

March 25, 2020

Richard K. Struckmeyer  
Materials Safety Licensing and Tribal Liaison Branch  
Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission

RE: Responses to Request for Additional Information / Control Number 618178

Dear Mr. Struckmeyer,

Thank you for your prompt review of our application for a new U.S. Nuclear Regulatory Commission exempt-distribution license for the Prism Optics Module Validation Tool (OMVT). This device has been previously licensed under license 12-24014-01E and license 42-23864-01E. This device has not changed significantly since its initial application in 1998.

I am enclosing the additional information you requested in your letter sent to me via email on March 18<sup>th</sup>, 2020.

Sincerely,



Steven Ellingson  
Manager Environmental Health & Safety  
Abbott Transfusion Medicine

Attachments:  
Supporting Data

## Supporting Data

Below are the answers and supporting data to the three questions from the letter from Richard Struckmeyer to Steven Ellingson, sent via email on March 18<sup>th</sup>, 2020.

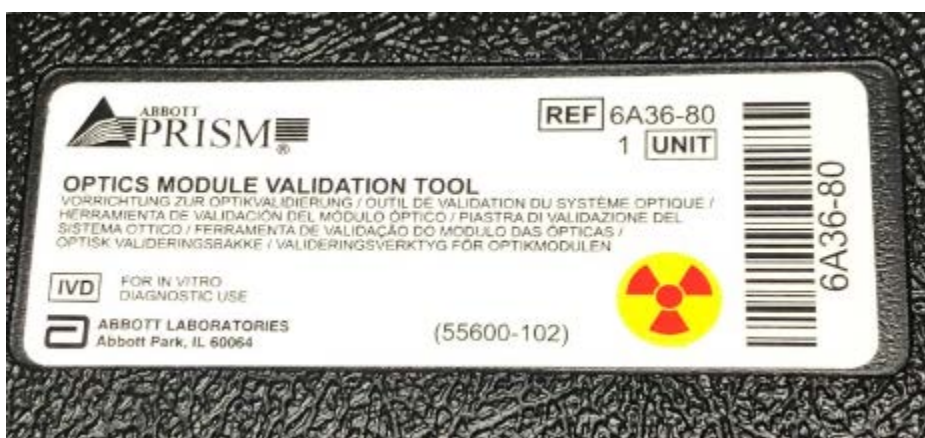
1. **From Nuclear Regulatory Commission:** 10 CFR 32.18(d) requires the applicant to submit copies of prototype labels and brochures, and that the Commission approve such labels and brochures, in order to demonstrate compliance with 10 CFR 32.19(c) and (d). Please provide copies of the labels on the immediate container of check sources, and the accompanying brochure, if any, that may be distributed along with the byproduct material.

**Abbott Laboratories Response:** Picture 1 is of the label on the immediate container of check sources which demonstrates compliance with 10 CFR 32.19(c). Picture 2 is of the plastic case in which the device is stored. Attachment 1 contains the brochure which accompanies each individually packaged device. This brochure demonstrates compliance with 10 CFR 32.19(d).

Picture 1.



Picture 2.



2. **From Nuclear Regulatory Commission:** 10 CFR 32.19(b) requires that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 30.18 of this chapter. The outer

package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour. Although you paraphrased this requirement in your application, you did not explicitly describe how you would comply. Please describe how you shall meet the requirements of 10 CFR 32.19(b), including how the dose rate at the external surface of the package is determined.

**Abbott Laboratories Response:** The Prism Optics Module Validation Tool (OMVT) is received at our facility at 1921 Hurd Drive, Irving, Texas. The device is then packaged and labeled according to approved manufacturing instruction VLN6A36-80. These instructions specify packing a single OMVT into a single outer box. No other configurations are allowed.

Prior to receipt at our Irving, Texas facility, the supplier is required to take surface readings on all sides of each box using a calibrated, certified meter to ensure that the external surface of the package does not exceed 0.5 millirem per hour.

3. **From Nuclear Regulatory Commission:** 10 CFR 32.19(c) requires that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and quantity of radioactivity, and (2) bears the words "Radioactive Material." Your application does not appear to provide a description of how this requirement will be met. Please describe and provide a sample or copy of the labels you plan to use in meeting this requirement. The description should include the factors that ensure the labels' durability, including the type of material used for the label and how it is attached.

**Abbott Laboratories Response:** See response to question 1 for a Picture of the labels which demonstrate compliance with 10 CFR 32.19(c). These labels are composed of 2 MIL white polyester with a 1 MIL clear laminate overcoat for durability. They are attached with permanent acrylic adhesive.

**THIS PACKAGE CONFORMS TO THE CONDITIONS AND LIMITATIONS SPECIFIED  
IN 49 CFR 173.421 FOR RADIOACTIVE MATERIAL, EXCEPTED PACKAGE - LIMITED  
QUANTITY OF MATERIAL, UN2910.**

**ABBOTT LABORATORIES  
1921 HURD DRIVE  
IRVING, TX 75038  
(972) 518-6000**

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**The following is intended for sites under United States (U.S.) jurisdiction.  
For non-U.S. jurisdiction, follow local regulations as applicable.**

**INSTRUCTIONS RELATING TO THE HANDLING, USE, STORAGE, AND  
RETURN/DISPOSAL OF THE ABBOTT PRISM® OPTICS MODULE VALIDATION TOOL  
(OMVT)**

**This document should be kept for reference.**

The contents of the OMVT are exempt from Nuclear Regulatory Commission (NRC) or Agreement State licensing requirements.

Radioactive Material - Not for Human Use - Introduction Into Foods, Beverages Cosmetics, Drugs, or Medicinals or Into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not be Combined.

### **1. Handling**

Although the quantity of radioactive material contained in the OMVT is extremely small, the basic radiation principles of time, distance and shielding should be practiced as effective methods for minimizing exposure.

Use of radioactive material should be only by responsible persons in authorized areas.

Eating, drinking, smoking and the application of cosmetics should be prohibited in areas of use.

### **2. Use**

Exempt quantity licensed products containing radioactive material should be used only as intended by the manufacturer and in accordance with the instructions provided with the products.

### **3. Storage**

All radioactive materials should be securely stored when not in use.

### **4. Return/Disposal**

The recommendation is to return the OMVT to Abbott Laboratories. The return package must contain a copy of this letter. Contact your Abbott Representative to arrange for return of the OMVT. Also, you may contact the Customer Support Center for U.S. Customers (1-800-323-9100) for assistance with returning the OMVT.

Per conditions of the Abbott Laboratories, Dallas, TX, Nuclear Regulatory Commission E-License, the OMVT may be disposed of in regular waste without regard to its radioactive content providing the customer is not a specific licensee and all radiation symbols have been removed or defaced. If the recipient of the license exempt OMVT is a specific licensee, then you are subject to the requirements of 10 CFR Part 20 in areas where 10 CFR 30.18 is silent (e.g., waste disposal).