UNITED STATES
NUCLEAR REGULATORYCOMMISSION
WASHINGTON, D.C. 20555-0001

August 10, 2021

Gary Ilko
Manufacturing Manager
Radiation Safety Officer
Thermo Eberline, LLC
One Thermo Fisher Way
Oakwood Village, OH 44146

SUBJECT: THERMO EBERLINE, LLC REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Ilko:

This letter refers to your applications dated May 26, 2021 and June 29, 2021, Agencywide Documents Access and Management System (ADAMS) Accession No. ML21181A095 and ML21181A094, concerning your request for an Exempt Distribution Materials License and Sealed Source and Device Registration. In reviewing your applications, we find additional information is required to complete our review. In order to continue our review, we need clarification and additional information. In the enclosure to this letter, we have summarized the issues that need to be addressed.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application. Any correspondence regarding your application should reference the mail control number specified below.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the U.S. Nuclear Regulatory Commission's (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 ADAMS. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html

If you have any questions regarding the Sealed Source and Device Registration you can contact Lymari Sepulveda at (301) 415-5619 or by email at Lymari.Sepulveda@nrc.gov.
For questions related to the exempt distribution license, please contact me at (301) 415-3257 or email at Michelle.Hammond@nrc.gov.

Sincerely,

Michelle M. Hammond

Digitally signed by Michelle M. Hammond
Date: 2021.08.10 07:30:43 -05'00'

Michelle M. Hammond, M.Sc.
Materials Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Materials Safety and Safeguards

Docket No. 030-39278
Mail Control No. 627137

Enclosure:
Request for Additional Information

THERMO EBERLINE, LLC
REGISTRATION CERTIFICATE APPLICATION DATED MAY 26, 2021
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Thermo Eberline, LLC (dba Thermo Fisher Scientific) application dated May 26, 2021 and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

Description/Construction

1. As noted in NUREG-1556, Volume 3, Revision 2, Section 10.3, "Construction of the Product", an application for a sealed source and device evaluation should include descriptive information such as engineering drawings. The drawings submitted as part of the Thermo Eberline, LLC application dated May 26, 2021, were limited to drawings of the shielding for the Model DMA. Please provide complete engineering drawings of the Model Density Meter Accessory (DMA). These drawings should also include a drawing of the DMA separate from the Thermo RadEye detector and one showing the location/installation of the DMA in the RadEye detector.

2. Please describe how the Model DMA will be assembled (i.e. screws, welds, etc.). Please describe whether the Model DMA includes any tamper-resistant hardware that prevents users from accessing the radioactive material.

3. Describe how the Thermo RadEye detector is attached to the Model DMA.

4. Please described how the radioactive material will be mounted and secured to the Model DMA.

5. Please describe if there is potential for corrosion between unlike materials used in the Model DMA.

6. Please indicate what features will prevent the shutter to be locked in the open position. Please indicate whether engaging the manual safety lock will prevent the shutter from being returned to the safe position.

Prototype Testing

7. In your application, under "Section 5: Prototype Testing" you provided the ANSI classification for the sealed source, however, there was no discussion regarding the prototype testing performed on the Model DMA. Please provide the prototype testing information for the Model DMA.

   The NRC may accept one of the following methods to demonstrate the product ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions: (1) testing a prototype of the product, (2) performing an engineering analysis, (3) operational history of the product, or (4) comparison to a similar or equivalent model

previously reviewed and registered. Please note that Section 10.5 of Volume 3, Revision 2 of the NUREG-1556 series provides guidance on each of these methods.

As required under 10 CFR 32.30(b)(11) and 10 CFR 32.30(b)(12) please provide the procedures and results of prototype testing, or provide one of the other acceptable methods of prototype testing, of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use and disposal of the device.

8. We note that on page 12 of your application the ANSI classification ANSI-23-985-985-R1 was assigned to the DMA. Please provide the test results of how that classification was determined.

Quality Assurance

9. In Section 7 of your application, you stated that, "Thermo implements a Quality Management System that is certified to meet ISO 9001:2015 standards." The NRC can accept the accreditation, however, please confirm that the Quality Assurance program also includes the following:

    - There is full design conformity in accordance with the statements and commitments submitted in support of the application (including materials of construction, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling).
    - All units are leak tested to 185 Bq [0.005 µCi].
    - All units are tested for proper operation of all safety features.
    - All units are verified that the radiation levels do not exceed the maximum values stated in the application.

10. In Attachment C of your application, you provided the ISO 9001:2015 certificate for the Thermo Scientific Portable Analytical facility in Tewksbury, Massachusetts. In your application you have stated that the DMA will also be manufactured at the Thermo Eberline, LLC facility in Oakwood Village, Ohio. Please provide the ISO 9001:2015 certificate for the facility in Oakwood Village and confirm that the facility will adhere to commitments noted above in Question #9.

    If the facility in Oakwood Village is not ISO 9001:2015 certified, please provide a copy of Thermo Eberline, LLC's quality assurance program. The quality assurance program must ensure that: (a) the materials of construction and the final assembly meet the design specifications; (b) the final product is leak test; (c) a final radiation profile is performed, (d) a test that verifies the product operates as intended, including all safety functions is performed; and (e) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Please see NUREG-1556, Volume 3, Revision 2, Section 10.7, "Quality Assurance and Quality Control," for more information.

Accompanying Documentation

11. Please discuss whether the DMA is distributed with leak test results and radiation surveys.

12. Please provide a copy of the DMA user instructions.

THERMO EBERLINE, LLC
EXEMPT DISTRIBUTION APPLICATION DATED JUNE 29, 2021
REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Thermo Eberline, LLC (dba Thermo Fisher Scientific) application dated June 29, 2021 and determined that additional information is needed. In order to continue with our review, please address the issues listed below. This information is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.30 and described in the relevant guidance document NUREG-1556, Volume 8, Revision 1, titled "Program-Specific Guidance About Exempt Distribution Licenses."

1. Please provide maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

2. In Section 2, page 4 of the application stated: *"Without direct knowledge of the dose to each of the NRC defined organs and tissue types, EDE can be estimated using measurements of Deep Dose Equivalent (DDE) and methodology described in ANSI/HPS N13.41-2011"Criteria for Performing Multiple Dosimetry."*

   However, 10 CFR 20.1003 defines "Organ Dose Weighting Factors." Please revise that section and subsequent sections using the NRC defined organ dose weighting factor(s) for calculation(s).

3. Please provide the calculation for the accumulated dose for storage of the quantities of exempt units likely in one location.

4. Please provide the calculation for the external radiation dose in any one year from disposal of the quantities of units likely to accumulate in the same disposal site.

5. Please provide the dose estimation for the use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device. Please confirm if the probability is low that the containment, shielding, or other safety features of the device would **fail** under such circumstances.