



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 19, 2023

EA-22-031

Thermo Fisher Scientific
ATTN: Mark Prack
Site Leader / Associate Director of Operations
Chemical Analysis Division
1 Thermo Fisher Way
Oakwood Village, Ohio 44146

SUBJECT: EXPORT OF SPECIAL NUCLEAR MATERIAL UNDER U.S. NUCLEAR REGULATORY COMMISSION'S LICENSING AUTHORITY AND REPORTING REQUIREMENTS UNDER 10 CFR 150 – NOTICE OF VIOLATION

Dear Mark Prack:

This letter refers to the records review conducted by the U.S. Nuclear Regulatory Commission (NRC) in December 2021 through October 2022. The review examined (1) your export of special nuclear material (SNM) to a nuclear power plant in the Republic of Korea in 2021, (2) your attempted export of SNM to Spain in 2022, and (3) your submissions of nuclear material transaction reports to the Nuclear Materials Management and Safeguards System (NMMSS). In the letter transmitting the results of our review, dated January 26, 2023 (ADAMS Accession No. ML22188A104), we provided you the opportunity to address the apparent violations identified in the letter by either participating in a predecisional enforcement conference (PEC) or by providing a written response before we made our final enforcement decision.

On March 7, 2023, a PEC was conducted at NRC Headquarters to discuss the apparent violations, their significance, their root causes, and your corrective actions. Thermo Fisher Scientific provided written information at the PEC (ADAMS Accession No. ML23079A098). In addition, Thermo Fisher Scientific submitted supplemental written response dated March 17, 2023 (ML23079A099).

Based on the information developed during the records review and the information that you provided at the PEC and in your written response, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). The circumstances surrounding the violations were described in NRC's letter dated January 26, 2023 (ADAMS Accession No. ML22188A104).

The violations in the Notice involve: (1) two exports of special nuclear material (SNM) (i.e., shipments of fission chambers that contained greater than 3 grams of enriched uranium-235) that were not authorized under a specific license; (2) failing to report a nuclear material transaction report to NMMSS for shipment of SNM in a quantity of one gram or more of uranium-235 within 24-hours; and (3) failing to annually submit material status reports and reconciling data with NMMSS.

The failure to conduct activities in accordance with a license is significant because it impacts the NRC's ability to conduct its regulatory responsibilities of ensuring exports were in accordance with requirements. The failure to report nuclear material transaction reports to NMMSS inhibited the NRC's process of regulatory oversight. The issuance of this SLIII violation constitutes escalated enforcement action that may subject you to increased inspection effort in the future. The NRC Enforcement Policy may be found on the NRC website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Thermo Fisher Scientific restored compliance for the two unauthorized exports of special nuclear material by obtaining specific export licenses approved by the U.S. Department of State, the government of the Republic of Korea and Euratom. Your corrective actions included: (1) submitting required DOE/NRC 741, 742 and 742C forms to NMMSS; (2) completing NMMSS's Fundamentals of Reporting to NMMSS course on 12/6/2022; (3) updating the Oakwood Radiation Safety Manual to include reporting requirements for nuclear material transaction reports and annual inventory reporting; (4) updating the Oakwood Radiation Safety Manual to include licensing requirements for exports of SNM; and (5) adding a NMMSS training requirement for the Oakwood Radiation Safety Officer (RSO) position.

NRC determined that your corrective actions appear adequate to correct the non-compliance and to prevent future reoccurrence. Therefore, to encourage prompt identification and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, the NRC will not propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

The NRC has concluded that: (1) the reasons for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved have already been adequately addressed on the docket in the information you provided at the predecisional enforcement conference and in your supplemental written response. Therefore, you are not required to respond to this letter and Notice unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedures," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. If you choose to respond to this letter and Notice, to the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of

withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Please contact Andrea R. Jones at (404) 997-4443 or James Rubenstone at (301) 415-7231, if you have any questions regarding this matter.

Sincerely,

David L. Pelton, Director
Office of Enforcement

Enclosure:
Notice of Violation

cc:
State of Ohio

SUBJECT: EXPORT OF SPECIAL NUCLEAR MATERIAL UNDER U.S. NUCLEAR REGULATORY COMMISSION'S LICENSING AUTHORITY AND REPORTING REQUIREMENTS UNDER 10 CFR 150 – NOTICE OF VIOLATION DATED: 5/19/2023

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ADAMS Accession No.: ML23129A192 *concurrence via e-mail

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OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Thermo Fisher Scientific
Oakwood Village, Ohio

EA-22-031

Based on the U.S. Nuclear Regulatory Commission's (NRC's) evaluation of records associated with Thermo Fisher Scientific's: (1) export of special nuclear material to a nuclear power plant in the Republic of Korea in 2021, (2) attempted export of special nuclear material to Spain in 2022, and (3) submissions of material transaction reports to the Nuclear Materials Management and Safeguards System (NMMSS), three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

VIOLATION 1:

Title 10 of Code of Federal Regulations (CFR) 110.5 states, in part, that no person may export any nuclear equipment or material listed in 10 CFR 110.9, unless authorized by a general or specific license issued under 10 CFR Part 110. The list in 10 CFR 110.9 includes special nuclear material.

10 CFR 110.9, states, in part, special nuclear material is under NRC's export licensing authority. 10 CFR 110.20(a) states, in part, that if an export or import is not covered by the NRC general licenses in §§ 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with §§ 110.31 through 110.32.

10 CFR 110.21(a) states, in part, that a general license is issued to any person to export special nuclear material, other than plutonium-236 and plutonium-238, in sensing components in instruments, if no more than 3 grams of enriched uranium are contained in each sensing component.

Contrary to the above, Thermo Fisher Scientific exported special nuclear material without a general or specific license. Specifically, on December 28, 2018, Thermo Fisher Scientific exported special nuclear material in sensing components containing more than 3 grams of enriched uranium to the Republic of Korea, without obtaining a specific license authorizing its export as required by 10 CFR 110.5. The export contained two neutron detectors with a total of 21.6 grams of uranium-235 (each detector contained three fission chambers with 3.6 grams per fission chamber for a total of 10.8 grams uranium-235 per detector). In addition, on July 1, 2022, Thermo Fisher Scientific attempted to export special nuclear material in sensing components containing more than 3 grams of enriched uranium to Spain, without obtaining a specific license authorizing its export as required by 10 CFR 110.5. The failed export contained two neutron detectors with a total of 7.2 grams of U-235 (each detector contained one fission chamber with 3.6 grams of U-235).

This is a Severity Level III Violation (NRC Enforcement Policy Section 6.15).

VIOLATION 2:

Title 10 CFR 150.16(a)(1) requires reporting a transfer of 1 gram or more of special nuclear material within one day to the Nuclear Materials Management and Safeguards System (NMMSS). These reporting requirements extend to Agreement State Licensees and are

Enclosure

reflective of reporting requirements for all possessors of special nuclear material as described in Part 74; furthermore, Part 74.15(a) prescribes the submission of an electronic nuclear material transaction report (NRC/DOE Form 741) to NMMSS no later than the close of business the next working day.

Contrary to the above, Thermo Fisher Scientific failed to report the transfer of 1 gram or more of special nuclear material no later than close of business the next working day. Specifically, on December 28, 2018, Thermo Fisher Scientific transferred a total of 22 grams of special nuclear material and failed to report no later than close of business on December 29, 2018.

This is a Severity Level III Violation (NRC Enforcement Policy Section 6.9).

VIOLATION 3:

Title 10 CFR 150.17(a), in part, requires a licensee that has possessed in the previous reporting period, at any one time and location, under an Agreement State license, special nuclear material in a quantity totaling one gram or more of contained uranium-235, uranium-233, or plutonium, to complete and submit, in computer-readable format Material Balance Reports concerning special nuclear material that the licensee has received, produced, possessed, transferred, consumed, disposed of, or lost. The annual reports for the previous annual reporting period (typically calendar year (CY)) must be filed by March 31 of each year.

Contrary to the above, Thermo Fisher Scientific failed to submit annual reports for the previous annual reporting period by March 31. Specifically, Thermo Fisher Scientific failed to submit the annual reports for the annual reporting periods covering CY2018 and CY2019 by March 31 of the following year.

This is a Severity Level III Violation (NRC Enforcement Policy Section 6.9).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, was already adequately addressed in the information you provide at the March 7, 2023, predecisional enforcement conference and your March 17, 2023, supplemental written response. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201, within 30 days of the date of the letter transmitting this Notice, if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-22-031" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with copies to the (1) U.S. Nuclear Regulatory Commission, ATTN: David Skeen, Director, Office of International Programs, Washington, DC 20555-0001, and (2) U.S. Nuclear Regulatory Commission, ATTN: Shana Helton, Director, Division of Fuel Management/NMSS, Washington, DC 20555-0001.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: David Pelton, Director, Office of Enforcement, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should

not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Dated this 19th day of May 2023.