millirad at 1 centimeter. In your response, you stated:

The measurement of Kr-85 was conducted by the China factory which is certified by FDA. They are able to provide accurate testing for each model of Ceramic Metal Halide.

Please provide us with documentation specific to the lamps that details the radiation survey methodology.

2. In #5 of our letter dated April 2, 2018, per our request, you did not provide test results to show that the material is properly contained in the product under severe conditions. Title 10 of the *Code of Federal Regulations* (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.
3. In #6 of our letter dated April 2, 2018, we asked 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. In your response, you stated:

Cultilux will inspect every product before it's shipped out. The package is designed to be open without any broken parts. Every receiver will be informed that the defective or broken products can be used and must be returned to Cultilux or properly recycled by certified waste management companies recommended by Cultilux.

Please provide us with the operating procedure or quality control standards to be used to prevent distribution of a defective product.

4. Please provide us with a copy of your State of Louisiana possession license.

Any correspondence regarding your application should reference Control Number 602108.

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

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

Sincerely,

/RA/

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

CULTILUX, SECOND REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR A NEW LICENSE

Date: May 22, 2018

Certified Mailing No.: 7015 0640 0003 2910 1610

ML18010A110 (pkg.)

ML18141A833 (letter)

OFC	NMSS/MSST/MSLB	NMSS/MSST/MSLB	NMSS/MSST/MSLB	NMSS/MSST/MSLB
NAME	Don Lowman	Deborah Weaver	Shirley Xu	Don Lowman
DATE	5/22/18	5/22/18	5/22/18	5/22/18

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