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

January 8, 2020

Mr. Jacob Clos
Quality Assurance Manager
Fisher Controls International, LLC
1702 South 12th Avenue
Marshalltown, IA 50158

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF FISHER CONTROLS INTERNATIONAL, LLC NO. 99900105/2019-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Clos:

From November 4 through November 8, 2019, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an unannounced routine inspection at the Fisher Controls International, LLC's (hereafter referred to as Fisher Controls) facility in Marshalltown, IA. The purpose of this limited-scope inspection was to assess Fisher Controls' compliance with 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 Fisher Controls' implementation of the quality activities associated with the design, fabrication, assembly, and testing of valves, actuators, actuator accessories, replacement parts and/or appurtenances being supplied to the U.S. nuclear power plants. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC's endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program did not meet certain regulatory requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that Fisher Controls was not fully implementing its QA program in the area of design control. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed Notice of Nonconformance (NON), Fisher Controls should document the results of the extent of condition review for this finding and determine if there are any effects on other components. In addition, the NRC expects Fisher Controls to adequately evaluate and determine the significance the NON has on the components that had already been shipped and delivered.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. This response should document the results from Fisher Controls' evaluation on the significance of the NON as requested above. 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," the NRC will make available electronically for public inspection

a copy of this letter, its enclosure, and your response through the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response (and 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, 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 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 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."

Sincerely,

/RA/

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

Docket No.: 99900105

EPID No.: I-2019-201-0064

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99900105/2019-201
   and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF FISHER CONTROLS INTERNATIONAL, LLC'S NO. 99900105/2019-201 AND NOTICE OF NONCONFORMANCE

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NOTICE OF NONCONFORMANCE

Fisher Controls International, LLC
1702 South 12th Avenue
Marshalltown, IA 50158

Docket No. 99900105
Report No. 2019-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Fisher Controls International, LLC's (hereafter referred to as Fisher Controls) facility in Marshalltown, IA, from November 4, 2019, through November 8, 2019, Fisher Controls did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon Fisher Controls by its customers or NRC licensees:

A. Criterion III, "Design Control," 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," states, in part, that "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions for the structures, systems and components. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions."

   Contrary to the above, as of November 8, 2019, Fisher Controls failed to adequately seismically qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing to verify the adequacy of the design. Specifically, Fisher Controls certified that the 546NS electro-pneumatic transducers met the requirements of the 1975 and 1987 Editions of the Institute of Electrical and Electronics Engineers (IEEE) standard No. 344, "IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations." However, the NRC inspection team determined that Fisher Controls failed to performed the operating basis earthquake and safe shutdown earthquake testing as required by IEEE 344-1975/1987 to demonstrate the 546NS electro-pneumatic transducers can withstand the effects of earthquakes without the loss of their capability to perform their intended safety function during and after a design basis seismic event.

   This issue has been identified as Nonconformance 99900105/2019-201-01.

B. Criterion III of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions for the structures, systems and components. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions."

   Contrary to the above, as of November 8, 2019, Fisher Controls failed to adequately environmentally qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing under the most adverse design conditions to verify the adequacy of the design. Specifically, Fisher Controls failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations":

1. Test the electro-pneumatic transducers in a configuration similar to how it would be used once installed in a system.

2. Demonstrate that qualification testing was performed with service conditions and equipment specification considering a 10-50mA direct current design input.

3. Justify the selection methodology of the activation energies used in the thermal aging analysis/calculations to ensure the most conservative activation energies were used for establishing a qualified life.

4. Identify and evaluate the required maintenance during the aging portion of the qualification testing for the relay and feedback bellows replacement.

5. Adequately calibrate the test specimen prior to baseline testing.

6. Evaluate how eight test anomalies affected the qualification of the electro-pneumatic transducers.

This issue has been identified as Nonconformance 99900105/2019-201-02.

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, 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 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 and the results achieved; (3) the corrective steps that will be to avoid further noncompliance; and (4) the date when the corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

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’s 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, your response should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the NRC 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 8th day of January 2020.

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

Docket No.:	99900105
Report No.:	99900105/2019-201
Vendor:	Fisher Controls International, LLC 1702 South 12th Avenue Marshalltown, IA 50158
Vendor Contact:	Mr. Jacob Clos Quality Assurance Manager Email: Jacob.Clos@Emerson.com Phone: 641-754-2108
Nuclear Industry Activity:	Fisher Controls International, LLC, (hereafter referred to as Fisher Controls) is an American Society of Mechanical Engineers (ASME) N (nuclear components) and NPT (nuclear parts) Certificate Holder. Fisher Controls' scope of supply for the U.S. nuclear power plants includes design, fabrication, maintenance, repair, and replacement of ASME and non-ASME control valves; including spare/replacement parts, components, associated engineering, and field services.
Inspection Dates:	November 4 - 8, 2019

Inspectors:		
Yamir Diaz-Castillo	NRR/DRO/IQVB	Team Leader
Andrea Keim	NRR/DRO/IQVB	
Raju Patel	NRR/DRO/IQVB	
Nicholas Savwoir	NRR/DRO/IQVB	

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

EXECUTIVE SUMMARY

Fisher Controls International, LLC
99900105/2019-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted an unannounced routine vendor inspection at the Fisher Controls International, LLC's (hereafter referred to as Fisher Controls) facility in Marshalltown, IA, 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." In addition, the NRC inspection team verified that Fisher Controls had implemented a program in accordance with the applicable requirements of Section III, "Rules for Construction of Nuclear Facility Components," Section V, "Nondestructive Examination," and Section IX, "Welding, Brazing, and Fusing Qualifications," of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code. The NRC inspection team conducted this inspection on November 4 - 8, 2019. This was the third NRC inspection at the Fisher Controls facility in Marshalltown, IA.

This technically-focused inspection specifically evaluated Fisher Controls' implementation of quality activities associated with the design, fabrication, assembly, and testing of ASME and non-ASME valves, actuators, actuator accessories, replacement parts and/or appurtenances being supplied to the U.S. nuclear power plants.

These 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," dated January 27, 2017, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017, and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

With the exception of nonconformances described below, the NRC inspection team concluded that Fisher Controls' QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that Fisher Controls' personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program. The NRC inspection team: (1) reviewed the 10 CFR Part 21 postings; (2) reviewed a sample of purchase orders (POs); and (3) verified that Fisher Controls' nonconformance and corrective action programs provide a link to the 10 CFR Part 21 program. No findings of significance were identified.

Design Control

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 and with the applicable requirements of Subsection NCA, "General Requirements for Division 1 and Division 2," Subsection NB, "Class 1 Components," Subsection NC, "Class 2 Components," and Subsection ND, "Class 3 Components," of Section III of the ASME B&PV Code. The NRC inspection team reviewed a sample of four design reports for valves and confirmed that the design and procurement specifications were properly translated into Fisher Controls' specification sheets, drawings, procedures, and engineering calculations. The NRC inspection team also reviewed Fisher Controls' software validation and verification process for the ANSYS Finite Analysis software and confirmed that it was adequately verified and validated prior to its use and installation. The NRC inspection team identified two nonconformances associated with Fisher Controls' implementation of its design control program.

Nonconformance 99900105/2019-201-01 was issued for Fisher Controls' failure to adequately seismically qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing to verify the adequacy of the design. Fisher Controls only performed vibration testing of the electro-pneumatic transducers and did not perform the operating basis earthquake and safe shutdown earthquake testing as required by the 1975 and 1987 IEEE standard No. 344, "IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations." Fisher Controls initiated CAR No. 1896 to address this issue.

Nonconformance 99900105/2019-201-02 was issued for Fisher Controls' failure to adequately environmentally qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing under the most adverse design conditions to verify the adequacy of the design. Fisher Controls did not: (1) test the electro-pneumatic transducers in a configuration similar to how they are used once installed in a nuclear power plant; (2) show that qualification testing was performed considering a 10 to 50mA direct current design input; (3) justify the selection of the activation energies to ensure the most conservative energies were used; (4) identify and evaluate the required maintenance during the aging portion of the qualification testing; (5) adequately calibrate the test specimen prior to baseline testing; and (6) evaluate eight test anomalies, in accordance with the requirements of the IEEE No. 323-1983, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations." Fisher Controls initiated CAR No. 1896 to address this issue.

The NRC inspection team identified that the 546NS electro-pneumatic transducers were also supplied to Point Beach Nuclear Plant, Seabrook Station, Indian Point Nuclear Generating Station, Turkey Point Nuclear Generating Station, Calvert Cliffs Nuclear Power Plant, Watts Bar Nuclear Plant, Comanche Peak Nuclear Power Plant, and Nine Mile Point Nuclear Station.

Commercial-Grade Dedication

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its commercial-grade dedication program to verify compliance with the requirements of Criterion III and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of commercial-grade dedication packages to verify that the commercial-grade dedication process was being adequately implemented. The NRC inspection team also reviewed a sample

of commercial-grade surveys and verified they contained the objective evidence necessary to demonstrate adequate control of the critical characteristics. The NRC inspection team identified one minor issue associated with Fisher Controls' implementation of its commercial-grade dedication program.

During the review of a sample of commercial-grade dedication packages for material testing services, the NRC inspection team noted that Fisher Controls did not identify training and qualification of personnel and control of measuring and test equipment (M&TE) as critical characteristics in the technical evaluation for material testing services. The NRC inspection team determined this issue to be minor because Fisher Controls did verify these critical characteristics as part of the commercial-grade surveys performed of the material testing suppliers. Fisher Controls initiated CAR No. 1894 to address this issue.

Supplier Oversight

The NRC inspection team reviewed Fisher Controls' 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 of Appendix B to 10 CFR Part 50. The NRC inspection team also reviewed a sample of POs and external audit reports of suppliers and material suppliers qualified as Material Organizations in accordance with the requirements of NCA-3842.2, "Evaluation of the Qualified Material Organization's Program by Certified Material Organizations of Certificate Holders," of Subsection NCA of Section III of the ASME B&PV Code. The NRC inspection team confirmed that the POs contained the applicable technical and regulatory requirements and that the external audits were performed by qualified individuals using checklists and/or procedures, and that these checklists and/or procedures included an audit plan, documented objective evidence, audit results, and a review of audit results by responsible management. No findings of significance were identified.

Material Identification and Traceability

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its material identification and traceability program to verify compliance with the regulatory requirements of Criterion VIII, "Identification and Control of Material, Parts, and Components," of Appendix B to 10 CFR Part 50. The NRC inspection team performed a walk-down of the following areas at Fisher Controls' facility: receipt inspection, fabrication and storage, M&TE, and nonconformances storage. The NRC inspection team confirmed that materials were adequately identified with Fisher Controls' unique identification code, traceable to Fisher Controls' POs and vendor certification reports. The NRC inspection team confirmed that only specified and accepted items are used, and that markings are applied using materials and methods that provide a clear and legible identification and do not adversely affect the function or service life of the item. No findings of significance were identified.

Manufacturing Control

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of it manufacturing control program to verify compliance with the regulatory requirements of Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50, as well as Section V and Section IX of the ASME B&PV Code. The NRC inspection team also reviewed a sample of weld procedure specifications, procedure qualification reports, and liquid penetrant testing reports. In addition, the NRC inspection team

reviewed Fisher Controls' procedures for the certification and qualification of non-destructive testing personnel and confirmed they were consistent with the latest revision of the American Society for Nondestructive Testing Recommended Practice SNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing," and Section III of the ASME B&PV Code. Furthermore, the NRC inspection team reviewed a sample of welders' performance qualification records and confirmed they were consistent with the requirements of Section III and Section IX of ASME B&PV Code.

The NRC inspection team performed a walk-down of the weld filler material storage and weld filler material issue areas and verified that welding material was adequately controlled to prevent degradation, inadvertent use, or loss of traceability. The NRC inspection team confirmed that covered weld electrodes were kept in ovens held at specified temperatures to control moisture, as applicable, in accordance with the requirements of Section IX of the ASME B&PV Code. No findings of significance were identified.

Test Control

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its test control program to verify compliance with the requirements of Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of test reports for four valve data packages and confirmed that applicable customer specifications were correctly translated into production orders and test procedures. The NRC inspection team confirmed the tests were performed in accordance with Fisher Controls' test procedures by qualified test personnel using calibrated M&TE, and that the test was independently verified by a Quality Control inspector. The NRC inspection team identified one minor issue associated with Fisher Controls' implementation of its test control program.

During the review of a sample of test reports for deionized water used for hydrostatic testing of valves, the NRC inspection team noted that the water conductivity value exceeded the acceptance criteria from Fisher Controls' procedure No. 12B3, "Deionized Water - Testing and Control in compliance with NQA-1-1994 and ASME N45.2.1-1980," Revision 8, dated April 29, 2013. The NRC inspection team determined this issue to be minor because Fisher Controls did not use this water for the hydrostatic testing of any safety-related valves. Fisher Controls initiated CAR No. 1893 to address this issue.

Control of Measuring and Test Equipment

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its control of 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 observed that M&TE was calibrated, labeled, tagged, handled, stored, or otherwise controlled to indicate the calibration status and its traceability to nationally recognized standards. In addition, the NRC inspection team confirmed that when M&TE is found to be out of calibration, Fisher Controls initiates a nonconformance report and performs an evaluation to determine the extent of condition. No findings of significance were identified.

Nonconforming Material, Parts, or Components and Corrective Action

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its nonconforming materials, parts or components and corrective

action programs to verify compliance with the regulatory 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 reviewed a sample of nonconformance reports and confirmed that they were adequately documented, reviewed, tracked, and dispositioned. The NRC inspection team also reviewed a sample of CARs and confirmed that they were adequately reviewed, implemented, and approved by appropriate personnel in a timely manner. No findings of significance were identified.

The NRC inspection team reviewed the corrective actions taken by Fisher Controls to address Notice of Nonconformance (NON) 99900105/2015-201-01, documented in NRC Inspection Report No. 99900105/2015-201, dated May 22, 2015 (Agencywide Documents Access and Management System Accession No. ML15134A432). The NRC inspection team reviewed the documentation that provided objective evidence that all corrective actions were completed and adequately implemented. Based on this review and interviews with Fisher Controls' staff, the NRC inspection team closed NON 99900105/2015-201-01.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The NRC inspection team reviewed Fisher Controls International, LLC's (hereafter referred to as Fisher Controls) 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. The NRC inspection team also evaluated the 10 CFR Part 21 postings and a sample of Fisher Controls' 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." In addition, the NRC inspection team also verified that Fisher Controls' nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. Furthermore, for a sample of 10 CFR Part 21 evaluations performed by Fisher Controls, the NRC inspection team verified that Fisher Controls had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, as applicable.

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

   b. Observations and Findings

   No findings of significance were identified.

   c. Conclusion

   The NRC inspection team concluded that Fisher Controls is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Fisher Controls is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

   a. Inspection Scope

   The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 "Domestic Licensing of Production and Utilization Facilities," and with the applicable requirements of Subsection NCA, "General Requirements for Division 1 and Division 2," Subsection NB, "Class 1 Components," Subsection NC, "Class 2 Components," and Subsection ND, "Class 3 Components," of

Section III, “Rules for Construction of Nuclear Facility Components,” of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code.

The NRC inspection team reviewed a sample of four design reports for safety-related valves shipped to domestic nuclear power plants and confirmed that the design requirements specified by the customer POs were adequately translated into the design specifications and design drawings. The NRC inspection team also confirmed that: (1) the appropriate quality standards were specified and included in design documents; (2) independent verifications and checks were integrated into the process and were being performed; (3) required qualification tests were being performed; and (4) design changes were being effectively controlled and approved.

The NRC inspection team also reviewed Fisher Controls’ software validation and verification process for the ANSYS Finite Analysis software and confirmed that the software was adequately verified and validated prior to its use and installation. The NRC inspection team verified that each new version of the ANSYS software program was subject to verification through regression testing to previous software versions known to be acceptable, and that the calculations supported the conclusions. The validation and verification report consist of system/user interface, source code listing, description of program logic, verification documentation, input data, output data examples, installation report, program installation records, documentation file changes, project records, and independent test results. The NRC inspection team also confirmed that Fisher Controls is evaluating all incoming ANSYS software error reports for their impact on previous design analysis and calculations.

The NRC inspection team also reviewed the EQ of the 546NS electro-pneumatic transducers in response to a non-cited violation (NCV) issued to Turkey Point by the NRC as documented in an inspection report dated September 30, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19274C217). The NCV cited the licensee for their failure to verify the adequacy of the EQ testing and equipment installation methods to maintain EQ, which resulted in unqualified electro-pneumatic transducers being installed in the plant.

The NRC inspection team also discussed the design control program with Fisher Controls’ management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

Seismic Qualification of the 546NS Electro-Pneumatic Transducers

During the review of the 546NS electro-pneumatic transducers’ EQ, the NRC inspection team noted that Fisher Controls certified that the 546NS electro-pneumatic transducers met the requirements of the 1975 and 1987 Editions of standard No. 344, “IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations.” IEEE 344-1975/1987 requires the user to demonstrate or yield data to substantiate the capability of a component to withstand the effects of earthquakes without the loss of its capability to perform its intended safety functions. Equipment seismically qualified in accordance with IEEE 344-1975/1987 must remain functional after exposure to operating basis earthquakes (OBEs) followed by a safe shutdown earthquake (SSE).

Fisher Controls' seismic qualification of the 546NS electro-pneumatic transducers is documented in Thermodyne's EQ Test Report No. 4F-3-1-2, Revision 0, dated February 15, 1995. Seismic qualification testing may be performed as a separate sequence of tests or integrated into the sequence of EQ tests. In both cases, the seismic qualification testing shall address resonance search, OBE, and SSE. The NRC inspection team noted that the EQ test report documented the performance of seismic event simulation vibration testing and uniaxial seismic dwell test for a design basis event. However, Fisher Controls did not provide objective evidence that it had performed random motion biaxial testing to demonstrate seismic capability as required by Section 3, "Earthquake Environment and Equipment Response," of IEEE 344-1975. In addition, the NRC inspection team noted that Fisher Controls did not provide objective evidence that the 546NS electro-pneumatic transducers met the performance requirements in accordance with sections "Seismic Qualification Requirements", "Analysis," "Testing," or "Documentation," of IEEE-344-1975. Furthermore, the NRC inspection team noted that Fisher Controls did not provide data gained from operating experience in accordance with the requirements of Section 9, "Experience," or objective evidence of the method used for qualification in accordance with the requirements of Section 4, "Seismic Qualification Approach," of IEEE 344-1987.

The NRC inspection team identified this issue as Nonconformance 99900105/2019-201-01 for Fisher Controls' failure to verify the adequacy of the design of the 546NS electro-pneumatic transducers through suitable seismic qualification testing. Fisher Controls initiated CAR No. 1896 to address this issue.

Environmental Qualification of the 546NS Electro-Pneumatic Transducers

During the review of qualification drawings, test setup, and the test configurations as part of the Thermodyme EQ Test Report No. 4F-3-1-2, the NRC inspection team noted that Fisher Controls did perform the EQ of the 546NS electro-pneumatic transducers in accordance with the requirements of IEEE 323-1983 which was specified in customers' POs. It's important to note that the NRC has not endorsed IEEE 323-1983, however, the requirements of IEEE-323-1983 shall be met when specified in POs.

The NRC inspection team noted that Fisher Controls did not perform the qualification in a test configuration similar to how it would be used once installed in a system at a nuclear power plant as required by Section 6.1.2, "Interfaces," of IEEE 323-1983 "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations." Adequate configuration is necessary to demonstrate the electro-pneumatic signal transducer receives a current (mA direct current (DC)) input signal and transmits a proportional pneumatic output pressure to a final control element. The 546NS electro-pneumatic transducers' safety function consists of converting a current or voltage input into a proportional output pressure and demonstrating the force balance principle. The NRC inspection team identified that Fisher Controls failed to demonstrate and consider interfaces using a connected air operated valve or pneumatic positioner. The pressures developed between the diaphragm interfaces and test environment configuration demonstrate the ability to perform its safety function. For example, motive power or control signal inputs and outputs, and the physical manner by which they are supplied shall be specified. Control, indicating, and other auxiliary devices mounted internal or externally to the equipment that are required for proper operation shall be included in the test configuration to demonstrate interfaces performance do not adversely affect the

performance of Class 1E equipment and systems as required by Section 6.1.2 of IEEE 323-1983.

Section 6.1.5, “Service Condition,” of IEEE 323-1983 requires that the service conditions (e.g., electrical loadings and signals and operating cycles) for the equipment shall be specified. The NRC inspection team noted that the 546NS electro-pneumatic transducers were qualified using a 4mA to 20mA DC input design current, however, Fisher Controls manufactured and supplied the 546NS electro-pneumatic transducers with 10mA to 50mA DC input currents. The 10mA to 50mA DC inputs are associated with higher line voltages and Fisher Controls’ did not demonstrate, identify or evaluate a 10mA - 50mA DC design input. In addition, as part of the qualification, the 546NS electro-pneumatic transducers were cycled a limited number of times, but the EQ testing failed to demonstrate the capability of a modulating control valve set point to maintain flow similar to how it would be used.

The NRC inspection team also noted that Fisher Controls provided the activation energy for the elastomers originally used in the thermal aging analysis/calculations but failed to justify the selection methodology of the activation energies used to ensure the most conservative activation energy was used for establishing a qualified life consistent with Section 6.2.2, “Qualified Life Objective,” of IEEE 323-1983. Specifically, Fisher Controls did not consider or determine the activation energies of the EPDM/NOMEX elastomer over nitrile diaphragms and coil assembly consisting of a nylon bobbin wound with wire (white plastic coil bobbin). When performing thermal aging calculations, the most conservative activation energy must be selected for the various mechanisms of failure. The selection should also consider the most limiting combination of activation energies and temperatures associated with the materials in question. Material application is important because the method is only accurate over a limited temperature range for any given material and does not account for all synergistic effects.

The ability of Class 1E equipment to perform its safety function is affected by environmental phenomena over time (aging). The effect of aging can be addressed by testing or analysis and based on an evaluation of the specific design of the equipment. An aging mechanism is significant if in the normal or abnormal service environment it can cause degradation. The NRC inspection team identified that Fisher Controls did not identify or evaluate the required maintenance during the aging portion of the qualification testing for the relay and feedback bellows replacement as required by Section 6.2.4, “Maintenance,” of IEEE 323-1983.

In addition, the NRC inspection team identified that the test specimen for the 546NS electro-pneumatic transducers was not calibrated to an acceptance criteria prior to baseline testing. Section 6.3.2, “Test Sequence,” of IEEE 323-1983 requires that steps in type testing shall be run in a specified appropriate sequence to the postulated set of service conditions for each equipment application. The 546NS electro-pneumatic transducers have an adjustable zero screw and span screw which can potentially manipulate accuracy limits and specification. Calibration should be checked to identify accuracy shifts and assess repeatability.

Furthermore, the NRC inspection team noted that Thermodyne’s EQ Test Report No. 4F-3-1-2 identified eight test anomalies. Anomalies included issues with the schematic of the electrical and pneumatic test item and instrumentation hookup for baseline test, deviation in cycle inputs, input signal accuracy (0.01mA DC), calibration data of input

monitoring ammeter, seismic dwell evaluation ability to hold a steady mid-range output, and full span excursions should have been administered at each seismic dwell point to achieve output span. Fisher Controls did not open any nonconformances or corrective actions to evaluate how the anomalies affected the qualification of the 546NS electro-pneumatic transducers or determine if the anomalies could invalidate the qualification.

The NRC inspection team identified these issues as examples of Nonconformance 99900105/2019-201-02 for Fisher Controls' failure to adequately qualify the design of the 546NS electro-pneumatic transducers through suitable environmental qualification testing under the most adverse design conditions to verify the adequacy of the design. Fisher Controls initiated CAR No. 1896 to address these issues.

c. Conclusion

The NRC inspection team issued Nonconformances 99900105/2019-201-01 and 99900105/2019-201-02 in association with Fisher Controls' failure to implement the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Nonconformance 99900105/2019-201-01 cites Fisher Controls for failing failure to adequately seismically qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing. Nonconformance 99900105/2019-201-02 cites Fisher Controls for failing to adequately environmentally qualify the design of the 546NS electro-pneumatic transducers through suitable qualification testing under the most adverse design conditions to verify the adequacy of the design.

3. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its commercial-grade dedication program to verify compliance with the requirements of Criterion III and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of commercial-grade dedication packages to assess the different elements of the commercial-grade dedication program, including POs, the technical evaluation process, design drawings, work package instructions, commercial-grade surveys, and inspection reports. The NRC inspection team also evaluated the criteria for the identification of the item's functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, and the identification of verification methods to verify effective implementation of Fisher Controls' commercial-grade dedication process. In addition, the NRC inspection team verified that commercial-grade surveys contained the objective evidence necessary to demonstrate adequate control of the critical characteristics.

The NRC inspection team also discussed the commercial-grade dedication program with Fisher Controls' management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

During the review of a sample of commercial-grade dedication packages for material testing services, the NRC inspection team noted that Fisher Controls did not identify

training and qualification of personnel and control of measuring and test equipment (M&TE) as critical characteristics in the technical evaluation for material testing services. The NRC inspection team determined this issue to be minor because Fisher Controls did verify these critical characteristics as part of the commercial-grade surveys performed of the material testing suppliers. Fisher Controls initiated CAR No. 1894 to address this issue.

c. Conclusion

With the exception of the minor issue identified above, the NRC inspection team concluded that Fisher Controls is implementing its commercial-grade dedication program 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 documents reviewed, the NRC inspection team also determined that Fisher Controls is implementing its policies and procedures associated with the commercial-grade dedication program. No findings of significance were identified.

4. Supplier Oversight

b. Inspection Scope

The NRC inspection team reviewed Fisher Controls' 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 of Appendix B to 10 CFR Part 50.

For a sample of POs, the NRC inspection team verified that the POs included, as appropriate: the scope of work, right of access to facilities, and extension of contractual requirements to sub-suppliers. The NRC inspection team also confirmed that the POs adequately invoked the regulatory requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.

For a sample of external audits, the NRC inspection team verified that Fisher Controls had prepared and approved plans that identified the audit scope and applicable checklist criteria before the initiation of the audit activity. The NRC inspection team confirmed that audit reports contained objective evidence of the review of the relevant quality assurance criteria of Appendix B to 10 CFR Part 50. For audits that resulted in findings, the NRC inspection team verified that the supplier had established a plan for corrective action and that Fisher Controls had reviewed and approved the corrective action and verified its satisfactory completion and proper documentation. In addition, the NRC inspection team confirmed that the qualified and approved suppliers performing safety-related work for Fisher Controls were adequately listed on the Nuclear Approved Suppliers List.

The NRC inspection team also discussed the supplier oversight program with Fisher Controls' management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Fisher Controls 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 Fisher Controls is implementing its policies and procedures associated with the supplier oversight program. No findings of significance were identified.

5. Material Identification and Traceability

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its material identification and traceability program to verify compliance with the regulatory requirements of Criterion VIII, "Identification and Control of Material, Parts, and Components," of Appendix B to 10 CFR Part 50.

The NRC inspection team performed a walk-down of the following areas at Fisher Controls' manufacturing facility: receipt and final inspection, fabrication and storage, testing, and nonconforming material storage. The NRC inspection team confirmed that materials were adequately identified with Fisher Controls' unique identification code, which is traceable to the POs and vendor certification reports. The NRC inspection team verified that Fisher Controls' personnel appropriately maintained the material identification and traceability markings during various stages of fabrication.

The NRC inspection team also discussed the material traceability program with Fisher Controls' management and technical staff. The attachment to this inspection report lists the 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 Fisher Controls is implementing its material identification and traceability program in accordance with the regulatory requirements of Criterion VIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Fisher Controls is implementing its policies and procedures associated with the material identification and traceability program. No findings of significance were identified.

6. Manufacturing Control

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its manufacturing control program to verify compliance with the regulatory requirements of Criterion IX, "Control of Special

Processes," of Appendix B to 10 CFR Part 50 and with the applicable requirements of Section III, Section V, "Nondestructive Examination," and Section IX, "Welding, Brazing and Fusing Qualifications," of the ASME B&PV Code, and the American Society for Nondestructive Testing (ASNT) SNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing."

During the week of the inspection, welding and non-destructive testing (NDT) activities were not being performed on components destined for any U.S. nuclear power plant. As such, the NRC inspection team reviewed a sample of completed weld procedure specifications (WPS) and supporting procedure qualification records (PQRs). The NRC inspection team verified that the applicable welding data was adequately recorded in the WPSs and PQRs (e.g., procedures used, type of weld filler material, etc.). The NRC inspection team also performed a walk-down of the weld storage area and confirmed that weld filler materials were adequately controlled to prevent degradation, inadvertent use, or loss of traceability. The weld filler materials were kept in containers and ovens at specified temperatures to control moisture, as applicable, and the environmental condition of the weld filler material storage facility was adequately controlled. The temperature indications for the storage areas were all within calibration periodicity.

The NRC inspection team also reviewed the associated welder performance qualification records and confirmed that the welders had completed the required training and had maintained their qualifications in accordance with the applicable Fisher Controls procedures. The NRC inspection team also verified that Fisher Controls' procedure for welder qualification meets the applicable requirements of Sections III and IX of the ASME B&PV Code.

In addition, the NRC inspection team reviewed a sample of procedures and test reports associated with liquid penetrant testing, Level II and Level III inspector qualifications, and the calibration certificates of the M&TE. The NRC inspection team confirmed that the NDT personnel were qualified in accordance with the requirements of ASNT SNT-TC-1A.

The NRC inspection team also discussed the manufacturing control program with Fisher Controls' management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observation and Findings

No findings of significance were identified.

c. Conclusion

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

7. Test Control

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its test control program to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50.

During the week of the inspection, testing activities were not being performed on safety-related components destined for any U.S. nuclear power plant. As such, the NRC inspection team selected four completed assembly and test records (ATRs). The NRC inspection team verified the ATRs of safety-related valves shipped to domestic nuclear power plants documented the required qualitative and quantitative acceptance criteria and confirmed the test activity was performed in accordance with Fisher Controls' test procedure, conducted by a qualified assembler/test personnel, using calibrated M&TE, and the test results independently verified by a Quality Control inspector and witnessed by the Authorized Nuclear Inspector.

The NRC inspection team discussed the test control program with Fisher Controls' management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

During the review of the water analysis report for the month of October 2019, the NRC inspection team noted that the water conductivity value exceeded the acceptance criteria as required by Fisher Controls' Manufacturing Procedure (FMP) No. 12B3, "Deionized Water - Testing and Control in compliance with NQA-1-1994 and ASME N45.2.1-1980," Revision 8, dated April 29, 2013. FMP-12B3 stipulates the water specification requirements for the acceptance of deionized water used for hydrostatic test of safety-related valves.

Upon further discussion with Fisher Controls' staff, the NRC inspection team learned that the water analysis discrepancy was an isolated incident since the previous water analysis results were within acceptance criteria of FMP-12B3 and that no safety-related valves had been hydrostatically tested during the month of October. In addition, Fisher Controls provided the NRC inspection team with water analysis reports from September 2018 through October 2019, as well as the nuclear test gage calibration log sheets for review. The nuclear test gage calibration log sheet documents the pressure gage serial number that was calibrated pre and post-test, with the valve serial number and the customer's PO number for traceability. Upon review of the additional information, the NRC inspection team confirmed that the October 2019 water analysis report was an isolated incident and that deionized water had not been used for hydrostatic testing of safety-related valves. The NRC inspection team determined this issue to be minor because Fisher Controls did not use the deionized water for testing of safety-related valves. Fisher Controls initiated CAR No.1893 to address this issue.

No findings of significance were identified.

c. Conclusion

With the exception of the minor issue identified above, the NRC inspection team concluded that Fisher Controls is implementing its test control program in accordance with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Fisher Controls is implementing its policies and procedures associated with the test control program. No findings of significance were identified.

8. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its 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.

For a sample of M&TE, the NRC inspection team verified that the M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The NRC inspection team also verified that M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. The calibration records associated with the M&TE indicated the as-found or as-left conditions, accuracy required, calibration results, calibration dates, the due date for recalibration, and the applicable National Institute of Standards and Technology traceable reference equipment used in the calibration.

The NRC inspection team also verified that when M&TE is found to be out of tolerance when being calibrated, or when the M&TE is lost, Fisher Controls initiates a nonconformance report (NCR) to identify items that have been accepted using this equipment since the last valid calibration date and to perform an extent of condition evaluation. In addition, the NRC inspection team performed a walk-down of Fisher Controls' calibration laboratory to ensure that equipment located in the M&TE storage area, the M&TE hold area, and inspection and test facility were labeled, handled, and stored in a manner that indicated the calibration status of the instrument and ensured its traceability to calibration test data.

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

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Fisher Controls 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 Fisher Controls is implementing its policies and

procedures associated with the M&TE program. No findings of significance were identified.

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

a. Inspection Scope

The NRC inspection team reviewed Fisher Controls' policies and implementing procedures that govern the implementation of its nonconforming materials, parts, or components and corrective action programs 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.

For a sample of NCRs, the NRC inspection team verified that Fisher Controls: (1) dispositioned the NCRs in accordance with the applicable procedures, (2) documented an appropriate technical justification for various dispositions, and (3) took adequate corrective action with regard to the nonconforming items.

Similarly, for a sample of CARs, the NRC inspection team verified that Fisher Controls: (1) ensured that conditions adverse to quality and significant conditions adverse to quality were promptly identified and corrected, (2) adequately documented and described conditions adverse to quality and significant conditions adverse to quality; (3) conducted an appropriate analysis of the cause of these conditions and took corrective actions taken to prevent recurrence, as applicable; (4) provided direction for review and approval by the responsible authority; (5) described the current status of the corrective actions; and (6) took follow-up actions to verify timely and effective implementation of the corrective actions.

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

b. Observations and Findings

Corrective Action Associated with Nonconformance No. 99900105/2015-201-01

Following the April 2015 NRC inspection of Fisher Controls, the NRC issued Nonconformance 99900105/2015-201-01 for Fisher Controls' failure to ensure that conditions adverse to quality were promptly identified and corrected, and for their failure to ensure that significant conditions adverse to quality were corrected to preclude repetition. Specifically, Fisher Controls failed to: (1) provide adequate corrective action in response to Notice of Nonconformance (NON) 99900105/2011-201-05 related to Fisher Controls' failure to adopt a Corrective Action Program that meets the requirements of Criterion XVI of Appendix B to 10 CFR Part 50; (2) failed to ensure that the corrective actions taken for CAR No. 1551, dated April 9, 2012, related to a significant condition adverse to quality, were sufficient to preclude repetition; and (3) ensure that the corrective actions taken for CAR No. 1697, dated June 30, 2014, were adequate.

In its responses dated June 15, 2015 and August 12, 2015 (ADAMS Accession Nos. ML15190A242 and ML15259A519, respectively), Fisher Controls stated that it had initiated three CARs: 1744 (issue No. 1 above), 1745 (issue No. 2 above), and 1752 (issue No. 3 above) to address the NON. CAR No. 1744 directed Fisher Controls to update its corrective action procedure to include a clear definition of significant condition adverse to quality, along with a differentiated processing requirement from that for conditions adverse to quality. In addition, the corrective action procedure was revised to ensure appropriate levels of management are notified. CAR No. 1745 directed Fisher Controls to develop a corrective action review board process for each significant condition adverse to quality. CAR No. 1752 directed Fisher Controls to develop an engineer standard that would contain the radiation capabilities of elastomers used in the nuclear applications by Fisher Controls.

The NRC inspection team reviewed the documentation that provided objective evidence that all corrective actions were completed and adequately implemented. The NRC inspection team confirmed that the corrective action procedure was updated, the corrective action review board was established, and Engineering Standard (ES) No. 63, "Elastomeric Material Radiation information for use in Nuclear Design," Revision A, dated October 14, 2015, was created. The NRC inspection team also confirmed that both the updated corrective action procedure and ES No. 63, as well as the corrective action review board are being adequately implemented. Based on this review and interviews with Fisher Controls' staff, the NRC inspection team closed NON 99900105/2015-201-01.

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Fisher Controls 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 Fisher Controls 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.

10. Entrance and Exit Meetings

On November 4, 2019, the NRC inspection team discussed the scope of the inspection with Mr. Rande Jones, Plant Manager, and other members of Fisher Controls' management and technical staff. On November 8, 2019, the NRC inspection team presented the inspection results and observations during an exit meeting with Ms. Stephanie Bouder, Vice-President of Operations for the Americas, and other members of Fisher Controls' management and technical staff. On November 26, 2019, the NRC inspection team conducted a re-exit meeting via a teleconference call with Mr. Joseph Clos, Quality Assurance (QA) Manager, and Mr. Daniel Zuelke, QA Engineering Manager, to present additional inspection results and observations. The attachment to this report lists the attendees of the entrance and both exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance Meeting	Exit Meeting	Re-Exit Meeting	Interviewed
Stephanie Bouder	Vice-President Operations Americas	Fisher Controls		X		
Ben Ahrens	Director Quality Americas	Fisher Controls		X		
Tim Parrie	Nuclear Director Americas	Fisher Controls		X		
Rande Jones	Plant Manager	Fisher Controls	X	X		
Darrin Nuese	Operations Manager	Fisher Controls	X	X		
Thomas Steven	Nuclear Valve Stream Manager	Fisher Controls	X	X		
Jacob Clos	Quality Assurance (QA) Manager	Fisher Controls	X	X	X	X
Andrew Wright	Quality Control (QC) Manager	Fisher Controls	X	X		X
Daniel Zuelke	QA Engineering Manager	Fisher Controls	X	X	X	X
Zach Mailahn	Nuclear Engineering Manager	Fisher Controls		X		X
Adin Mann	Lead Simulator Technology Manager	Fisher Controls				X
Trevor Seibold	QC Supervisor	Fisher Controls				X
José Núñez	Assembly/Testing Supervisor	Fisher Controls				X
Jay Jackson	Paint Supervisor	Fisher Controls				X
Jason Russell	Quality Engineer	Fisher Controls	X	X		X

Name	Title	Affiliation	Entrance Meeting	Exit Meeting	Re-Exit Meeting	Interviewed
Ronald Cook	Quality Engineer	Fisher Controls				X
Mike Ketchum	Quality Engineer	Fisher Controls				X
John Brones	QC Technician	Fisher Controls				X
Ethan Haughey	Project Manager	Fisher Controls				X
Aaron Wogan	Nuclear Value Stream Planner	Fisher Controls				X
Eric McReynolds	Level III	Fisher Controls				X
Justin Love	Paint Applicator	Fisher Controls				X
Deanna Daters	Weld Shop Scheduler	Fisher Controls				X
Yamir Diaz-Castillo	Inspection Team Leader	NRC	X	X	X	
Andrea Keim	Inspector	NRC	X	X	X	
Raju Patel	Inspector	NRC	X	X		
Nicholas Savwoir	Inspector	NRC	X	X	X	
Jeffrey Jacobson	Senior NRC Staff	NRC			X	
Kerri Kavanagh	Branch Chief	NRC		X*	X	

*by phone

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, “Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance,” dated May 16, 2019.

IP 43002, “Routine Inspections of Nuclear Vendors,” dated January 27, 2017.

IP 43004, “Inspection of Commercial-Grade Dedication Programs,” dated January 27, 2017.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99900105/2015-201-01	CLOSED	Notice of Nonconformance (NON)	Criterion XVI
99900105/2019-201-01	OPENED	NON	Criterion III
99900105/2019-201-02	OPENED	NON	Criterion III

4. DOCUMENTS REVIEWED

Policies and Procedures

- Fisher Controls International, LLC's Nuclear Quality Assurance Manual, Revision 16, dated March 8, 2019
- Engineering Procedure (EP) 9, "A Guide to Nuclear Qualification," Revision EU, dated May 13, 2019
- EP 63, "Elastomeric Material Radiation information for use in Nuclear Design," Revision A, dated October 14, 2015
- Engineering Standard (ES) 2, "Method for Revising Drawings and Other Engineering Documents," Revision EU, dated May 13, 2019
- ES 93, "Nuclear Valve Design Reports - ASME B&PV Code, Section III, Nuclear Power Plant Components," Revision R, dated August 17, 2017
- ES 118, "Design Verification Requirements for Valve and Regulator Components," Revision N, dated September 10, 2008
- ES 119, "Design Control Requirements," Revision AD, dated September 5, 2019
- ES 172, "Qualification and Duties of Personnel Engaged in ASME B&PV Code Section III, Certifying Activities," Revision L, dated October 31, 2018
- ES 192, "Engineering Change Request Procedure," Revision AG, dated November 6, 2019
- ES 243, "Control Standard for Calibration and Use of Research and Engineering Lab Test and Measuring Equipment," Revision G, dated May 31, 2016
- ES 256, "Code and Specification Reconciliation for Nuclear Service Replacement Parts & Components," Revision C, dated August 25, 2008

- Fisher Controls' General Specification (FGS) 4L5, "Seat Leak Tests for Control Valves," Revision AQ, dated April 15, 2016

- FGS 15B15.5, "Reporting of Potential Defects and Noncompliance in Accordance with 10 CFR Part 21, US Code of Federal Regulations," Revision F, dated April 19, 2018

- Fisher Controls' Manufacturing Procedure (FMP) 2A11, "Engineering Change Request Notification Process," Revision 4, dated December 9, 2016

- FMP 2C6, "Operational Test for Piston and Diaphragm Actuated Valves on Sliding Stem and Rotary Valves," Revision 8, dated December 9, 2013

- FMP 2C2.11, "Valve Closure Test Procedure," Revision 3, dated March 4, 1982

- FMP 2C14, "Operational Testing of AP1000 Nuclear Valves," Revision 11, dated April 28, 2017

- FMP 2G12, "Radiographic Examination Procedure for Welds, Forgings, and Bar," Revision 18, dated June 4, 2012

- FMP 2G30, "Fluorescent Dye Water-Washable Liquid Penetrant Inspection," Revision 10, dated August 14, 2019

- FMP 2G30.3, "Visible Dye Water-Washable Liquid Penetrant Inspection," Revision 10, dated August 14, 2019

- FMP 2G31, "Dry Powder Magnetic Particle Inspection," Revision 9, dated December 14, 2018

- FMP 2H1, "Pressure Gauge Calibration," Revision 24, dated September 28, 2017

- FMP 2H2, "Procedure for Control and Calibration of Gauges, Measurement Equipment and Examination Equipment," Revision 61, dated July 12, 2019

- FMP 2H8, "Welding Machine Calibration Verification," Revision 9, dated November 28, 2018

- FMP 2J1, "Nondestructive Testing Personnel Qualification and Certification," Revision 33, dated October 22, 2019

- FMP2J2, "Qualification of Assembly/Assembly Test Personnel," Revision 13, dated July 29, 2014

- FMP 2K1, "Supplier Evaluation - NCA 3800 and Appendix B Material Organizations," Revision 19, dated December 21, 2017

- FMP 2K1.6, "Certification of Unqualified Source Material as ASME Code Material," Revision 4, dated December 21, 2017

- FMP 2K9, “Procedure for Corrective Action,” Revision 30, dated July 26, 2017
- FMP 2K27.3, “Control of M&TE Commercial Grade Items to be Dedicated for Use in Nuclear Applications,” Revision 11, dated August 20, 2019
- FMP 2K29, “Processing of Nonconforming Materials and Items,” Revision 20, dated September 6, 2017
- FMP 20A22, “Work Instruction - Material Review Board Process,” Revision 2, dated May 19, 2015
- FMP 2K37, “Supplier Checklists - 10 CFR Part 50 Appendix B,” Revision 7, dated August 4, 2015
- FMP 2K37.1, “Supplier Checklists - 10 CFR Part 50 Appendix B Software,” Revision 0, dated 2013
- FMP 2K43, “Supplier Evaluation - Commercial Grade Survey,” Revision 5, dated October 24, 2019
- FMP 2K43.1, “Supplier Evaluation - Survey (code), Commercial Grade Survey - Calibration Services,” Revision 5, dated November 5, 2015
- FMP 2K43.1.1, “Supplier Evaluation - Accreditation - Calibration Services,” Revision 5, dated August 29, 2019
- FMP 2K43.2, “Supplier Evaluation - Survey (code), Commercial Grade Survey - Laboratory Services,” Revision 3, dated May 22, 2013
- FMP 2Q12, “Nuclear Order Processing System - Determination of Project/Order Processing Requirements,” Revision 14, dated March 26, 2019
- FMP 2Q19, “Nuclear Order Processing System - Change Order Processing,” Revision 9, dated September 15, 2016
- FMP 2Q23, “Reconciliation of ASME Section III, Division 1 Replacement Orders,” Revision 9, dated September 18, 2017
- FMP 2S9, “Control of Shop Orders Through Production,” Revision 14, February 20, 2019
- FMP 2S18, “Heat Number Marking,” Revision 1, dated December 5, 2018
- FMP 5A1, “Control of Covered Welding Electrodes,” Revision 12, dated March 17, 2014
- FMP 5A3, “Storage and Handling of Submerged Arc Fluxes,” Revision 0, dated February 13, 2015

- FMP 5A4, “Control of Bare Filler Material,” Revision 1, dated August 29, 2017

- FMP 5B5, “Test and Evaluation Requirements for Welder Performance Qualification Tests,” Revision 8, dated November 10, 2014

- FMP 5C76.2, “GTAW/SMAW, P10H - P10H, BMT = 3/18 - 8”, (Ferralium 255), Revision 4, dated January 17, 2014

- FMP 12B3, “Deionized Water - Testing and Control in compliance with NQA-1-1994 and ASME N45.2.1-1980,” Revision 8, dated April 29, 2013

Design and Commercial-Grade Dedication Records

- Document No. 08QN21-DR-02, “Design Report for Class 1, 4-inch 84PSV4 W/ Schedule 120 BWE,” Revision C, dated October 31, 2018

- Document No. 10QN78-DR-01, “Design Report for 14-inch Class 1725 SS-264, Class 1 valve,” Revision D, dated April 9, 2018

- Document No. 11QN09-DR-18, “Design Report for Class 3 Components per ASME BPVC Section III, Division 1, 1998 Edition, 2000 Addenda,” Revision A, dated May 27, 2016

- Document No. 11QN09-SA-18, “Seismic Qualification Report for Vogtle Units 3 & 4,” Revision B, dated August 4, 2016

- Document No. 11QN09-DR-18.04, “Design Report for 1-inch Class 1680 HPNS Air operated Globe Valve w/Schedule 80S BWE, Class 3,” Revision B, dated September 30, 2016

- Analysis Report No. AN11010, “Seismic Analysis of Size 4 HPNS with 667NS2 Size 80B Actuator - Project No. 08QN51,” dated August 19, 2014

- Fisher Controls’ Project No. 86JA03, “ANSYS Finite Element Analysis Program File for Version 2019R2,” Revision AG, dated July 15, 2019

- Fisher Controls’ evaluation of “ANSYS Class 3 Error Report WB2015-08,” date September 21, 2015

- Fisher Controls’ evaluation of “ANSYS Class 3 Error Report 2019-02 for Version 18.0”, dated April 2, 2019

- Fisher Controls’ Project No. 86JA01, “SEISMIC4 Structural Analysis Program,” Revision B, dated August 19, 2008

- Supplemental Non-Conformance Reconciliation for Code Design Report 11QN09-DR-18, Revision A, valve serial No. 0019089954, dated October 12, 2016

- Order Review file for Project No. 1345483, valve tag No. SW-TV-201B, dated October 31, 2018

- Order Review file for Project No. 3262079/ CSP-0536883, valve tag No. MCV-227, dated February 15, 2019

- Order Review file for Project No. 1169579, pressurizer spray valves PV63 DS100, dated December 12, 2017

- Design Reconciliation Review form for Project No. 3262079, for a body wafer, dated March 22, 2019

- Drawing No. GH01481, "1-inch socket globe valve EZ-657NS," Revision D, dated February 26, 2019

- Drawing No. GH01482, "2-inch flanged globe valve EZ-657NS," Revision D, dated February 26, 2019

- Technical Evaluation TE_MAT, "Material Testing Services," Revision A, dated February 10, 2016

- Technical Evaluation TE_CAL, "Calibration of Measuring & Test Equipment," Revision D, dated September 4, 2018

- Thermodyne Test Report No. 4F-3-1-2, Revision 0, dated February 15, 1995

- Fisher Qualification Report No. 82, "546NS Qualification Report," Revision A, dated August 24, 2006

- 19QN66-TC-1, Revision A, dated August 7, 2019 (Electronic correspondence from Turkey Point Nuclear Generating Station)

- 19QP008, dated August 7, 2019 (10 CFR Part 21 Evaluation)

- Radiation Test Set-Up drawing No. 4F-3-1-100, Revision 0, dated November 4, 1994

- Thermal Aging Test Set-Up drawing No. 4F-3-1-200, Revision 0, dated November 4, 1994

- Seismic Test Set-Up drawing No. 4F-3-1-300, Revision 0, dated November 4, 1994

- Environmental Qualification Test Drawing No. 4F-3-1-400, Revision 1, December 12, 1994

<u>American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel (B&PV) Code and Welding Records</u>

- ASME NPV-1 Code Data Report for 1-inch HPNS globe valve tag No. APP-PV14-Z0D-118, dated November 2, 2016

- ASME NPV-1 code data report for 10-inch Type 9200 valve serial No. F002031632, dated March 20, 2019

- ASME NPV-1 code data report for 16-inch A11 valve serial No. F001763919, dated September 16, 2019

- ASME NPV-1 code data report for EZ 2-inch valve serial No. F002087978, dated August 6, 2019

- ASME NPV-1 Code Data report for 8-inch A11 Class 3 valve serial No. F002097893, dated July 25, 2019

- Weld Procedure Specification (WPS) FWPS Alloy 6B.P8-TN-J1, "Fabrication; R30016/R30006 to P-No; GTAW, No PWHT," Revision B

- WPS 5CP1.1G1.2TSNI, "GTAW-SMAW, P1-P1G1&2, BMT=5/8"-8 w/PED," Revision 1, dated March 11, 2013

- Procedure Qualification Record (PQR) 78-2010, "S31603 to R30016, GTAW, 1", BMT, No PWHT," Revision C

- PQR-01-2009 for WPS FWPS Alloy 6B.p8-TN-J1, Revision 1, dated February 6, 2009

Calibration, Non-Destructive Testing, and Test Records

- Certificate of Calibration for a Rockwell hardness tester, serial No. G17976#1, calibrated on May 21, 2019

- Certificate of Calibration for a digital pressure gage, serial No. 2715073, calibrated on June 26, 2019

- Certificate of Calibration for a vacuum pressure gage, serial No. 3189170, calibrated on October 18, 2019

- Certificate of Calibration for a vacuum pressure gage, serial No. 3762409, calibrated on October 18, 2019

- Certificate of Calibration for a pressure monitor, serial No. 4036358, calibrated on September 24, 2019

- Certificate of Calibration for the nuclear furnace's temperature monitors, calibrated on August 21, 2019

- Certified Material Test Report (CMTR) for a round bar for Stem AB002075, heat No. 552N, lot No. W03909-01, dated May 24, 2019

- CMTR for ½ inch studs AB002005, heat No. 100791206, lot 50576083, dated May 21, 2019

- CMTR for nuts, heat No. 50575824, lot No. 10567390, dated May 20, 2019
- CMTR for valve bonnets, heat treatment dated July 19, 2019
- Liquid Penetrant Testing (PT) Examination Reports of the plug/stem weld, all accessible finished machined surfaces, and the plug/stem fabrication weld of a plug/stem assembly, Part No. GE45480X052, material SA479/R30016, inspection performed on July 1, 2015
- PT Examination Report of all accessible machined surfaces of a plug block, Part No. GE45479X052, material R30016, inspection performed on January 20, 2015
- PT Examination Report of all accessible machined surfaces of a stem, Part No. GE45472X092, material SA479, inspection performed on September 25, 2014
- PT Examination Report No. PT00003883 of all accessible machined surfaces of wafer body, Part No. V163586X032, inspection performed on July 19, 2019
- PT Examination Report No. PT00003882 of the stop to body fabrication weld of a wafer body, Part No. V163586X032, inspection performed on July 19, 2019
- Assembly Test Report (ATR) for 1-inch HPNS Globe Valve tag No. APP-PV14-Z0D-118 dated September 2, 2016
- ATR for valve serial No. F002031632, dated March 14, 2019
- ATR for valve serial No. F00208798, dated August 5, 2019
- September 2019 Water Analysis Report No. 4780093211 for demineralized water for NV2 500 Ton Hydro, dated September 17, 2019
- Fisher Controls' FMP2H1 Form, "Nuclear Hydrostatic Calibration Record," dated September 3, 2019
- Certificate of Compliance (CoC) for Point Beach Nuclear Plant, dated February 14, 2002
- CoC for Comanche Peak Nuclear Power Plant, dated June 8, 2016
- CoC for Nine Mile Point Nuclear Station, dated August 1, 2014
- CoC for Indian Point Nuclear Generating Unit 3, dated December 6, 2004

<u>Purchase Orders, Audit Reports, and Commercial-Grade Surveys</u>

- Fisher Controls' Nuclear Approved Suppliers List
- Purchase Order (PO) No. 4780235171 for calibration of torque wrenches and torque multipliers, Revision 0, dated November 4, 2019

- PO No. 4870171999 for calibration of hardness testers, Revision 0, dated June 10, 2019
- PO No. 4780184507 for a diaphragm, Revision 3, dated August 26, 2019
- PO No. 4123831495 for a bonnet, Revision 8, dated December 20, 2018
- PO No. 4780047083 for a seal protector ring, Revision 2, dated December 5, 2018
- PO No. 4780150759 for a disc, Revision 2, dated May 1, 2019
- PO No. 4123601413, for Class 1E position indicator switch, dated March 8, 2016
- PO No. 4780215025 for calibration services, Revision 0, dated September 18, 2019
- PO No. 4780202087 for calibration services, Revision 0, dated August 19, 2019
- PO No. 4780211642, for Carbo-Zinc 11SG paint, dated September 10, 2019
- PO No. 4500407119 from Wisconsin Energies Point Beach Nuclear
- PO No. 02170726 from North Atlantic Energy Seabrook, dated February 6, 2002
- PO No. 337849 from Luminant, dated April 4, 2016
- PO No. S 0569472 6D2 from Luminant, dated March 12, 2008
- PO No. 4125065938 from Nine Mile Point Nuclear Station, dated June 14, 2013
- PO No. 4500530127 from Entergy Nuclear Operations, dated September 3, 2004
- Audit Report for supplier No. 150020278, audit conducted on December 6 - 7, 2016
- Audit Report for supplier No. 150080767, audit conducted on March 23 - 29, 2019
- Audit Report for supplier No.150000110, audit conducted on February 21 - 22, 2017
- Audit Report for supplier No. 150011948, audit conducted on March 6, 2019
- Audit Report of a switch supplier, dated November 13, 2018
- Audit Report of a paint supplier, dated October 16, 2019
- Commercial-Grade Survey report for supplier No. 150024620, survey conducted on March 29, 2019

- Commercial-Grade Survey report for supplier No. 150017931, survey conducted on January 18, 2018

- Commercial-grade survey of a commercial water test analysis service supplier, dated April 4, 2019

- Specification No. CSP-QR003, “Nuclear Quality Program Restriction,” Revision 5, dated September 30, 2018

- Specification No. CSP-QR004, “Nuclear Quality Program Restriction,” Revision 10, dated November 7, 2018

- Specification No. CSP-QR038, “Nuclear Quality Program Restriction,” Revision 5, dated July 31, 2018

- Specification No. CSP-QR047, “Nuclear Quality Program Restriction,” Revision 3, dated February 28, 2019

- Specification No. CSP-QR057, “Nuclear Quality Program Restriction,” Revision 4, dated November 9, 2018

- Specification No. CSP-QR096, “Nuclear Quality Program Restriction,” Revision 3, dated September 12, 2018

- Specification No. CSP-QR105, “Nuclear Quality Program Restriction,” Revision 5, dated July 19, 2019

- Specification No. CSP-QR112, “Nuclear Quality Program Restriction,” Revision 3, dated September 12, 2018

- Supplier Checklist - Accreditation Evaluation - Calibration Services for supplier No. 150081133, dated January 15, 2019

Nonconformance Reports

- 178530, 179520, 179529, 179533, 179537, 186735, 243067, 254486, 255803, 256697, 267502, 270316, 270345, 272918, 273101, 276225, 280065, 280587, and 284934

Corrective Action Reports

- 1697, 1727, 1744, 1745, 1752, 1817, 1831, 1845, 1846, 1847, 1848, 1851, 1854, 1855, 1860, 1870, 1823, 1826, and 1885

Corrective Action Report Opened During the NRC Inspection

- 1893 and 1894

Training and Qualification Records

- Non-Destructive Testing training records for inspectors qualified in Liquid Penetrant (Level II and Level III), Magnetic Particle (Level II and Level III), Radiographic Inspection (Level II and Level III), Ultrasonic Inspection (Level III), and Visual Inspection (Level III) testing

- Welder Performance Qualification of welder with ID No. 5896, stamp No. S184, WPS record No. 5C76.2, qualified to ASME Section IX, "Welding and Brazing Qualification"

- Assembly Qualification Record for Mass Spectrometer Leak Test qualification, dated September 18, 2019

- Re-Evaluation qualification record for two assembler/tester, dated April 5, 2019Qualification for a diaphragm to case leak tester, dated October 24, 2019

- Qualification for a hydro tester, dated June 21, 2019

- Qualification records for three Registered Professional Engineers, dated April 2019

Miscellaneous

- Fisher Information Notice (FIN) 2018-02, "Vee-Ball Valve Body-Bracket Bolting Dedication," dated July 2, 2018

- FIN 2018-03, "DVC6000 and DVC6200 Environmental Qualification," dated October 31, 2018

- FIN 2019-01, "Mechanical Settling of Disk/Taper Pins," dated August 23, 2019

- Installation Instructions D103982X012, "Mechanical Setting of Disk/Stem Taper Pins," dated September 2019