



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

December 3, 2023

Mr. Frank Fryson
Quality Assurance Manager
Thermo Fisher Scientific
One Thermo Fisher Way
Oakwood Village, OH 44146

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF THERMO FISHER SCIENTIFIC NO. 99901460/2023-201, AND NOTICE OF VIOLATION

Dear Mr. Fryson:

On October 16 - 20, 2023, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Thermo Fisher Scientific's (hereafter referred to as TFS) facility in Oakwood Village, OH. The purpose of the limited scope routine inspection was to assess TFS's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically focused inspection specifically evaluated TFS's implementation of quality activities associated with the manufacture of Excore Neutron Flux Monitoring System spare and replacement parts for U.S. nuclear power plants. The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of TFS's overall quality assurance (QA) or 10 CFR Part 21 programs. In addition, the NRC inspection team evaluated TFS's closure of the inspection findings documented in inspection report No. 99901460/2015- 201, dated July 16, 2015 (Agency Documents Access and Management System (ADAMS) Accession No. ML15187A193).

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The NRC evaluated the violation in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The enclosed Notice of Violation (NOV) cites the violation, and the subject inspection report details the circumstances surrounding the violation. Violation 99901460/2023-201-01 cites TFS for failing to evaluate a deviation to determine whether the deviation could lead to a substantial safety hazard, as required by 10 CFR Part 21.21(a)(1).

You are required to respond to this letter and to follow the instructions specified in the enclosed NOV when preparing your response. In your response to the enclosed NOV, TFS should document the results of the extent of condition review for this finding and determine if there are any effects on other safety-related components. If you have additional information that you

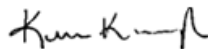
believe the NRC should consider, you may provide it in your response to the NOV. The NRC's review of your response to the NOV also will determine if further enforcement action is necessary to ensure compliance with regulatory requirements.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NOV. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information (SGI) 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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).

If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of safeguards information: performance requirements."

Sincerely,



Signed by Kavanagh, Kerri
on 12/03/23

Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99901460

EPID No.: I-2023-201-0052

Enclosures:

1. Notice of Violation
2. Inspection Report No. 99901460/2023-201 and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF THERMO FISHER SCIENTIFIC NO. 99901460/2023-201, AND NOTICE OF VIOLATION DATE: December 3, 2023

DISTRIBUTION:

Public
RFelts, NRR
PMcKenna , NRR
AZoulis, NRR
ABowie, NRR
NRR_DRO_IQVB Distribution
frank.fryson@thermofisher.com

ADAMS Accession No.: ML23331A790

NRR-106

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IRAB	NRR/DRO/IQVB
NAME	DPark	RRomero-Devore	BHughes	KKavanagh
DATE	11/28/2023	11/29/2023	11/29/2023	12/3/2023

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Thermo Fisher Scientific
One Thermo Fisher Way
Oakwood Village, OH 44146

Docket No. 99901460
Report No. 2023-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Thermo Fisher Scientific's (hereafter referred to as TFS) facility in Oakwood Village, OH, on October 16 through October 20, 2023, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21.21, "Notification of failure to comply or existence of a defect and its evaluation," Section (a)(1) requires in part that entities subject to Part 21, "evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable."

Section 5.2.2 of TFS' procedure No. QP 2.06.003, "Reporting of Defects and Noncompliance as Required By 10 CFR 21," Revision P, dated July 14, 2021, states that "The Quality Assurance Manager, upon receiving such notification (Date of Discovery), shall establish an Evaluation Board, comprised of, at a minimum, the engineering, manufacturing, the project manager, and him or herself. A Material Review Board Evaluation form shall be generated to document the actions of the Evaluation Board. The Board shall evaluate the reported deviation or failure to comply to determine there is sufficient data to perform an Evaluation for Reportability."

Contrary to the above, as of October 20, 2023, TFS failed to evaluate a deviation to identify defects associated with substantial safety hazards as soon as practicable. Specifically, TFS received information from an NRC licensee that a screw was missing on the base/back panel of a safety-related power supply, No. 201401-101, Serial Number 514, Revision T. Upon further inspection, TFS also discovered that a wrong base/back panel was installed and mislabeled. The part installed was No. 201458-101 and mislabeled as 201458-102. TFS failed to evaluate the reported deviation and document the actions in the material review board evaluation form in order to determine if a reportable defect exists that could create a substantial safety hazard.

This issue has been identified as Violation 99901460/2023-201-01.

This is a Severity Level IV violation (Section 6.9.d of the NRC Enforcement Policy).

Pursuant to the provisions of 10 CFR Part 2.201, "Notice of Violation," TFS is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" and should include (1) the reason for the violation or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence if the correspondence adequately

addresses the required response. Where good cause is shown, the NRC will consider extending the response time.

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

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible it should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the agency can make it 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 that such material be withheld, 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 would 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). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated this XXth day of December 2023.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT**

Docket No.: 99901460

Report No.: 99901460/2023-201

Vendor: Thermo Fisher Scientific
One Thermo Fisher Way
Oakwood Village, OH 44146

Vendor Contact: Mr. Frank Fryson
Quality Assurance Manager
Email: frank.fryson@thermofisher.com
Office: (440) 703-1477

Nuclear Industry Activity: Thermo Fisher Scientific manufactures Excore Neutron Flux Monitoring System spare and replacement parts for NRC regulated facilities.

Inspection Dates: October 16 - 20, 2023

Inspectors: Dong Park NRR/DRO/IQVB, Team Leader
Rebecca Romero-Devore NRR/DRO/IQVB, Trainee

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

Thermo Fisher Scientific

REPORT NO. 99901460/2023-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a vendor inspection at the Thermo Fisher Scientific's (hereafter referred to as TFS) facility in Oakwood Village, OH, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC inspection team conducted this inspection on-site from October 16 – 20, 2023.

This technically-focused inspection specifically evaluated TFS's implementation of its QA and 10 CFR Part 21 programs associated with the manufacture of Excore Neutron Flux Monitoring System spare and replacement parts, calibration, and repair services of safety-related applications at U.S. nuclear power plants.

The following regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During the course of this inspection, the NRC inspection team implemented the following inspection procedures (IP): IP 43002, "Routine Inspections of Nuclear Vendors," dated February 10, 2023; and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 10, 2023.

The results of the inspection are summarized below.

10 CFR Part 21

The NRC inspection team issued Violation 99901460/2023-201-01 in association with TFS's failure to implement the regulatory requirements of 10 CFR Part 21. Violation 99901460/2023-201-01 cites TFS for failure to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable. Specifically, TFS received information from an NRC licensee of a deviation in a safety-related power supply. TFS failed to evaluate the reported deviation and document the actions in the material review board evaluation form in order to determine if a reportable defect exists that could create a substantial safety hazard.

Nonconforming Materials, Parts, or Components and Corrective Action

The NRC inspection team reviewed discrepancy reports and corrective action reports to ensure that technical and manufacturing deficiencies have been appropriately evaluated, dispositioned, and reported to customers as required. The NRC inspection team reviewed the corrective actions that TFS took to address Notice of Violation (NOV) 99901460/2015-201-01, and Notice of Nonconformance (NON) 99901460/2015- 201-02, documented in Inspection Report No. 99901460/2015-201, dated July 16, 2015. The NRC inspection team reviewed the documentation that provided the objective evidence that all the corrective actions were completed and adequately implemented. Based on this review, the NRC inspection team closed NOV 99901460/2015-201-01, and NON 99901460/2015-201-02.

Other Inspection Areas

The NRC inspection team determined that TFS established its programs for nonconforming material, parts, or components, corrective action, supplier oversight, and measuring and test equipment in accordance with the applicable regulatory requirements of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that TFS is implementing its policies and procedures associated with these programs. No findings of significance were identified in these areas.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Thermo Fisher Scientific's (hereafter referred to as TFS) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of TFS's purchase orders (PO) for compliance with the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and 10 CFR 21.31, "Procurement Documents." The NRC inspection team also verified that TFS's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program.

The NRC inspection team also discussed the 10 CFR Part 21 program with TFS's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified that the postings required in 10 CFR 21.6, "Posting requirements" were incomplete. The NRC inspection team found that TFS QP 2.06.003, "Reporting of Defects and Noncompliance as Required By 10 CFR 21," Revision P, dated July 14, 2021, was missing, and instead of Section 206 of the Energy Reorganization Act of 1974, TFS had Attachment 1 to IN 87-15, "SUBSECTION 223b OF THE ATOMIC ENERGY ACT OF 1954." The NRC has determined this issue to be minor because TFS maintains a Part 21 training program with records indicating personnel receive 10 CFR Part 21 training. TFS also maintains a current version of Part 21 posted, while the posting of an outdated version of Section 206 of the Energy Reorganization Act of 1974 is considered administrative. TFS initiated corrective action reports (CAR) 23-022 to address this issue.

During the review of discrepancy reports (DRs) and CARs, one report identified information received from an NRC licensee of a missing screw on the base panel of a safety-related power supply, 201401-101. TFS authorized the return of the item. Upon further inspection, TFS also discovered that a wrong base panel was installed, and the base panel 201458-102, was also mislabeled. The part installed was a 201458-101. During the TFS facility move from San Diego to Oakwood Village in 2020, TFS transferred these base panels in inventory. CAR 21-005 was written to address the customer complaint of the missing screw on the base panel.

TFS' procedure, QP 2.06.003, Section 5.2.2, states that, "The Quality Assurance Manager, upon receiving such notification (Date of Discovery), shall establish an Evaluation Board, comprised of, at a minimum, the engineering, manufacturing, the project manager, and him or herself. A Material Review Board Evaluation form shall be generated to document the actions of the Evaluation Board. The Board shall evaluate the reported deviation or failure to comply to determine there is sufficient data to perform

an Evaluation for Reportability.” Per QP 2.06.003, TFS failed to evaluate the reported deviation and document the actions in the material review board evaluation form in order to determine if a reportable defect exists that could create a substantial safety hazard. This issue is cited in notice of violation 99901460/2023-201-01.

c. Conclusion

The NRC inspection team issued Violation 99901460/2023-201-01 in association with TFS’s failure to implement the regulatory requirements of 10 CFR Part 21. Violation 99901460/2023- 201-01 cites TFS for failing to adequately evaluate a deviation associated with a substantial safety hazard. Specifically, TFS failed to evaluate the reported deviation and document the actions in the material review board evaluation form in order to determine if a reportable defect exists that could create a substantial safety hazard.

2. Procurement Document Control and Supplier Oversight

a. Inspection Scope

The NRC inspection team reviewed TFS’s policies and implementing procedures that govern the implementation of its supplier oversight program to verify compliance with the requirements of Criterion IV, “Procurement Document Control,” and Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed TFS’s approved supplier list (ASL), a sample of POs, supplier audits, and receipt inspection records. The NRC inspection team confirmed that POs adequately imposed the applicable technical, regulatory, and quality requirements. In addition, the NRC inspection team reviewed a sample of completed receipt inspection records to verify that inspections were conducted in accordance with receipt inspection procedures. The NRC inspection team observed a receipt inspection and performed a walkdown of the quality control inspection area.

The NRC inspection team selected a sample of suppliers from the ASL to review the methodology for conducting and documenting audits and the review of third-party audits to verify adequate evaluation of the suppliers’ controls for meeting the applicable requirements of Appendix B to 10 CFR 50.

The NRC inspection team also discussed the supplier oversight program with TFS’s management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified that TFS had not performed annual evaluations for two suppliers that had recent POs issued. The TFS procedure does have adequate guidance for the conduct and scheduling of annual evaluations. Additionally, nonconformances are tracked and monitored for each supplier. The NRC inspection team determined this issue to be minor because TFS performs additional tests and inspections as a part of the receipt inspection process. The results of the tests and inspections provide evidence of reasonable assurance that the suppliers continue to

demonstrate adequate controls over technical and quality requirements and are providing products that meet the applicable requirements. TFS initiated CAR 23-024 to address this issue.

c. Conclusion

The NRC inspection team concluded that TFS is implementing its supplier oversight program in accordance with the regulatory requirements of Criterion IV and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that TFS is implementing its policies and procedures associated with the supplier oversight program. No findings of significance were identified.

3. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed TFS's policies and implementing procedures that govern the M&TE program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team sampled the calibration records used for the manufacturing of the Excore Neutron Flux Monitoring System spare and replacement parts and observed that the calibrations were performed in accordance with TFS's M&TE procedures and adequately documented.

The NRC inspection team performed a walkdown of the Excore Neutron Flux Monitoring System assembly area and selected a sample of M&TE for review. The NRC inspection team verified the M&TE were labeled, handled, and stored in a manner that indicated the calibration status of the instrument and ensured its traceability to calibration test data, including appropriate calibration stickers and current calibration dates. The NRC inspection team also verified that the M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. Additionally, the NRC inspection team verified that the certificate of calibration stated the traceability to a nationally recognized standard. The NRC inspection team confirmed that when M&TE is found to be out of calibration, a discrepancy report (DR) is initiated, and an evaluation is performed to determine if the M&TE was previously used.

The NRC inspection team also discussed the M&TE program with TFS's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that TFS is implementing its M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC

inspection team also determined that TFS is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

4. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed TFS's policies and implementing procedures that govern the control of nonconformances to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

The NRC inspection team determined that TFS's processes and procedures provide for the identification, documentation, segregation, evaluation, and disposition of nonconforming items. The NRC inspection team also reviewed that TFS's nonconformance process provides guidance to evaluate nonconformances for reportability under TFS's 10 CFR Part 21 program. The nonconformance process is also linked to the corrective action program.

The NRC inspection team observed TFS's assembly floor and verified that nonconforming materials were properly identified, marked, and segregated, when practical, to ensure that they were not reintroduced into the production processes.

The NRC inspection team reviewed a sample of DRs and confirmed that TFS: (1) dispositioned the DRs in accordance with the applicable procedures; (2) documented an appropriate technical justification for the dispositions; and (3) took adequate corrective action regarding the nonconforming items to prevent recurrence. The NRC inspection team also reviewed a sample of CARs and confirmed: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence; and (3) direction for review and approval by the responsible authority to verify effective implementation of the corrective actions.

The NRC inspection team also reviewed TFS's corrective actions in response to the inspection findings identified in NRC Inspection Report IR No. 99901460/2015-201 dated July 16, 2015 (Agencywide Document Access and Management System (ADAMS) Accession No. ML15187A193).

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with TFS's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

1. Corrective Action Associated with Violation 99901460/2015-201-01

Following the June 2015 inspection of TFS, the NRC issued Violation 99901460/2015-201-01 for TFS's failure notify the NRC when they had information on March 24, 2015, reasonably indicating a defect in a basic component (Power

Range Detector, Part No. 201872-101, Serial No. 006) supplied to a licensee in the United States.

In its response to the NRC, dated August 7, 2015, (ADAMS Accession No. ML15232A462) TFS stated that CAR 15-006 was opened to address customer's letter of the potential defect. The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions. Based on its review, the NRC inspection team closed Violation 99901460/2015-201-01.

2. Corrective Action Associated with Nonconformance 99901460/2015-201-02

The NRC also issued Nonconformance 99901460/2015-201-02 for TFS's failure to ensure that measuring devices were identified with a serial number and calibrated at periodic intervals to maintain accuracy within necessary limits. Specifically, K-type thermocouples used in conjunction with a dual input digital thermometer during testing of mineral insulated cable were not identified with a serial number and were never calibrated but were used in safety-related applications.

In its response to the NRC, dated August 7, 2015, (ADAMS Accession No. ML15232A461) TFS stated that it had purchased new K-type thermocouples to have them calibrated and compared to the existing thermocouples to assess the impact of the nonconformance. TFS opened CAR 15-019 to address this nonconformance. The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions. Based on its review, the NRC inspection team closed Nonconformance 99901460/2015-201-02.

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that TFS is implementing its nonconforming materials, parts, or components and corrective action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that TFS is implementing its policies and procedures associated with the control of nonconforming materials, parts, or components and corrective action. No findings of significance were identified.

5. Entrance and Exit Meetings

On October 16, 2023, the NRC inspection team discussed the scope of the inspection with Mr. Frank Fryson, and other members of TFS's management and technical staff. On October 20, 2023, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Frank Fryson and other members of TFS's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Frank Fryson	Quality Assurance Manager	Thermo Fisher Scientific (TFS)	X	X	X
Danielle Cummings	Quality Supervisor	TFS	X	X	X
Mark Prack	Director of Operation (Site Leader)	TFS	X	X	
Gary Ilko	Manufacturing Manager	TFS	X	X	X
Bruce Kormanec	Supplier Quality	TFS	X	X	X
Jerry Alexander	Quality Control Supervisor	TFS	X	X	
Cynthia Maciejowski	Quality Document Control	TFS	X	X	
StoAnna Brewer	Senior Quality Technician	TFS			X
Deanna Zhang*	Branch Chief (Acting)	Nuclear Regulatory Commission (NRC)	X	X	
Dong Park	Inspection Team Leader	NRC	X	X	
Rebecca Romero-Devore	Inspector	NRC	X	X	

*Remote

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated February 10, 2023

IP 43002, "Routine Inspections of Nuclear Vendors," dated February 10, 2023

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901460/2015-201-01	CLOSED	NOV	10 CFR Part 21
99901460/2015-201-02	CLOSED	NON	Criterion XII
99901460/2023-201-01	OPENED	NOV	10 CFR Part 21

4. DOCUMENTS REVIEWED

Policies and Procedures

Thermo Fisher Scientific (TFS) Nuclear Quality Assurance Manual, Revision 27, dated September 20, 2023

TFS QP 2.06.001, "Control of Nonconforming Material," Revision AB, dated July 14, 2021

TFS QP 2.06.003, "Reporting of Defects and Noncompliance as Required By 10 CFR 21," Revision P, dated July 14, 2021

TFS QP-2.01.004, "Corrective Action," Revision Q, dated October 11, 2021

TFS QP 2.03.004, "Control and Calibration of Measuring and Test Equipment," Revision V, dated June 9, 2023

TFS QP 2.03.005, "Inspection Plan," Revision R, dated October 12, 2023

TFS QP 2.04.001, "Supplier Control," Revision U, dated July 26, 2022

TFS QP 2.04.004, "Supplier Deviation Requests," Revision E, dated April 17, 2020

TFS QP 2.07.001, "Audit & Surveys," Revision P, dated September 29, 2021

M&TE Records

Calibration Status Log (current)

M&TE Receipt Inspection/Dedication Record for T-231, "True RMS Multimeter," dated October 11, 2023

Certificate of Calibration from Tektronix, "Digital Multimeter," S/N MY56100025, dated July 25, 2023

M&TE Receipt Inspection/Dedication Record for T-139, "Precision Current Source," dated October 16, 2023

Certificate of Calibration from Tektronix, "Precision Current Source," S/N 21294, dated July 24, 2023

M&TE Receipt Inspection/Dedication Record for 4573978, "Pico Ammeter," dated October 16, 2023

Certificate of Calibration from Tektronix, "Pico Ammeter," S/N 4573978, dated July 21, 2023

M&TE Receipt Inspection/Dedication Record for T-279, "Source Meter," dated October 11, 2023

Certificate of Calibration from Tektronix, "Source Meter," S/N 000477E, dated August 23, 2023

M&TE Receipt Inspection/Dedication Record for 4581343, "Pico Ammeter," dated October 11, 2023

Certificate of Calibration from Tektronix, "Pico Ammeter," S/N 4573978, dated August 21, 2023

Certificate of Calibration from Simco, "Thermocouple, Type-K," Asset No. K-003, dated June 08, 2017

Certificate of Calibration from Simco, "Thermocouple, Type-K," Asset No. K-005, dated March 08, 2016

Certificate of Calibration from Simco, "Thermocouple, Type-K," Asset No. K-006, dated March 08, 2016

Certificate of Calibration from Simco, "Thermocouple, Type-K," Asset No. K-009, dated August 05, 2016

Nonconformance Records (NCRs) / Discrepancy Report (DR)

Discrepancy Report Log from 2021, 2022, and 2023

DR-23-007

DR-23-027

DR-23-032

DR-23-033

DR-23-036

DR-23-044

DR-23-054

DR-23-055

DR-23-056

DR-23-057

DR-23-059

DR-23-060

DR-23-061

DR-23-062

DR-23-063

DR-23-066

DR-23-067

DR-23-068

DR-23-069

DR-23-070
DR-22-013
DR-22-014
DR-21-020
DR-21-021
DR-21-022
DR-21-029

Corrective Action Records (CARs)

CAR Log from 2021, 2022, and 2023
CAR 15-006
CAR 15-019
CAR 22-001
CAR 21-005
CAR 20-016
CAR 23-021

Corrective Action Requests Opened During the NRC Inspection

CAR 23-022
CAR 23-023
CAR 23-024

Audit and Survey Documents

NIAC Audit report for Imaging and Sensing Technology (Mirion), dated February 16-18, 2021

NIAC Audit Report for Rockbestos Surprenant Wire and Cable, dated October 5-8, 2021

Approved Supplier List for Neutron Flux Monitoring Equipment Items & Services, dated October 11, 2023

Purchase Orders

PV81952, Rev. 00, dated December 30, 2021

PV84394, Rev. 00, dated July 02, 2022

PV84395, Rev. 00, dated July 02, 2022

PV84776, Rev. 00, dated August 16, 2022

PV84790, Rev. 00, dated August 17, 2022

PO 4500642538, dated November 7, 2020

PO 4500633589, dated September 25, 2020

PO 4500644750, dated November 18, 2020

Training Records

Quality Engineer Training Record for Diaz de la Vega, Rodrigo

Material Handler/Stockroom Training Record for Ratinoff, Ismael

TFS OV Responsibilities Training Matrix

Screenshot of Employee Training Records Folders