



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

September 21, 2021

Ashley Pearson, Radiation Safety Officer
Thermo Fisher Scientific, Inc.
27 Forge Parkway
Franklin, MA 02038

**SUBJECT: THERMO FISHER SCIENTIFIC, INC. - NRC INSPECTION NO.
03036808/2021-001 AND NOTICE OF VIOLATION**

Dear Ms. Pearson:

This letter refers to the inspection conducted on August 5, 2021, at your Franklin, Massachusetts (MA) facility and in-office review on July 28, 2021; and August 9 through 20, 2021; and September 9, 2021. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. An exit meeting was conducted on September 9, 2021, between you, other members of your organization, and Steven Courtemanche of this office, to discuss the inspection findings.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket and include: the submission of an exempt distribution report for Calendar Years 2016 and 2017, setting up a reminder system so that exempt distribution reports are submitted to the NRC prior to January 31st of each year, and ceasing the practice of distributing exempt devices directly from the manufacturer to customers instead of distributing only from the facility in Franklin, MA. Therefore, you are not required to respond to this letter unless the description herein 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 "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent

A. Pearson

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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 you have any questions regarding this matter, please contact Steven Courtemanche of my staff at 610-337-5075 or via electronic mail at Steven.Courtemanche@nrc.gov.

Thank you for your cooperation.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

Docket No. 03036808
License No. 20-23922-01E

Enclosure:
Notice of Violation

cc w/ enclosure
Commonwealth of Massachusetts

THERMO FISHER SCIENTIFIC, INC. - NRC INSPECTION NO. 03036808/2021-001 AND NOTICE OF VIOLATION DATED SEPTEMBER 21, 2021

DOCUMENT NAME: https://usnrc.sharepoint.com/:w:/r/teams/Region-I-CIRDA/_layouts/15/Doc.aspx?sourcedoc=%7B3A726C0B-FF70-46BA-845C-9C78BCE6A133%7D&file=L20-23922-01E.2021001.docx&action=default&mobileredirect=true

ACCESSION NO:

ML21264A117

<input checked="" type="checkbox"/> SUNSI Review		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive		<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available	
OFFICE	RI:DRSS	RI:DRSS			
NAME	SCourtemanche (src)	CCahill (cgc)			
DATE	09/21/2021	09/21/2021			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Thermo Fisher Scientific, Inc.
Franklin, MA

Docket No. 03036808
License No. 20-23922-01E

During an NRC inspection conducted onsite on August 5, 2021, and remotely on July 28, 2021 and August 9 through 20, 2021, and September 9, 2021, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 32.29(c)(4)(i) requires, in part, that the licensee shall file a report with the Director of the Office of Nuclear Materials Safety and Safeguards, covering the preceding year, on or before January 31 of each year.

Contrary to the above, between January 1, 2017 and September 9, 2021, the licensee failed to file a report with the Director of the Office of Nuclear Materials Safety and Safeguards, covering the preceding year, on or before January 31 of each year. Specifically, the licensee failed to file a report for Calendar Years 2016 and 2017.

This is a Severity Level IV violation (Enforcement Policy Section 6.9).

The licensee did not find any evidence that a report had been filed for Calendar Years 2016 and 2017 and submitted reports subsequent to the onsite inspection. The licensee instituted a reminder system for the individual responsible for regulatory compliance so that future reports would be filed in a timely manner.

- B. License Condition 11 of NRC License Number 20-23922-01E requires that the licensee may distribute only from its facilities located at 27 Forge Parkway, Franklin, MA 02038.

Contrary to the above, from December 14, 2015 to September 9, 2021, the licensee failed to distribute only from its facilities located at 27 Forge Parkway, Franklin, MA 02038. Specifically, the licensee distributed devices directly from its manufacturers in Germany and China to its customers in the United States.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The licensee believed that the direct shipments had been authorized by the NRC in its license renewal application in 2015. Also, the direct shipments were mentioned in the annual reports and were acknowledged during the 2015 NRC inspection without comment. The NRC Regional Counsel and NRC's Office of the General Counsel concluded that the devices had to go to the licensee's Franklin, MA facility. The licensee indicated that the practice would be discontinued and distribution would only occur from locations listed on the NRC license.

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 will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 21 day of September 2021