

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 03, 2020

Mr. Warren Obenski KH Imports, LLC 600 Eagleview Blvd, Suite 300 Exton, PA 19341

SUBJECT: KH IMPORTS, LLC, REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Obenski:

This letter is in response to your request for a change of address to your license Exempt-Distribution License 09-35517-01E, dated January 4, 2020. In your letter, you did not request an amendment to your Sealed Source and Device (SSD) Registration Certificate NR-1497-D-101-E. Please note that the registration certificate will be amended concurrently with your license amendment request. It is our understanding that your amendment request is associated with a transfer of control of ownership of KH Imports, LLC. At this time, we do not have sufficient information to proceed with the amendment of your registration certificate. In the enclosure to this letter (Request for Additional Information) you will find the list of the questions and items not addressed in your application.

The information related to review of your Exempt-Distribution License application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Sections 32.23, 32.24, and 32.26 and is described in the relevant guidance document NUREG-1556, Volume 8, Revision 1, titled "Program-Specific Guidance About Exempt Distribution Licenses."

The information related to review of your Sealed Source and Device amendment application is required by 10 CFR 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

W. Obenski

If you have any questions regarding the SSD Registration Certificate you can contact Lymari Sepulveda at (301) 415-5619 or by e-mail at Lymari.Sepulveda@nrc.gov. For questions related to the Exempt Distribution License, please contact me at (301) 415-7640 or by e-mail at Shirley.Xu@nrc.gov.

2

Sincerely,

4/3/2020

Lymari Sepulveda

Mechanical Engineer

Signed by: Lymari Sepulveda

Materials Safety and Tribal Liaison Branch Division of Material Safety, Security, States, and Tribal Programs Office of Nuclear Material Safety and Safeguards

Enclosure: As stated

KH IMPORTS, LLC, REQUEST FOR ADDITIONAL INFORMATION DATED APRIL 03, 2020

ML(pkg)20043E108 ML20092P294 (Letter)

| OFC | NMSS/MSTB | NMSS/MSTB | NMSS/MSTB | NMSS/MSTB |
|------|--------------|------------|------------------|------------|
| NAME | SXu (e-mail) | LSepulveda | THerrera(e-mail) | LSepulveda |
| DATE | 4/02/2020 | 4/02/2020 | 4/02/2020 | 4/03/2020 |

OFFICIAL RECORD COPY

KH Imports, LLC Amendment Request dated January 4, 2020 Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the KH Imports, LLC, amendment request dated January 4, 2020, and 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 sealed source and device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt distribution license application is required by 10 CFR 32.14, 32.15, 32.16, 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

A. Questions Related to the Sealed Source and Device Application

- 1. Please delineate the facility's name and location where the products will be distributed from.
- 2. Please indicate if there are any changes to the facility who will manufacture the devices.
- 3. Specify the serial number of the last unit that was distributed before the address change, and the number of completed units that were transferred to be distributed from the new location.
- 4. If this is a change of ownership, please provide information discussing the transfer of products, and records custody.
- 5. Confirm that no changes were have been made to the product since its last amendment.
- 6. Please confirm that the previous commitment made to obtain a registration certificate have not change.
- 7. Please provide details about the quality assurance program at the new location.

B. Questions Related to the Exempt Distribution License Application

Provide information needed for Transfer of Control. If any items are not applicable, state so.

1. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc.

- 2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.
- 3. Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.
- 4. Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.
- 5. Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.