

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 30, 2021

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

SUBJECT: THERMO EBERLINE, LLC DBA THERMO FISHER SCIENTIFIC, NEW EXEMPT

DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE

REGISTRATION CERTIFICATE

Dear Mr. Ilko:

In response to your applications dated May 26, 2021 and June 29, 2021, enclosed is U.S. Nuclear Regulatory Commission (NRC) Exempt Distribution License No. 34-35645-01E authorizing the distribution of Thermo Scientific Density Meter Accessory (Model DMA) to persons exempt from licensing pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 30.22, or equivalent regulations of an Agreement State, and a new Sealed Source and Device (SSD) registration certificate No. NR-1219-D-106-E.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact the NRC Headquarters staff so that we may provide appropriate corrections or answers.

Please be advised that you must distribute the products in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your license and registration certificate if applicable. As a general rule, you must request and obtain an amendment to the license before you make changes or modifications to the information submitted to obtain them. You are also obligated to notify us promptly in writing should you decide to no longer distribute the product

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the NRC, now or hereafter in effect, to include the following:

 Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations. NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

- 2. Distribute only those products containing radioactive material which are specifically authorized in your license.
- 3. Notify NRC in writing within 30 days of any change in mailing address.
- 4. In accordance with 10 CFR Sections 30.33, 30.34 and 30.38, please file appropriate documentation with the NRC prior to any changes to your organization, change locations of distribution of products containing radioactive material, facilities, equipment, procedures, change in the contact person or the person responsible for the quality assurance program for licensed activities, or any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with the NRC.
- 5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
- 6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

Please be aware that, as a holder of an NRC license, you may be subject to the NRC's annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the Accounts Receivable Branch at (301) 415-7554.

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 the 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. If you have any questions regarding your Exempt Distribution License, you may contact me at (301) 415-3257, or by e-mail at Michelle.Hammond@nrc.gov. For questions regarding

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your Sealed Source and Device registration certificate, please contact Tomas Herrera at (301) 415-7138, or by e-mail at Tomas.Herrera@nrc.gov.

Sincerely,

Hammond Date: 2021.11.30 18:10:09 -06'00'

Michelle M. Digitally signed by Michelle M. Hammond

Michelle M. Hammond, M.Sc., Health Physicist Materials Safety and Tribal Liaison Branch Division of Materials Safety, Security, State, and Tribal Program Office of Nuclear Material Safety and Safeguards

License No. 34-35645-01E Docket No. 030-39278 Mail Control No. 627137

Enclosures:

1. Exempt License No. 34-35645-01E

2. SSD Certificate No. NR-1219-D-106-E

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OFC	NMSS/MSST/MSTB	NMSS/MSST/MSTB	NMSS/MSST/MSTB	NMSS/MSST/MSTB
NAME	Michelle Hammond	Marcia Pringle	Tomas Herrera	Lymari Sepulveda
DATE	11/04/2021	11/05/2021	11/19/2021	11/19/2021
OFC	NMSS/MSST/MSTB	NMSS/MSST/MSTB		
NAME	Shirley Xu	Michelle Hammond		
DATE	11/30/2021	11/30/2021		

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