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December 14, 2023

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

Subject:	Reply to a Notice of Violation
Reference:	NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF THERMO FISHER SCIENTIFIC NO. 99901460/2023-201, AND NOTICE OF VIOLATION
Attachments:	Attachment 1: Corrective Action Request CAR-23-023
	Attachment 2: Supporting Document - Material Review Board Evaluation
	Attachment 3: Supporting Document - Revised Corrective Action Request Form
	Attachment 4: Supporting Document - Training Record

Dear Ms. Kavanagh:

I am writing in response to the Notice of Violation 99901460/2023-201-01 received, 12/05/2023, which was identified 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. The details of the violation are as follows:

> 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),

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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.

Outlined below are the specific actions we have taking to rectify the situation:

1) CAPA Initiation: Immediately upon identification of the non-compliance during the NRC audit, our team opened a corrective action (CAR-23-023) and began a thorough investigation to understand the root causes of the non-compliance and assess its potential impact on safety and regulatory requirements. Completed 12/14/2023, see attached signed copy of CAR-23-023 for details and proof of implementation.
2) Worked with our Engineering team to complete Engineering Technical Assessment of condition. Completed 10/19/2023, see attached "MATERIAL REVIEW BOARD EVALUATION", Section 3: Evaluation for proof of implementation.
3) Assembled Material Review Board for Evaluation. Initial meeting completed 10/23/2023.
4) Completed Material Review Board Evaluation. Completed 12/13/2023, see attached "MATERIAL REVIEW BOARD EVALUATION" for proof of implementation.
5) Revised Corrective Action Request Form to reference Material Review Board evaluation by adding "If yes, complete Material Review Board Evaluation Form per QP 2.06.003" to section with initial screening for Potential 10CFR Condition. Completed 12/11/2023, see attached revised form for proof of implementation.
6) Retrained Quality Supervision, Quality Engineers, Engineering, Manufacturing Supervision, and Project Manager on QP 2.06.003, Section 5.2., Completed 12/12/2023, see attached training record as proof of implementation.

Sincerely,

Frank Fryson
Quality Assurance Manager
Thermo Fisher Scientific

Attachment 1:
Corrective Action Request CAR-23-023

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CORRECTIVE ACTION REQUEST CAR No. 23-023

(This form is controlled by QP 2.01.004. Modifications to this document must be approved by QA)

TO: **Dimitria Kontoveros**		RESPONSE DUE DATE:	**11/19/2023**
ADDRESS & PHONE NO.: Thermo Fisher 1 Thermo Fisher Way Oakwood Village, Ohio			
COPIES TO: **Danielle Cummings**			
ORIGINATOR: **Dimitria Kontoveros**		REQUEST DATE:	**10/19/2023**
PART NUMBER: 201401-101; 201458-102/101		DISCREPANCY REPORT NO.:	N/A
PART NAME: HVPS; Base HVPS		LOCATION WHERE FOUND:	NRC Audit
POTENTIAL 10CFR21 CONDITION: YES ___ NO _X_		POTENTIAL CONDITION SIGNIFICANTLY ADVERSE TO QUALITY: YES ___	NO _X_

DESCRIPTION OF CONDITION:

Requirement:
QP 2.06.003, "Reporting of Defects and Noncompliance as Required By 10 CFR 21," Revision P, dated July 14, 2021, Section 5.2.2 states "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.

Nonconformance:
CAR-21-005 did not contain a Material Review Board Evaluation form documenting the evaluation of the incorrect back panel use of 201458-101 in the field on existing HVPS 201401-101.

APPLICABLE SPECS CODES, PROCEDURES, ETC:
10CFR21, QP 2.06.003, "Reporting of Defects and Noncompliance as Required By 10 CFR 21,"

APPARENT CAUSE:

To be determined through investigation and documented below.

THIS SECTION TO BE COMPLETED BY ADDRESSEE BY RESPONSE DUE DATE AND RETURNED TO ORIGINATOR

ACTUAL CAUSE:

The evaluation of 10CFR21 condition conducted under CAR-21-005 was not properly documented, per procedure QP 2.06.003, section 5.2.2.

ACTION TAKEN TO PREVENT RECURRENCE:

- Complete Engineering Technical Assessment of condition. Completed 10/19/2023, see attached "MATERIAL REVIEW BOARD EVALUATION", Section 3: Evaluation for proof of implementation.
- Assemble Material Review Board for Evaluation. Initial meeting completed 10/23/2023.
- Complete Material Review Board Evaluation. Completed 12/13/2023, see attached "MATERIAL REVIEW BOARD EVALUATION" for proof of implementation.
- Revise Corrective Action Request Form to reference Material Review Board evaluation by adding "If yes, complete Material Review Board Evaluation Form per QP 2.06.003" to section with initial screening for Potential 10CFR Condition. Completed 12/11/2023, see attached revised form for proof of implementation.
- Retrain Quality Supervision, Quality Engineers, Engineering, Manufacturing Supervision, and Project Manager on QP 2.06.003, Section 5.2., Completed 12/12/2023, see attached training record as proof of implementation.

PRINT NAME:	TITLE:	
Danielle Cummings	**Quality Supervisor**	
SIGNATURE: *Danielle Cummings*	DATE: 12/14/2023	EXPECTED DATE OF IMPLEMENTATION: 12/14/2023

RESPONSE APPROVED BY (PRINT NAME):	SIGNATURE:		DATE:
Frank Fryson	Frank Fryson		12/14/2023
IMPLEMENTATION VERIFIED BY (PRINT NAME):	**SIGNATURE:**	**DATE:**	**ACTUAL DATE OF IMPLEMENTATION:**
Frank Fryson	Frank Fryson	12/14/23	12/14/2023

Attachment 2:
Supporting Document- Material Review Board Evaluation

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Explain:

Engineering Evaluation of Condition Impact on Safety:

An engineering evaluation comparing the differences between the two base plate variants when installed in the 201401-101 assembly found there to be no significant effects on the critical characteristics, operation, or safety of the high voltage power supply. The 201458-101 is identical in material and size to the 201458-102 with the exception that the -101 base plate includes 15 additional mounting holes and two mounting slots that are not present on the -102 base plate and are not used in the 201401 assembly. These additional holes do not affect qualification of the assembly for seismic, environmental, or EMC.

Seismic performance can be affected by changes in structural rigidity, mass, or center of gravity. The additional mounting holes have minimal effect on overall rigidity on the assembly, therefore do not affect the seismic qualification. The total mass difference due to the additional drilled holes in the aluminum base plate is less than 3 grams, which is negligible when compared to the overall mass of the assembly and does not impact seismic qualification. Additionally, the holes are distributed across the base plate so the variation in mass minimally changes center of gravity of the power supply.

Environmental performance of the assembly is also not affected by the additional mounting holes in the base plate. The base plate functions as part of the power supply enclosure, but it does not contact any internal components of the assembly and does not contribute to the thermal regulation of the electronics within. The enclosure is not air-tight and includes gaps and unused holes that allow ambient air to flow in and out, and the additional mounting holes on the base plate have no impact on airflow or thermal performance. Therefore, the use of the -101 base plate rather than -102 does not affect the environmental qualification of the assembly.

Finally, there is no significant change to the EMC performance of the supply due to the additional mounting holes. The enclosure of the 201401-101 power supply has multiple openings that allow RF waves to pass freely throughout the assembly and the existing openings are much larger than the additional mounting holes on the base plate. Additionally, there are no high frequency AC signals generated within the supply, so the additional mounting holes are not of a sufficient aperture size to increase the radiated emissions from the assembly by a significant amount. Radiated and received emissions are further attenuated when the HVPS is installed in a higher-level assembly enclosure in which it is qualified to operate as part of a class 1-E safety system. EMC qualification is not affected by the change in base plate.

Section 4: Notifications Required	Yes	Date
Responsible Officer	N/A	
NRC	N/A	
Customer	N/A	

Additional actions to be taken: (references)

No 10CFR21 reportable condition.

MRB Attendee Review	Organization	MRB Attendee Review	Organization
Danielle Cummings	Quality Assurance	Jeff Chizmar	Engineering
Dimitria Kontoveros	Quality Assurance	Dien Vo	Project Manager
Gary Ilko	Manufacturing	Mark Prack	Director of Operations / Site Leader

Material Review Board Chair Approval Signature: Frank Fryson **Date:** 12/13/2023

Attachment 3:
Supporting Document- Revised Corrective Action Request Form

CORRECTIVE ACTION REQUEST CAR No. _____

(This form is controlled by QP 2.01.004. Modifications to this document must be approved by QA)

TO:	**RESPONSE DUE DATE:**
ADDRESS & PHONE NO.:	
COPIES TO:	
ORIGINATOR:	**REQUEST DATE:**
PART NUMBER:	**DISCREPANCY REPORT NO.:**
PART NAME:	**LOCATION WHERE FOUND:**
POTENTIAL 10CFR21 CONDITION?: YES ____ NO ____ If yes, complete Material Review Board Evaluation Form per QP 2.06.003	**POTENTIAL CONDITION SIGNIFICANTLY ADVERSE TO QUALITY?: YES ____ NO ____**
DESCRIPTION OF CONDITION:	
APPLICABLE SPECS CODES, PROCEDURES, ETC:	
APPARENT CAUSE:	

THIS SECTION TO BE COMPLETED BY ADDRESSEE BY RESPONSE DUE DATE AND RETURNED TO ORIGINATOR		
ACTUAL CAUSE:		
ACTION TAKEN TO PREVENT RECURRENCE:		
PRINT NAME:	**TITLE:**	
SIGNATURE:	**DATE:**	**EXPECTED DATE OF IMPLEMENTATION:**

RESPONSE APPROVED BY (PRINT NAME):	**SIGNATURE:**		**DATE:**
IMPLEMENTATION VERIFIED BY (PRINT NAME):	**SIGNATURE:**	**DATE:**	**ACTUAL DATE OF IMPLEMENTATION:**

Attachment 4:
Supporting Document- Training Record

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TRAINING RECORD

Subject: CAR-23-023 Retraining on QP 2.06.003, Section 5.2.

Instructor: Self-Review **Date:** 12/11/2023

Name (print)	Signature
Danielle Cummings	Danielle Cummings
Dimitria Kontoveros	Dimitria Kontoveros
Bruce Kormanec	
Mark Prack	
Jeff Chizmar	
Andrew Magro	
Andrea Norris	
Gary Ilko	
Dien Vo	

(This form is controlled by QP 2.02.001. Modifications to this form must be approved by QA)

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QUALITY PROCEDURE

NO	2.06.003
REV	P
DATE	07/1 4/2021
APVD	F. Fryson FF
QA APVD	J. Wolff JW 7-14-21
PAGE	1 OF 4

REPORTING OF DEFECTS AND NONCOMPLIANCE AS REQUIRED BY 10CFR21

1.0 PURPOSE

1.1 To establish the policy and assign responsibilities for reporting as required by Title 10, Part 21, of the Code of Federal Regulations.

2.0 SCOPE

2.1 This procedure is applicable to the Neutron Flux Monitoring System product line safety-related component or assembly that is discovered to contain a deviation or failure to comply, as defined below.

3.0 APPLICABLE DOCUMENTS

3.1 Reference Documents

Thermo Fisher Scientific QP 2.01.004	*Corrective Action*
Thermo Fisher Scientific Form	*Corrective Action Request*
Thermo Fisher Scientific Form	*Discrepancy Report*
Thermo Fisher Scientific Form	*Material Review Board Evaluation*
Energy Reorganization Act of 1974	*Section 206 Noncompliance*
Supplier QA Program Spec. for NPP NSSS I&C QC 1 Equipment	***NQAPS-001A***
Title 10 of the Code of Federal Regulations, Part 21 (10CFR21)	*Reporting of Defects and Noncompliance*

3.2 Related Documents

Thermo Fisher Scientific QP 2.06.001	*Control of Nonconforming Material*

4.0 GLOSSARY

Responsible Officer	Director of Operations / Site Leader, or if applicable – Corporate Legal Department.
Material Review Board (MRB)	A committee consisting of a member each from Manufacturing, Engineering, Purchasing, and Quality Assurance, who reviews and evaluates nonconforming material to determine its disposition.

See the latest revision of *10CFR21.3* for the definition of other words and phrases used in this procedure as they apply to *10CFR21*.

5.0 REQUIREMENTS

5.1 Employee Responsibilities

5.1.1 Any employee who discovers a deviation or failure to comply in nuclear safety-related equipment, which has been delivered to a nuclear facility, shall immediately notify the Quality Assurance (QA) Manager.

5.2 Quality Assurance Manager's and Material Review Board's Responsibilities

5.2.1 Upon review of a *Discrepancy Report* or a *Corrective Action Request* or other issues such as Findings, customer returned material, or complaints shall be reviewed for *10CFR21* applicability. When determined by the Material Review Board, engineering or the quality department that the deficiency is *10CFR Part 21* applicable the below process shall be performed.

5.2.2 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. If it is determined there is inadequate data to perform the evaluation the Quality Assurance Manager notifies the affected purchaser or licensee within five (5) working days of this determination so that they may evaluate the deviation or failure to comply condition.

5.2.3 If the determination concludes there is sufficient data to perform an Evaluation for Reportability, it shall be completed within 60 days of discovery. In the event that the evaluation of a deviation or failure to comply cannot be completed within 60 days of discovery, an interim report shall be submitted in writing to the NRC. The interim report shall describe the deviation or failure to comply that is being evaluated and when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply. If the Board determines that the deviation constitutes a defect or the failure to comply could create a substantial safety hazard that is reportable in accordance with the requirements of *10CFR21*, and the facility concerned is licensed in accordance with the *Atomic Energy Act of 1954*, the Board shall notify the Responsible Officer within five (5) working days of completion of the evaluation.

5.2.4 If the facility is not licensed in accordance with the *Atomic Energy Act of 1954*, the Material Review Board shall notify the customer as appropriate under local law, or in accordance with the customer purchase order requirements.

5.2.5 The Quality Assurance Manager shall implement a Corrective Action Request in accordance with *QP 2.01.004, Corrective Action*, to track and ensure that *10CFR21* notification is performed in accordance with regulatory requirements.

5.2.6 The Quality Assurance Manager shall ensure a five (5) year retention of all investigative (evaluation) documents associated with *10CFR21* notifications.

5.3 Responsible Officer's Responsibilities (Director of Operations / Site Leader)

5.3.1 In the event that the evaluation of a deviation or failure to comply cannot be completed within 60 days of discovery, an interim report shall be submitted in writing to the NRC through the Responsible Officer. The interim report shall describe the deviation or failure to comply that is being evaluated and when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

5.3.2 The Responsible Officer shall contact the licensee or purchaser of the affected equipment and the NRC when he/she obtains information reasonably indicating a defect or failure to comply that could create a substantial safety hazard. If it is determined that the deviation constitutes a defect, or that the noncompliance could create a substantial safety hazard, and that the Nuclear Regulatory Commission has not been notified in writing, he/she shall notify the NRC. The initial notification to either the licensee or purchaser of the affected equipment, or the NRC, shall be made within two (2) days following the determination of reportability.

5.3.3 The Responsible Officer may authorize an individual to provide the notification required by the above criteria, provided this shall not relieve the Responsible Officer of his or her responsibility.

5.4 Notification Requirements

5.4.1 Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the Responsible Officer on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. A written report to the NRC, at the address shown in *10CFR21*, must follow within thirty (30) days of determination of reportability or a failure to comply. The written report shall include pertinent information as required by *10CFR21*.

5.4.2 If it cannot be determined whether or not a defect exists or a substantial safety hazard could be caused by a non-compliance associated with the delivered equipment, the Responsible Officer must notify the purchaser or licensee within five (5) working days of this determination so that they may evaluate the deviation or failure to comply.

5.5 Posting Requirements

5.5.1 In a conspicuous location in the Company where the requirements of *Section 206* of the *Energy Reorganization Act of 1974*, The Regulation, this Procedure and states the name of the individual to whom reports are made shall be posted. When there is more than one building each building where the QA Program is implemented, and safety related activities are performed shall have a posting. Alternatively, a copy of *Section 206 Noncompliance*, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

5.5.2 The Quality Assurance Manager will maintain current copies of this procedure, *10CFR21*, and *Section 206 Noncompliance* of the *Energy Reorganization Act of 1974*. Reports generated by the requirements of *10CFR21* will be retained with the Quality Assurance Manager.

5.5.3 If the customer is Korean and regulated under KINS [Korean Institute of Nuclear Safety) (Doosan, KHNP, etc.), and there is a condition found where a nuclear safety-related component or assembly is discovered to contain a deviation or failure to comply, the customer's Purchasing Team (Doosan, KHNP, etc.), shall be notified by email, phone or orally. Details, related information and countermeasures shall be submitted in writing within 5 working days, including the following points:

- **Vendors responsible for counterfeit, fraudulent, or suspect cases with description of such cases**
- **Verification result on items ordered by Doosan against counterfeit or fraudulence**
- **Follow-up action plan and recurrence prevention measures**
- **Evidences in support of the description of counterfeit, fraudulent, or suspect cases and the verification result thereon**

6.0 RESPONSIBILITIES

6.1 The QA Manager is responsible for the implementation and maintenance of this procedure.

6.2 Those responsible for the actions identified in this procedure are shown in the Appendix.

APPENDIX
FLOW SHEET
Reporting of Defects and Noncompliance as Required by 10CFR21