



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

February 26, 2019

Ushio America Holdings, Inc.
ATTN: Rez Motamed
Senior Manager, Regulatory Compliance
5440 Cerritos Avenue
Cypress, CA 90630

**SUBJECT: USHIO AMERICA HOLDINGS, INC., REQUEST FOR ADDITIONAL
INFORMATION FOR RENEWAL OF EXEMPT DISTRIBUTION LICENSE
04-23968-01E**

Dear Mr. Motamed:

This letter refers to your license renewal application request dated February 11, 2019, for U.S. Nuclear Regulatory Commission (NRC) exempt distribution license number 04-23968-01E.

We do not have sufficient information to complete the review of your application. In order to continue our review, please address the issues listed in the enclosure to this letter. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.14, 32.15, 40.52 and 40.53. To ensure that the documentation supporting a renewed license is based on current and accurate information, you should respond to all of the regulatory requirements in the enclosure. You may provide previously submitted documents as long as they are current. These should be provided as attachments to your response to this letter.

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.

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 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).

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 this renewal application should reference control number 611385.

R. Motamed

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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 Licensing Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Materials Safety
and Safeguard

Docket No. 030-37966
Mail Control: 611385

Enclosure:
Request for Additional Information

USHIO AMERICA HOLDINGS, INC., AMENDED EXEMPT DISTRIBUTION LICENSE
04-23968-01E DATED FEBRUARY 26, 2019

Certified Mail No. 7015 3010 0000 7901 5744

ML19056A545

OFFICE	MSST/MSLB	MSST/MSLB	MSST/MSLB
NAME	Shirley Xu	Deborah Weaver	Shirley Xu
DATE	2/26/2019	2/ 26/2019	2/26/2019

OFFICIAL RECORD COPY

**Ushio America Holdings, Inc. Application dated February 11, 2019
Request for Additional Information**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Ushio America Holdings, Inc. application for exempt-distribution license renewal dated February 11, 2019, 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* (10 CFR) 32.14, 32.15, 40.52 and 40.53, and is described in the relevant guidance document NUREG-1556, Volume 8, Rev. 1, 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 provide the information required by each of the following regulations. You may need to obtain some of this information from your supplier(s).

1. 10 CFR 32.14(a) requires the applicant to satisfy the general requirements specified in Section 30.33 of 10 CFR. Please note that a renewal of your exempt distribution license will not be issued until we received your possession and use license.
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. Your application did not appear to address this requirement. Please provide this information.
3. 10 CFR 32.14(b)(2) requires the applicant to submit details of construction and design of each product. Please submit this information in your revised application. Please identify the appropriate enclosure(s) and provide descriptive text of the construction and design each product.
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. Please describe, or identify, the appropriate enclosure that describes the method by which Kr-85 gas is introduced and the glass tube is sealed.
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.
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 resubmit this information in your revised application.

Enclosure

7. 10 CFR 40.52(b)(1) requires the applicant to submit chemical and physical form and maximum quantity of source material in each product. Please submit this information as required.
8. 10 CFR 40.52(b)(2) requires the applicant to submit details of construction and design of each product. Please resubmit this information in your revised application. Please provide descriptive text of the construction and design of each product.
9. 10 CFR 40.52(b)(3) require the applicant submit quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet. Please submit quality control procedures for manufacturing thorium lamps.
10. 10 CFR 40.52(b)(4) require the applicant to submit the proposed method of labeling or marking each unit, and/or its container with the identification of the manufacturer or initial transferor of the product and the source material in the product. Please provide legible copies of the labels that will be used on each type of product (or container where the product is too small to be labeled).