

July 16, 2015

Mr. William Flick, Quality Assurance Manager
Thermo Fisher Scientific
10010 Mesa Rim Rd.
San Diego, CA 92121

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION OF
THERMO FISHER SCIENTIFIC REPORT NO. 99901460/2015-201, NOTICE
OF VIOLATION AND NOTICE OF NONCONFORMANCE

Dear Mr. Flick:

On June 1 to June 5, 2015, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection under the Multinational Design Evaluation Programme (MDEP) protocol Vendor Inspection Cooperation Working Group (VICWG)-01 at the Thermo Fisher Scientific (TFS) facility in San Diego, California. Using the MDEP protocol, the NRC inspection team was observed by inspectors from the Korea Institute of Nuclear Safety (KINS). The purpose of this limited-scope inspection was to assess TFS's compliance with the provisions of selected portions 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."

This technically-focused inspection specifically evaluated TFS's implementation of quality activities associated with the fabrication and testing of safety-related excore neutron flux monitoring systems supplied to U.S. operating reactor plants and to the Watts Bar Unit 2 completion project. The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC staff determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because TFS failed to notify the NRC that a defect existed in a Power Range Detector that was shipped to Palisades Nuclear Power Plant, as noted in an evaluation documented in a March 24, 2015, letter. This notification is required by 10 CFR 21.21 when information reasonably indicates a defect affected a basic component that was supplied to a 10 CFR Part 50 licensed facility within the United States.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC

review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

During this inspection, NRC inspectors also found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, TFS failed to ensure that K-type thermocouple measuring devices were identified with a serial number and calibrated at periodic intervals to maintain accuracy within necessary limits. The finding and references to the pertinent requirements are identified in the enclosures to this letter.

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

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 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 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).

Sincerely,

/RA/

Richard A. Rasmussen, Chief
Electrical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901460

Enclosures:

1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901460/2015-201

review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

During this inspection, NRC inspectors also found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, TFS failed to ensure that K-type thermocouple measuring devices were identified with a serial number and calibrated at periodic intervals to maintain accuracy within necessary limits. The finding and references to the pertinent requirements are identified in the enclosures to this letter.

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Sincerely,

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Richard A. Rasmussen, Chief
Electrical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
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1. Notice of Violation
2. Notice of Nonconformance
3. Inspection Report 99901460/2015-201

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See next page.

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NAME	EHuang	TFrye	RRasmussen
DATE	07/06/2015	07/08/2015	07/16/2015

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Letter to William Flick from Richard Rasmussen dated July 16, 2015

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION OF
THERMO FISHER SCIENTIFIC REPORT NO. 99901460/2015-201, NOTICE
OF VIOLATION AND NOTICE OF NONCONFORMANCE

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NOTICE OF VIOLATION

Thermo Fisher Scientific
10010 Mesa Rim Rd.
San Diego, CA 92121

Docket No.: 99901460
Report Number: 2015-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Thermo Fisher Scientific (TFS) facility in San Diego, CA on June 1, 2015, through June 5, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21, "Notification of failure to comply or existence of a defect and its evaluation," Section (d)(1) states, in part, that "A director or responsible officer subject to the regulations of this part or a person designated under Section 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting a basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to licensing under part 50." Section (d)(3)(i) requires an initial NRC notification by facsimile or telephone within two days and section (d)(3)(ii) requires a written NRC notification within 30 days following receipt of the information by the director or responsible officer.

TFS Quality Procedure 2.06.003, "Reporting of Defects and Noncompliance as required by 10CFR21," Revision K, dated April 2, 2014, section 5.3.2 states, in part, that "If it is determined that the deviation constitutes a defect, and the Nuclear Regulatory Commission has not been notified in writing, he/she shall notify the NRC. The initial notification shall be made within two days following the determination of the reportability." In addition, section 5.4.1 states, in part, that "A written report to the NRC, at the address shown in 10CFR21, must follow within thirty days of determination of reportability or failure to comply."

Contrary to the above, as of June 5, 2015, TFS failed to notify the NRC within both the initial two day and written 30 day time periods that a defect existed in a Power Range Detector (Part No. 201872-101, Serial No. 006) that was shipped to Palisades Nuclear Power Plant. The defect was documented in an evaluation dated March 24, 2015, and was conducted in response to written notification from a sub-supplier, Mirion Technologies IST, that an uncompensated ion chamber (PO No. M50426) used in the Power Range Detector had a potential defect and could fail under certain conditions.

This issue has been identified as Violation 99901460/2015-201-01.

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

Pursuant to the provisions of 10 CFR 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 20555-001 with a copy to the Chief, Electrical Vendor Inspection Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (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 previously docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to 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, and 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, 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 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). 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."

Dated this 16th day of July 2015.

NOTICE OF NONCONFORMANCE

Thermo Fisher Scientific
10010 Mesa Rim Rd.
San Diego, CA 92121

Docket No.: 99901460
Report Number: 2015-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted at Thermo Fisher Scientific (TFS) facility in San Diego, CA on June 1, 2015, through June 5, 2015, certain activities were not conducted in accordance with NRC requirements which were contractually imposed on TFS by NRC licensees:

- A. Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

Section 12 of the TFS QA program manual, "Control of Measuring and Test Equipment," section 3.1 states, "All inspection and test equipment used for acceptance of deliverable products are identified by a serial number and calibrated at periodic intervals to assure that the degree of required accuracy is maintained."

Contrary to the above, TFS failed 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 safety-related mineral insulated cable were not identified with a serial number and were never calibrated. The calibration was required to ensure that potential offset/drift tolerance were accounted for during temperature measurements which verified that mineral insulated cable reached the required temperature during production.

This issue has been identified as Nonconformance 99901460/2015-201-02.

Please provide 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, Electrical Vendor Inspection Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliance; and (4) the date when your corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Enclosure 2

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 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 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 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."

Dated this the 16th day of July 2015.

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT**

Docket No.: 99901460

Report No.: 99901460/2015-201

Vendor: Thermo Fisher Scientific (TFS)
10010 Mesa Rim Rd.
San Diego, CA 92121

Vendor Contact: Mr. William Flick, Quality Manager
William.Flick@thermofisher.com
(858) 882-1327

Nuclear Industry Activity: TFS provides safety-related components and services for operating power plants and the Watts Bar Unit 2 completion project under TFS and Gamma-Metrics brandnames. TFS primarily conducts commercial-grade dedication, assembly, testing and equipment qualification of excore flux monitoring systems.

Inspection Dates: June 1, 2015 - June 5, 2015

Inspectors: George Lipscomb NRC/NRO/DCIP/EVIB
Eugene Huang NRC/NRO/DCIP/EVIB
Brent Clarke NRC/NRO/DCIP/MVIB
Carl Jones NRC/R-II/DCI/CIB1
Su-Cheol Moon KINS - Observer
In Hyoung Booh KINS - Observer

Approved by: Richard A. Rasmussen, Chief
Electrical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

EXECUTIVE SUMMARY

Thermo Fisher Scientific
99901460/2015-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection under the Multinational Design Evaluation Programme (MDEP) protocol Vendor Inspection Cooperation Working Group (VICWG)-01 at the Thermo Fisher Scientific (TFS) facility in San Diego, California. Using the MDEP protocol, the NRC inspection team was observed by inspectors from the Korea Institute of Nuclear Safety (KINS). The purpose of this limited-scope inspection was to verify that TFS 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."

This technically-focused inspection evaluated TFS's implementation of quality activities associated with the fabrication and testing of safety-related excore neutron flux monitoring systems supplied to U.S. operating reactor plants and the Watts Bar Unit 2 completion project. In addition to observing these activities, the NRC inspection team evaluated test control and its effect on component qualification, design control, receipt and in-process inspections, commercial-grade dedication (CGD), problem resolution and reporting, and control of measuring and test equipment (M&TE).

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 Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors"; IP 43004, "Inspection of Commercial-Grade Dedication Programs"; and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance."

The information below summarizes the results of this inspection.

10 CFR Part 21 Program

The NRC inspection team issued Violation 99901460/2015-201-01 in association with TFS's failure to implement the regulatory requirements of 10 CFR Part 21. Specifically, TFS failed to 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 (Palisades Nuclear Power Plant). This notification is required by 10 CFR 21.21 when information reasonably indicates a defect affected a basic component that was supplied to a 10 CFR Part 50 licensed facility within the United States.

Test Control and Control of Measuring and Test Equipment (M&TE)

The NRC inspection team determined that TFS implemented adequate test control, but did not adequately implement the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901460/2015-201-02 in association with 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.

Commercial Grade Dedication and Receipt Inspection

The NRC inspection team concluded that TFS has established a program to control CGD and receipt inspection activities in accordance with the regulatory requirements of Criterion III, "Design Control," and Criterion VII, "Control of Purchased Materials, Equipment, and Services," of Appendix B to 10 CFR Part 50, which are supported by the CGD definitions in 10 CFR Part 21. Based on the limited sample of activities observed and documents reviewed, the inspectors also determined that TFS is implementing its policies and procedures associated with CGD and receipt inspection. No findings of significance were identified.

Design Control and Qualification

The NRC inspection team determined that TFS implemented adequate controls for design, including changes to design, of the neutron flux monitoring systems supplied to Tennessee Valley Authority (TVA) and McGuire Nuclear Station. Design controls effectively incorporated the requirements of Criterion III of Appendix B to 10 CFR Part 50. No findings of significance were identified.

Manufacturing Control

The NRC inspection team concluded that TFS has established a program to control manufacturing and inspection activities in accordance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," Criterion IX, "Special Processes," and Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. Based on the limited sample of activities observed and documents reviewed, the inspectors also determined that TFS is implementing its policies and procedures associated with manufacturing and in-process inspection. No findings of significance were identified.

Nonconformance Control and Corrective Action Program

The NRC inspection team concluded that TFS established nonconformance and corrective action programs in accordance with the regulatory requirements of Criterion XV, "Nonconforming Material, Parts and Components," and Criterion XVI, "Corrective Action," 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 its nonconformance and corrective action programs. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed TFS policies and implementing procedures that govern the facility's compliance with the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of TFS purchase orders (POs) 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 verified the content of TFS's 10 CFR Part 21 posting, as well as the location of the posting. 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 attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team identified that TFS failed to notify the NRC of a defect in a shipped basic component. In a letter titled, "Notification of Potential Defect Under the Atomic Energy Act of 1954 and 10 CFR Part 21," dated March 3, 2015, Mirion Technologies IST informed TFS of a potential defect in an uncompensated ion chamber shipped to TFS under PO No. M50426, dated January 23, 2014. TFS opened Corrective Action Request (CAR) 15-006 to evaluate the condition and documented on March 5, 2015, that TFS had used the uncompensated ion chamber in a Power Range Detector (Part No. 201872-101, Serial No. (S/N) 006) that was shipped to Palisades Nuclear Power Plant on December 15, 2014, in accordance with Entergy PO No. 10400128.

On March 24, 2015, TFS sent a letter to Mirion Technologies IST stating that the uncompensated ion chamber was used in the Power Range Detector and encouraged Mirion Technologies IST to provide a 10 CFR Part 21 notification to Palisades Nuclear Power Plant. However, this is contrary to 10 CFR Part 21.21(d)(1), which required TFS to notify the NRC of a defect in a basic component that they supplied to the licensee. As of June 2, 2015, there was no objective evidence that the NRC or Palisades Nuclear Power Plant were ever informed of this defect. This issue is identified as Violation 99901460/2015-201-01.

c. Conclusions

The NRC inspection team issued Violation 99901460/2015-201-01 in association with TFS's failure to implement the regulatory requirements of 10 CFR Part 21. Specifically, TFS failed to notify the NRC when they had information reasonably indicating a defect in a basic component (Power Range Detector, Part No. 201872-101, S/N 006) supplied to a licensee in the United States (Palisades Nuclear Power Plant).

2. Test Control and Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed the TFS policies and implementing procedures that govern test control and control of M&TE. The NRC inspection team observed a Test Department Production Meeting and the final testing of five safety-related Dual Bistable Trip printed circuit cards for Salem Nuclear Power Plant, and then verified the calibration of all M&TE used in that test. Further, the NRC inspection team verified that M&TE was traceable to national standards and that out-of-calibration M&TE was segregated to prevent inadvertent use.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

During review of M&TE, the NRC inspection team noted that TFS used digital thermometers to verify the temperature of an oven that was used to heat mineral insulated cable used in safety-related applications to a required 200°C. The digital thermometers were sent to Simco commercial calibration lab to be calibrated on a routine basis. However, it was discovered that the thermocouples used in conjunction with the digital thermometers were not identified by a serial number and were never calibrated. Additionally, there was no evaluation or justification of allowable tolerances for the thermocouples to ensure that offset and drift were accounted for in the temperature range that the ovens were required to meet. The NRC inspection team identified 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 as Nonconformance 99901460/2015-201-02.

c. Conclusions

The NRC inspection team determined that TFS implemented adequate test controls, but did not adequately implement the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team issued Nonconformance 99901460/2015-201-02 in association with 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 by a serial number and were never calibrated.

3. Commercial Grade Dedication and Receipt Inspection

a. Inspection Scope

The NRC inspection team reviewed TFS's CGD and receipt inspection policies and procedures to verify compliance with Criterion III, "Design Control," of Appendix B to 10 CFR Part 50, which is supported by the CGD definitions in 10 CFR Part 21, and Criterion VII, "Control of Purchased Materials, Equipment, and Services." In addition, the inspectors reviewed a sample of dedication activities associated with qualification packages to verify implementation and witnessed receipt and testing inspections in relation to a radio frequency (RF) choke subcomponent. The sample of completed documentation included drawings, determination of critical characteristics, technical evaluations, and selection of methods of acceptance.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that TFS has established a program to control CGD and receipt inspection activities in accordance with the regulatory requirements of Criterion III and Criterion VII, of Appendix B to 10 CFR Part 50. Based on the limited sample of activities observed and documents reviewed, the inspectors also determined that TFS is implementing its policies and procedures associated with CGD and receipt inspection. No findings of significance were identified.

4. Design Control and Qualification

a. Inspection Scope

The NRC inspection team used a top-down approach to evaluate control of customer requirements and implementation of design control. The inspection included a review of documents and records which showed the incorporation of customer requirements. The requirements were related to fabrication of neutron flux monitoring systems for delivery to TVA's Watts Bar Unit 2 and Duke Energy's McGuire Nuclear Station. The reviews, along with interviews with responsible engineering and QA personnel, were conducted to determine whether safety-related customer and regulatory requirements were incorporated into system drawings, specifications, and test plans. TFS's quality program procedures and records of changes to design were reviewed to determine whether safety-related design characteristics of the flux monitoring system were adequately maintained. The review included an evaluation of the use of document change notices (DCNs) for controlling and documenting the design changes.

Component designs reviewed included fission chamber detectors, interconnecting cables, local wide range amplifiers, an optical signal isolator/splitter, source range and intermediate range signal processors, a shutdown margin monitor, and an Appendix R wide range signal processor.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

The NRC inspection team determined that TFS implemented adequate controls for design, including changes to design, of the neutron flux monitoring systems supplied to TVA and McGuire. Design controls effectively incorporated the requirements of Criterion III of Appendix B to 10 CFR Part 50. No findings of significance were identified.

5. Manufacturing Control

a. Inspection Scope

The NRC inspection team reviewed policies and procedures associated with a selection of manufacturing control processes and observed a sample of critical equipment manufacturing and inspection activities to ensure proper implementation of requirements. Specifically, the inspectors discussed the assembly and inspection processes with TFS staff, observed daily operations meetings, and assessed on-going quality effecting activities for fabrication of nuclear instrumentation systems (NIS) and sub-components as follows:

- Pulse Buffer S/N 379 assembly under PSEG PO 4500823439 for a NIS upgrade for Salem Nuclear Generating Station Units 1 and 2
- Quality Control (QC) -1 inspection for Pulse Buffer S/N 379 for Salem Units 1 and 2
- Quad Isolator Printed Circuit S/N 241 and 242 assembly under Work Order (W/O) 37355 for St. Lucie Nuclear Generating Station
- Bi-stable Trip Printed Circuit S/N 235 and 236 assembly under W/O 37134 for stock

The inspectors also assessed training and qualification of manufacturing and inspection personnel, adherence to soldering special process requirements, and reviewed a sample of completed documentation from various portions of the manufacturing process to verify adherence to established procedures.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that TFS has established a program to control manufacturing and inspection activities in accordance with the regulatory requirements of Criterion V, "Instructions, Procedures, and Drawings," Criterion IX, "Special Processes," and Criterion X, "Inspection," of Appendix B to 10 CFR Part 50. Based on the limited sample of activities observed and documents reviewed, the inspectors also determined that TFS is implementing its policies and procedures associated with manufacturing and in-process inspection. No findings of significance were identified.

6. Nonconformance Control and Corrective Action Program

a. Inspection Scope

The NRC inspection team reviewed TFS policies and implementing procedures that govern the nonconformance and corrective action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Material, Parts and Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The inspectors discussed the nonconformance and corrective action programs with TFS staff and reviewed a sample of Discrepancy Reports (DRs), Return Material Evaluations (RMEs), and CARs for appropriate disposition. The DR sample included discrepancies associated with detector cables, power supplies, multiplexers, integrated circuits, and insulators. The RME sample included a mixture of customer and TFS field technician returned detectors and printed circuit assemblies. The CAR sample included actions associated with customer returns, internal audit findings, calibration, and fabrication.

The NRC inspection team also observed a Material Review Board (MRB) for open DRs, CARs and Quality Issues (QIs), and evaluated segregation of nonconforming parts. In addition, the inspectors verified that returned material dispositions were evaluated for corrective actions, if appropriate, and that the corrective action program provided a connection to the 10 CFR Part 21 program.

The attachment to this inspection report lists the individuals interviewed and documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that TFS established nonconformance 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 its nonconformance and corrective action programs. No findings of significance were identified.

7. Entrance and Exit Meetings

On June 1, 2015, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mr. Robert Barnes, Technical Support Manager, and other members of TFS management and technical staff. On June 5, 2015, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Robert Barnes, Technical Support Manager, and other members of TFS management and technical staff. The attachment to this report lists the attendees at 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
Robert Barnes	Technical Support Manager	TFS	X	X	X
William Flick	QA Manager	TFS	X	X	X
Leigh DeHuff	Quality Assurance Consultant	TFS	X	X	X
Ryan Bastrom	Lead Test Technician	TFS	X		X
Jeff Tuetken	Senior Engineer	TFS		X	X
Christopher Thompson	Test Technician	TFS			X
Michael Jackson	Operations Manager	TFS			X
Lisa Elliott	Inspector	TFS			X
Maria Cosio	Electrical Assembler	TFS			X
Levi Parsell	Electrical Engineer	TFS			X
Dan Miller	Senior Field Services Engineer	TFS			X
Patricia Kohler	Electrical Assembler	TFS			X
Dan Gaskill	Electrical Engineer	TFS			X
T. Cadrillono	Quality Control Inspector	TFS			X
P. Hale	Field Service Engineer	TFS			X
Jericho Ore	Electrical Assembler	TFS			X
Katherine Foster	Project Manager	TFS	X	X	
George Lipscomb	Lead Inspector	NRC	X	X	

Carl Jones	Inspector	NRC	X	X	
Brent Clarke	Inspector	NRC	X	X	
Eugene Huang	Inspector	NRC	X	X	
Richard Rasmussen	Observer	NRC		X	
In Hyoung Booh	Observer	KINS	X	X	
Su Cheol Moon	Observer	KINS	X	X	

2. INSPECTION PROCEDURES USED

IP 43002, "Routine Inspections of Nuclear Vendors"

IP 43004, "Inspection of Commercial-Grade Dedication Programs"

IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance"

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>ITAAC</u>	<u>Description</u>
99901460/2012-201-01	Opened	NOV	N/A	Part 21
99901460/2012-201-02	Opened	NON	N/A	App. B, Criterion XII

4. LIST OF ACRONYMS USED

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
CAR	corrective action request
CGD	commercial-grade-dedication
DCN	document change notice
DR	discrepancy report
IP	inspection procedure
MDEP	Multinational Design Evaluation Programme
MRB	Material Review Board
M&TE	measuring and test equipment
NIS	nuclear instrumentation system
NON	Notice of Nonconformance
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
PN	part number
PO	purchase order
QA	quality assurance
QC	quality control
QI	quality issue
QP	quality procedure
QTR	qualification test report
RAIL	rolling action item list
RF	radio frequency
RME	return material evaluation
S/N	serial number
TFS	Thermo Fisher Scientific
TVA	Tennessee Valley Authority
VICWG	Vendor Inspection Cooperation Working Group
W/O	work order

5. DOCUMENTS REVIEWED

Procedures

“TFS Scientific Quality Assurance Program Manual,” Revision 21, dated December 15, 2014

QP 2.01.004, “Corrective Action,” Revision L, dated January 6, 2015

QP 2.02.001, “Training Plan,” Revision AB, dated February 2, 2015

QP 2.02.002, “Qualification of Inspection, Quality Engineering, Test, & Field Service Personnel,” Revision H, dated February 10, 2012

QP 2.03.001, “Workmanship Standards Procedure,” Revision D, dated April 29, 2014

QP 2.03.002, "Control of Special Processes," Revision C, dated November 26, 2014

QP 2.03.004, "Control and Calibration of Measuring and Test Equipment," Revision M, dated November 6, 2013

QP 2.03.005, "Inspection Plan," Revision K, dated February 3, 2015

QP 2.04.001, "Selection of Suppliers," Revision L, dated January 16, 2013

QP 2.06.001, "Control of Nonconforming Material," Revision U, dated February 3, 2015

QP 2.06.002, "Stop Work Order," Revision D, dated March 1, 2007

QP 2.06.004, "Control of Quality Issues," Revision 0, dated September 14, 2011

QP 2.07.002, "Safety-Related Supplier Audits," Revision H, dated January 19, 2012

QP 3.01.001, "Test Plan," Revision D, dated May 30, 2012

QP 3.01.002, "Test Operations," Revision D, dated October 31, 2013

QP 4.03.003, "Processing Field Returned Material," Revision F, dated February 20, 2013

QP 4.01.001, "Processing Purchase Orders," Revision L, dated November 19, 2012

QP 4.04.003, "Handling and Storing Sensitive Parts and Assemblies," Revision I, dated October 31, 2013

QP 5.01.001, "Serialization of Company Products," Revision C, dated March 7, 2007

QP 5.01.002, "Cleanliness of Product," Revision B, dated January 27, 2015

QP 5.01.003, "Manufacturing Operations," Revision A, dated September 1, 2009

QP 6.01.004, "Critical Characteristics for Parts Used in Safety-Related Systems," Revision J, dated April 29, 2015

QP 6.03.002, "Preparation of Engineering Specifications," Revision 0, dated January 31, 2014

QP 6.03.003, "Preparation of Test Plans," Revision 0, dated January 31, 2014

QP 6.04.002, "Document Change Notice," Revision F, dated February 3, 2015

QP 6.04.004, "Deviation Authorization," Revision E, dated June 2, 2009

QP 6.05.001, "Qualification of Class 1E Equipment," Revision F, dated July 22, 2014

QP 6.05.005, "Development And Control of Safety-Related Software," Revision F, dated February 3, 2015

QP 6.05.006, "Design Control," Revision B, dated February 3, 2015

QP 7.01.001, "Customer Contract and Purchase Order Review," Revision J, dated January 16, 2015

Procurement and Receiving Documents

TFS PO No. B63259 to Simco Electronics for calibration services, Revision 0, dated February 4, 2015

TFS PO No. M50426 to Mirion Technologies IST for Uncompensated Ion Chamber, dated January 23, 2014

TFS document, "Additional Purchase Order Requirements," dated January 17, 2013

PSEG PO 4500823439 to TFS for Excore Nuclear Instrumentation System (NIS) upgrade, Revision 2, dated December 23, 2014

RME 858 for Vogtle, "Part No. 100012-104, Serial No. 578," dated November 16, 2012

Certificate of Conformance, "Georgia Power Company PO No. SNG10045810," dated November 16, 2012

RME 820 for Catawba, "Part No. 101819-101 Rev B, Serial No. 015 and Part No. 100852-101 Rev E, Serial No. 060," dated October 18, 2011

Certificate of Conformance, "Duke Energy PO No. 00151262," dated November 8, 2011

RME 926 for McGuire, "Part No. 900519-101, Serial No. 004," dated August 19, 2014

Certificate of Conformance, "Duke Energy PO No. 00188943," dated August 26, 2014

RME 806 for Catawba, "Part No. 900528-101, Serial No. 002," dated October 11, 2011

Certificate of Conformance, "Duke Energy PO No. 0049659," dated December 20, 2011

RME 887 for Shin-Kori 3, "Part No. 101885-102, Serial No. 030," dated August 22, 2013

Certificate of Conformance, "Korea Hydro and Nuclear Power PO No. 2008001978," dated August 29, 2013

Certificate of Conformance, "Entergy PO No. 26175," dated December 12, 2014

Receiving inspection record for part no. 202770-001 for insert RF choke, dated June 3, 2015

Bill of Lading from Con-way Freight for PO No. 10400128, dated December 15, 2014

Certificate of Conformance, from TFS to Entergy, for PO No. 26175, dated December 12, 2014

TVA Purchase Order 75148, "Neutron Flux Monitoring System, Watts Bar Unit 2," Revision 2, dated February 10, 2009

TVA Procurement Data Sheet CNY156J, "Detector for Ex-Core Neutron Flux Monitoring System with 1128 Feet of Integral Cable," Revision 3, dated April 13, 2009

TVA Procurement Data Sheet CNY181K, "Wide Range Amplifier for Ex-Core Neutron Flux Monitoring Instrumentation," Revision 2, dated April 13, 2009

Excerpt from TVA Requisition 25402•Q11-MRA-JA37-00001, Revision 2, dated January 29, 2009

PO 00172315, dated May 22, 2013

Approved Supplier List, Revision 27 (current)

Drawings and Design Documents

Drawing No. 040423, "Test Procedure, Dual Bistable Trip," Revision W, dated August 12, 2014

Drawing No. 100660, "PC Assembly Bistable Trip," Revision V, dated September 17, 2012

Drawing No. 101196, "Schematic Diagram Bistable Trip," Revision H, dated February 14, 2018

Drawing No. 102012, "Schem Diag, RCS 300 SR RMSP," Revision B, dated September 30, 2009

Drawing No. 102014, "Schem Diag, WR RMSP," Revision C, dated May 2, 2012

Drawing No. 900599, "Cust Outl, SR RMSP, Watts Bar Unit 2, Sheet 1 of 4," dated March 19, 2009

Drawing No. 900602, "Cust Outl, SDMM Watts Bar Unit 2, Sheet 1 of 4" Revision B, dated March 19, 2009

DWG 201592, "Cable assembly transition, triax," Revision D

Drawing No. 200632, "PULSE BUFFER ASSY, ISLR," Revision G, dated April 8, 1998

Drawing No. PL200632, "PULSE BUFFER ASSY, ISLR," Revision G, dated April 8, 1998

Drawing No. 100179, "SCHEM DIAG PULSE BFR, ISLR," Revision G, dated April 8, 1998

Drawing No. WL200632, "WIRE LIST, PULSE BUFFER ASSY," Revision E, dated April 17, 1998

DCN 11197, "Release of New Assemblies for Watts Bar 2 SDMM and WR RMSP," Revision 0, dated July 13, 2009

DCN 11283, "Update Watts Bar 2 Source Range Signal Processor for As Built Condition," Revision 0, dated October 12, 2009

DCN 11315, "Initial Release of Watts Bar 2 FAT Procedure; and Update SDMM for Weight and Center of Gravity," Revision 0, dated November 2, 2009

Work Orders

WO 21211, dated March 27, 2009

WO 21212, dated March 27, 2009

WO 35118, dated August 12, 2013

WO 35119, dated August 12, 2013

WO 35120, dated August 13, 2013

WO 35121, dated August 5, 2013

WO 35987, dated March 28, 2014

WO 36674, dated June 3, 2015

WO 37356, dated June 30, 2015

Manufacturing and Inspection Documents

Traveler for Work Order No. 36674, "PC Assembly Bistable Trip for Salem NPP," dated December 1, 2014

In-Process Inspection Form for Work Order No. 36674, "PC Assembly Bistable Trip for Salem NPP," Revision V, dated May 25, 2015

Parts Sheet for Assembly 100660-115, "PC Assembly Bistable Trip," Revision V, dated September 13, 2012

Document No. 020002, "Workmanship Standards," Revision G, dated May 15, 2014

Traveler PN 200632-101 for Work Order 36692 S/N 379-388, "Pulse Buffer Assy, ISLR," (in-process)

Traveler PN 900531-101 for Work Order 33383 S/N 012, "SR, RMSP, Catawba," dated June 1, 2012

Traveler PN 101033-112 for Work Order 33385 S/N 204-205 Rev N, "PC Assy, Isolator, Quad," dated May 4, 2012

Test Documentation

Test Procedure 040423, "Dual Bistable Trip," Revision W, undated

Burn-In Parameters on various RCS assemblies form for Work Order No. 36674, dated June 1, 2015

Test Equipment Used form for Burn-In for Work Order 36674, dated June 1, 2015

Test Procedure 040338, "Test procedure for hardware for connector coaxial, type N," Revision D, March 28, 2014

Test Procedure 040529, "Test procedure, log count and rate," Revision AE, undated

Test Procedure 040943, "Test Procedure, Factory Acceptance Test, Watts Bar 2," Revision A, dated March 12, 2010

Test Procedure 040952, "Test Procedure, Processor Assembly, SR RMSP," Revision 0, dated October 12, 2009

Calibration Documents

Calibration Status Log (current)

Calibration Record, "Agilent Digital Multimeter," S/N TW47410136

Calibration Record, "Mitutoyu Digital Calipers," S/N 13437836

Calibration Record, "Tenney, BTRC, Temperature/Humidity Chamber," S/N 090300034

Calibration Record, "Thermo Scientific 1.25 CR .5 MO," S/N 35JN

Certificate of Calibration from Simco Electronics, "Agilent Digital Multimeter," S/N TW47410136, dated March 11, 2015

Certificate of Calibration from Simco Electronics, "Tenney, BTRC, Temperature/Humidity Chamber," dated July 9, 2014

Certificate of Calibration from Simco Electronics, "Mitutoyo Digital Caliper," S/N 13437836, dated June 18, 2014

Certificate of Calibration from Simco Electronics, "ROD-L Hipot Tester," S/N 21294, dated June 3, 2014

Certificate of Calibration from Simco Electronics, "Megger Insulation Tester," S/N 100310/4729, dated March 9, 2015

Certificate of Conformance from Nuclear Logistics Inc., "1.25Cr/0.5 MO Standard," S/N 35JN, dated July 29, 2013

Qualification Documents

Qualification Report 864, "Class 1E Qualification of Source Range, Intermediate Range, and Wide Range Channels for Watts Bar Nuclear Station Unit II," Revision 5, dated May 2012

QTR 010, "Gamma-Metrics RCS Series Neutron Flux Monitoring System Qualification Test Report," Revision 1, dated June 2, 1983

Supplementary information for qualification report No. 010, dated January 28, 1988

QTR012, "Gamma-Metrics RCS series neutron flux monitoring system seismic test report and MSLB/LOCA test report," Revision 0, undated

QTR 828, "Class 1E Qualification of source and intermediate range channels," dated May 2011

Addendum to qualification report No. 828, Revision 2 for Class 1E qualification of 201592 cables for McGuire Nuclear Station Units 1 and 2, dated April 2014

Qualification program plan, "Source and intermediate range channel nuclear instrumentation system," dated May 2010

QTR-104, "Qualification test report for silicone rubber o-ring seal in gamma-metrics junction box," dated August 8, 1989

QTR-887, "Electromagnetic interference qualifications of source and intermediate range channels," dated May 2010

QTR-040, "Qualification of mineral insulated cable in the detector cable assembly addendum to gamma-metrics RCS series QTR-010," Revision 3, dated November 6, 1985

QTR-732, "Class 1E qualification of replacement lambda low voltage power supply," Revision 4, dated October 2002

QTR 211, "Qualification testing of junction box o-ring installed in junction box used in gamma-metrics neutron flux monitoring systems," Revision 0, dated November 10, 1994

Audit and Survey Documents

Westinghouse Audit WES-2012-309, Mirion Technologies Corporation, dated October 5, 2012

NIAC Audit report for Meggitt Safety Systems, Inc., dated October 31, 2012

AREVA Audit 526-5 of TFS Inc., dated February 7, 2014

Audit Checklist for NIAC Audit 17034, Rockbestos Suprenant Cable Corporation, dated November 12, 2012

Training and Qualification Records

Qualification Record, "Nuclear Personnel, Level I Test Technician, Christopher Thompson," dated November 21, 2014

Qualification Record, "Nuclear Personnel, Level II Test Technician, Christopher Thompson," dated June 4, 2015

Qualification Record for Maria Cosio, Assembler, "Training Record - Fabrication," dated June 2, 2015

Training Log, "TFS Packaging Requirements," dated March 4, 2015

Corrective Action Requests (CAR) / Discrepancy Report (DR)

CAR 12-015, dated April 11, 2012

CAR 12-016, "Quality Assurance Program Manual did not address requirements of NQA-1-2000," dated May 16, 2012

CAR 12-023, "Instrument failed calibration," dated June 18, 2012

CAR 12-024, "Broken test equipment," dated August 27, 2012

CAR 12-027, "Quality Assurance Program Manual and Quality Procedure do not reference tri-annual audit of safety-related suppliers," dated August 27, 2012

CAR 13-001, "Used incorrect coaxial cables," dated February 4, 2013

CAR 14-005, dated February 10, 2014

CAR 14-024, dated September 2, 2014

CAR 14-028, "Digital Multimeter T-149 was found to be inoperable," dated October 10, 2014

CAR 14-046, "Low Voltage Power Supply incorrectly qualified," dated December 8, 2014

CAR 15-002, "Printed Circuit Assembly fails a certain qualification test," dated January 22, 2015

CAR 15-005, "Mineral insulated cables received without desiccant," dated February 25, 2015

CAR 15-006, "Mirion IST notification of potential 10CFR21 condition with uncompensated ion chambers," dated March 5, 2015

CAR 15-007, "Digital Multimeter significantly out of tolerance," dated March 12, 2015

CAR 15-008, "Scale significantly out of tolerance," dated March 24, 2015

CAR 15-012, "Test results did not meet acceptance criteria," dated May 25, 2015

DR 8712, "IC, Demultiplexer," dated July 28, 2014

DR 8765, "Cable Assy, MI, .200 OD," dated October 13, 2014

DR 8485, "Insulator Polycarbonate," dated May 9, 2013

DR 8618, "IC, Hi Rel/Military," dated March 10, 2014

DR 8682, "Power Supply, High Voltage," dated June 24, 2014

CARs / Quality Issue (QI) Tracking Forms opened during the inspection

CAR 15-013, "Plug and socket pair not installed per drawing," dated June 2, 2015

CAR 15-014, "Assemblers not following QP 02.03.006," dated June 4, 2015

CAR 15-030, "Test procedure for old test equipment," dated June 5, 2015

QI Tracking Form 15-029, dated June 3, 2015

QI Tracking Form 15-030, "Test procedure 040423 lists outdated equipment," dated June 4, 2015

QI Tracking Form 15-031, "PO for Simco contains note for NU3, SIMCO does not supply NU3 services," June 4, 2015

Miscellaneous Documents

TFS Grounding Strap Log, Test Department, dated June 2015

TFS Rolling Action Item List (RAIL) for Corrective Actions (current)

TFS Outstanding Quality Issues List (current)

CAR 14-046 Meeting Minutes, dated January 22, 2015

10 CFR Part 21 Notification of Shutdown Margin Monitor Noncompliance, dated February 6, 2015

Material Review Board Evaluation for CAR 14-046, dated December 8, 2014

Letter from TFS to Entergy Operations, "Part 21 – Dual Ion Chamber," dated June 2, 2015

Letter from TFS to Mirion Technologies IST, "Notification of Safety Related Application," dated March 24, 2015

Letter from Mirion Technologies IST Corporation to TFS, "Notification of Potential Defect under the Atomic Energy Act of 1954 and 10CFR Part 21," dated March 3, 2015

Configuration Record for Palisades Generating Plant for PO No. 10400128, dated December 12, 2014

Shipment Notification to TVA Watts Bar Unit 2 for PO No. 75148, dated June 22, 2011

Shipment Notification to Palisades Generating Plant for PO No. 10400128, dated December 15, 2014

Bill of Lading from Con-way Freight for PO No. 10400128, dated December 15, 2014

Qualification Effect Checklist, "Document Number(s): 040849, Rev Ltr: H," dated July 2, 2014

Qualification Effect Checklist, "Document Number(s): 040584, Rev Ltr: H," dated July 2, 2014

McGuire spec. MCS-1346.23-00-0001, dated September 7, 1983

MCS-1346.23-00-0002, "Source and intermediate range nuclear instrumentation," dated January 20, 2011

Data sheet 000183, "Triax plugs, jacks, receptacles and caps for Amphenol standard coaxial connectors," Revision I sheet 3