

Weaver, Deborah

From: Xu, Shirley
Sent: Thursday, October 26, 2017 2:56 PM
To: Motamed, Rez
Subject: RE: Distribution License 04-23956-01E

Rez,

We received your response letter dated October 18, 2017. As mentioned in our letter dated August 8, 2017 and email below, the labeling requirement for distribution of this product is under 10 CFR 40.52(b)(4), in that, it requires the 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.

Your response did not provide 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 source material in the product.

We will continue our review upon receipt of the labeling information. If we do not receive a reply from you within 30 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

Sincerely,

Shirley Xu

U.S. Nuclear Regulatory Commission

Office of NMSS

Mail Stop: T8E18

Washington, D.C. 20555-0001

Office: 301.415.7640

From: Motamed, Rez [mailto:rmotamed@ushio.com]
Sent: Wednesday, October 18, 2017 4:43 PM
To: Xu, Shirley <Shirley.Xu@nrc.gov>
Cc: Compliance <compliance@ushio.com>
Subject: [External_Sender] RE: RE: RE: Distribution License 04-23956-01E

Hi Shirley,

The official reply to your letter dated August, 8th 2017 is in the mail and you should be receiving it in a few days.

I would like to inform you that Mr. Martin Brown is no longer with us, can you please direct all your correspondences to me. I use the compliance@ushio.com email address, but I can also be reached at: rmotamed@ushio.com . Do I have to officially register with NRC ?

Martin spoke very highly of you, so I hope to continue that good professional relationship with you. I very much appreciate your support and input.

Sincerely,

Rez Motamed

Sr. Manager, Regulatory Compliance

USHIO AMERICA, INC.

5440 Cerritos Ave, Cypress, CA 90630

rmotamed@ushio.com

Tel: 714-229-3137

Cell: 714-718-5385

From: Xu, Shirley [<mailto:Shirley.Xu@nrc.gov>]
Sent: Thursday, September 28, 2017 10:57 AM
To: Motamed, Rez
Subject: RE: RE: RE: Distribution License 04-23956-01E

Rez,

You are right that there is no labeling requirement for transportation under DOT. However, the labeling requirement for distribution of this product is under 10 CFR 40.52(b)(4), in that, it requires the 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.

Regards,
Shirley

From: Motamed, Rez [<mailto:rmotamed@ushio.com>]
Sent: Thursday, September 28, 2017 1:47 PM
To: Xu, Shirley <Shirley.Xu@nrc.gov>
Subject: [External_Sender] RE: RE: Distribution License 04-23956-01E

Hi Shirley,

I was told you needed both Krypton-85 and Thorium documents. Thanks for the clarification.

Our lamps that contain Thorium are manufactured in Japan. Given that the amount of thorium is so extremely low, there are no laws that require us to label our individual lamps. The only regulation is from DOT that requires us to follow UN2911 labelling during overseas shipment. There are no labelling requirements when shipping lamps that contain a small amount of thorium within the United States. Europe and Asia have sticker regulations and we follow their stringent regulatory shipping requirements. When applicable, the UN2911 label is placed on the shipping box which contains large amount of lamps, not on individual boxes. I will mail you sample labels.

I am just waiting for the quality control documents to be translated into English. I am hoping to have all the documents mailed out to you within the next couple of weeks.

Regards

Rez Motamed

Sr. Manager, Regulatory Compliance

USHIO AMERICA, INC.

5440 Cerritos Ave, Cypress, CA 90630

rmotamed@ushio.com

Tel: 714-229-3137

Cell: 714-718-5385

From: Xu, Shirley [<mailto:Shirley.Xu@nrc.gov>]
Sent: Thursday, September 28, 2017 5:27 AM
To: Motamed, Rez
Subject: RE: RE: Distribution License 04-23956-01E

Rez,

The requested information are for thorium products only, not Krypton-85 products.

Here are the requested information listed in the letter dated August 8, 2017:

1. Please provide a copy of your radioactive material possession and use license issued by the State of California reflecting the authorization of thorium.
2. Provide details of construction and design of the product.
3. Provide 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 source material in the product.
4. Provide 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.

Regards,
Shirley

From: Motamed, Rez [<mailto:rmotamed@ushio.com>]
Sent: Wednesday, September 27, 2017 4:46 PM
To: Xu, Shirley <Shirley.Xu@nrc.gov>
Subject: [External_Sender] RE: Distribution License 04-23956-01E

Hi Shirley,

Thank you for calling me yesterday. I am glad we had the opportunity to talk and clarify the letter you sent us. As mentioned on the phone, it is impossible to get a low level radioactive materials certificate or license from suppliers in countries which do not require such licenses. The lightbulb manufacturing industry falls in such a category as the source materials used have such low level radioactive material.

In line with the discussion we had, I will send the following items from our major overseas suppliers:

1. Quality control procedure to demonstrate how Krypton-85 and Thorium are checked to insure they are in line with our product design.
2. Krypton-85 labelling on boxes are required and samples will be provided; however, Thorium labelling is not required, hence I do not have a sample to provide.
3. Images of lamps that use Thorium and Krypton-85.

Please feel free to call me if you have any question.

Regards.

Rez Motamed

Sr. Manager, Regulatory Compliance

USHIO AMERICA, INC.

5440 Cerritos Ave, Cypress, CA 90630

rmotamed@ushio.com

Tel: 714-229-3137

Cell: 714-718-5385

From: Motamed, Rez

Sent: Tuesday, September 26, 2017 10:19 AM

To: 'Xu, Shirley'

Subject: Distribution License 04-23956-01E

Hi Shirley,

I am working on a letter which was passed on to me by Mr. Martin Brown stating, you need more information from us (Letter dated August 8th, 2017 – Distribution License 04-23956-01E) by Friday. Unfortunately that will not be possible, our major suppliers are in Germany and Japan and by the time I get all the paperwork together, then translated into English will take a couple of weeks. I can mail out construction and design works, labelling methods and quality control standards to you by the end of today, but licenses will take time, especially from countries that licenses are not required for manufacturing light bulbs. I would need to know what will suffice your requirements for countries that do not require manufactures to obtain a license for low level radiation products. Such request has never been made so it is new to us.

I will try to call you later to have further discussion as I am eager to fulfill your requirements ASAP.

Regards.

Rez Motamed

Sr. Manager, Regulatory Compliance

USHIO AMERICA, INC.

5440 Cerritos Ave, Cypress, CA 90630

rmotamed@ushio.com

From: Xu, Shirley [<mailto:Shirley.Xu@nrc.gov>]
Sent: Thursday, June 29, 2017 11:06 AM
To: Motamed, Rez
Subject: RE: RE: RE: RE: Invoice number LFB 17-2462, Ushio America, Inc

Rez,

Your license authorization for Kr-85 products is under 10 CFR Part 30, and the authorization for thorium products will be under Part 40 regulation. The current application fee is \$2700.

You may include a cover letter to explain that the check is for your amendment request that was already sent to us.

Regards,
Shirley