



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

January 18, 2018

Nanolux Technology, Inc.
ATTN: Keith Harrington, President
1180 Holm Road, Suite-E
Petaluma, CA 94954

SUBJECT: NANOLUX TECHNOLOGY, INC., SUSPENSION OF THE REVIEW OF YOUR
LICENSE APPLICATION REQUEST

Dear Mr. Harrington:

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

After reviewing your application, the U.S. Nuclear Regulatory Commission (NRC) staff sent you a letter dated October 24, 2017, requesting additional information. Your undated response to this letter was received on or about December 22, 2017.

Due to incomplete information, the NRC staff is unable to complete a safety evaluation of application. Therefore, the NRC staff has discontinued the evaluation of your application (License Action Mail Control No. 600654). This action is taken without prejudice to submission of the additional information described in the attachment to this letter. Please note that when you resubmit your application at a later date, you may refer to Mail Control No. 600654 for the documentation you have already submitted. Also please note that for the NRC to continue processing your application, if the requested information is received by NRC more than 12 months after our receipt of your original application, you will be required to pay an additional license fee as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses."

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>.

K. Harrington

2

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

Sincerely,

/RA

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

Docket No. 030-39070
Mail Control: 600654

Enclosure:
Information Needed for Resubmittal
of Application

K. Harrington

3

NANOLUX TECHNOLOGY, INC., SUSPENSION OF THE REVIEW OF YOUR LICENSE APPLICATION REQUEST

Date: January 18, 2018

ML17249A090 (pkg.)

ML18016A690(Letter)

OFC	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
NAME	R Struckmeyer	D Weaver	T Herrera	R Struckmeyer
DATE	01/18/18	01/18/18	01/18/18	01/18 /18

OFFICIAL RECORD COPY

Nanolux Technology, Inc., Application dated August 15, 2017 Information Needed for Resubmittal of Application

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Nanolux Technology, Inc., application dated August 15, 2017, as well as the response to the initial Request for Additional Information, and has determined that additional information is needed if you choose to resubmit your application. In order to reopen 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 web site (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>). 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.

In our initial Request for Additional Information we stated 10 regulatory requirements for which your application lacked sufficient information. The responses to several of these items were not sufficient to allow us to approve your request for an exempt-distribution license. Each of the 10 items is repeated below and, where applicable, annotated with a description of the additional information needed.

Please provide the information required by each of the following regulations. You may need to obtain some of this information from your supplier(s). Note that it is the applicant's responsibility to confirm the validity of all information.

1. 10 CFR 32.14(a) requires the applicant to satisfy the general requirements specified in Section 30.33 of 10 CFR. *No additional information is required.*
2. 10 CFR 32.14(b)(1) requires the applicant to submit the chemical and physical form and maximum quantity of byproduct material in each product. In response to this item you provided two tables, MH Material List and CMH Material List.
 - Please resubmit these tables along with additional explanatory information, including but not necessarily limited to:
 - (a) Provide definitions of MH and CMH;
 - (b) Clarify whether "Specification" refers to the model numbers of the lamps you intend to distribute;
 - (c) Provide information to clarify the following: The column under the heading "Main Items" contains several terms that appear to be descriptive, but we are unable to determine whether each of these terms applies to every item in the "Specification" column;

Enclosure

- (d) Explain which of the terms listed under “Main Items” are described by the words “solid under cold state; gaseous under hot state” (in the column under the heading “Form”);
- (e) Define and/or explain the term “Maximum” in the header of the fourth column;
- (f) Define and/or explain the terms listed in the column under the heading “Maximum,” including, but not limited to what is meant by “yes,” “a little,” and “infinitesimal;”
- (g) Indicate whether each of the terms listed in the column under the heading “Maximum” is intended to apply in a one-to-one correspondence with each of the items listed in the column under the heading “Specification,” or whether some other explanation applies.
- Furthermore, please ensure that the list of items (presumably models) in these tables is complete. The information you provided in response to Question 3 appears to indicate that you intend to distribute 13 models, while the tables list just 12 items. If neither of these numbers is correct, please clarify the total number of models you intend to distribute, and clearly state the maximum quantity of byproduct material in each.
3. 10 CFR 32.14(b)(2) requires the applicant to submit details of construction and design of each product. *No additional information is required.*
 4. 10 CFR 32.14(b)(3) requires the applicant to submit the method of containment or binding of the byproduct material in the product. *No additional information is required.*
 5. 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 information you provided in response to this item did not appear to identify the byproduct material in the lamps, neither on the lamps themselves nor on the container(s). Please note that NUREG-1556, Volume 8, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,” states: “For those products requiring labeling, the regulations state that the item distributed must display the required label, or if this is not possible, then the label should be placed on the product’s immediate container. For example, if an electron tube is too small to label, then the label should be placed on the next smallest container or its immediate container, such as the bubble pack containing the electron tube.”

6. 10 CFR 32.14(b)(7) requires the applicant to submit the radiation level and the method of measurement for products for which limits on levels of radiation are specified in Section 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in Section 30.15 of this chapter. Section 30.15(a)(8) specifies that 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. Please indicate how you made this determination; i.e., your method of measurement or calculation.
 - In your combined response to Items 6 and 7, you provided “Testing Results” that indicate the quantity of krypton-85 but also indicate the presence of thorium-232 (Th-232), which was not specified in your application as a radioisotope used in your lamps. If Th-232 is present in your lamps, you will need to expand your application for authorization under 10 CFR 40.52. If Th-232 is not intentionally introduced into your products, please explain the reason for its appearance in the Testing Results.
 - Your combined response to Items 6 and 7 indicated the quantity of radionuclides present in your lamps (measured in Becquerels (Bq)), but did not indicate the levels of radiation (measured in Sieverts (Sv) or rem) and the method of measurement as required by 10 CFR 32.14(b)(7). Please provide the required information concerning the levels of radiation.
7. 10 CFR 32.14(c) states that each product will contain no more than the quantity of byproduct material specified for that product in Section 30.15 of this chapter. Section 30.15(a)(8) specifies a limit of 30 microcuries for electron tubes containing krypton-85. Please state what models of tubes you will distribute, and the quantity of Kr-85 in each model. Please indicate how you made this determination; i.e., your method of measurement or calculation.
 - In your combined response to Items 6 and 7, you provided “Testing Results” that indicate the quantity of krypton-85 but also indicate the presence of thorium-232 (Th-232), which was not specified in your application as a radioisotope used in your lamps. If Th-232 is present in your lamps, you will need to expand your application for authorization under 10 CFR 40.52. If Th-232 is not intentionally introduced into your products, please explain the reason for its appearance in the Testing Results.
 - Your response to Item 7 is does not appear to provide all of the required information; i.e., the quantity of Kr-85 in each model of lamp you plan to distribute. This requirement can be satisfied either by (a) listing each model with the corresponding quantity of Kr-85 it contains, or by (b) listing models in groups with the corresponding quantity of Kr-85 contained in models within these groups.
8. 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.

- The two diagrams and the two numbered statement that you provided in response to Item 8 do not appear to respond to this item. Please provide this information if you choose to resubmit your application.

9. 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.

- It appears that no response was provided to this item. Please provide this information if you choose to resubmit your application.

The following paragraph does not require a specific response; however, you should confirm that you understand the requirement contained in the cited regulation:

10. 10 CFR 32.16(a) requires each person licensed under Section 32.14 to maintain and report records of all transfers of byproduct material. *No additional information is required.*