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Feb 7, 2020

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to NRC Inspection Report No. 99900105/2019-201, Notices of Nonconformance

References: 1) NRC Notice of Nonconformance 99900105/2019-201-01.
2) NRC Notice of Nonconformance 99900105/2019-201-02.
3) NRC Report No. 99900105/2019-201

Fisher Controls International LLC ("Fisher") hereby responds to the aforementioned Notices of Nonconformance (Reference 1 & 2), dated January 8, 2020 and received by Fisher on January 8, 2020. The nonconformances were identified during the Nuclear Regulatory Commission's ("NRC") inspection (Reference 3) of Fisher's Marshalltown, Iowa facility, conducted November 4-8, 2019, by inspectors Yamir Diaz-Castillo, Andrea Keim, Raju Patel, Nicholas Savwoir.

Attached, please find Fisher's reply to the Notices of Nonconformance (Reference 1 & 2).

Fisher appreciates the opportunity the Inspection Report gives us to continuously improve our Quality Assurance Program and products supplied to the nuclear industry and to ensure our compliance with NRC regulations.

Please contact me at (641)754-2108 if you have any questions or need to discuss this matter further.

Sincerely,

Jacob Clos
Manager, Quality
Fisher Controls International LLC

Attachments

cc: Kerri A. Kavanagh, Chief Quality Assurance and Vendor Inspection Branch Division of Reactor Oversight Office of Nuclear Reactor Regulation, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Attachment 1
Opening Statement

In 1994 Fisher Controls International LLC ("Fisher") was approached by an international customer [redacted] to undergo qualification testing on the Type 546 I/P Transducer (Type 546) already in use in one of their plants [redacted]. During this testing program, the customer worked with Fisher through the Fisher sales representative [redacted].

The request was made to perform thermal, radiation, seismic, and LOCA/MSLB testing to qualify the Type 546 for this specific customer and their application with reference to specific customer Technical Specifications. During the quotation stage, it is noted as follows on the quote from [redacted] (quote 3994 Rev 0 dated 94/02/07):

> "the EQ offered follows, generally, that required by Technical Specification...and IEEE 323. The deviations are noted herein."

Of particular note in the proposed testing, seismic testing was to be as follows:

> "Except for minor deviations which may be required due to physical limitations of the test equipment, the seismic qualification shall consist of:
>
> a) Sine sweep testing at an input level of 1g in the range of 5-100 Hz to determine any natural frequencies.
>
> b) Single-axis sinusoidal testing at 8g at 5, 7, 9, 11, 14, 17, 20, 27, 33, 40 Hz and any resonances or half-resonances found in the 5-100 Hz range. Dwells at each frequency point shall be at least one minute long and sufficiently long to monitor output pressure and flow rate. Each of the three orthogonal axes shall be tested."

This proposed testing sequence did not include OBE testing or defined non-seismic vibration aging. It was also a part of the order contract that end user approval of the test procedure must be received prior to starting the test program sequence. The final test report was also required to be submitted to the end user for review and approval.

The customer did agree to this proposal and approved the final test report. As a result, the test program was said to have followed "applicable procedures of IEEE 323 – 1983 and 344-1987" because the customer had accepted the exceptions to the IEEE 323/344 testing sequence.

At the conclusion of this testing, a Fisher Qualification Report (FQR) was prepared for this customer summarizing the test sequence and results. This report is titled FQR-55.

In ensuing years, Fisher has received requests from other customers for a qualified I/P Transducer. Typically, the requests ask for an IEEE 323 qualification program. At the time of quotation, Fisher instead summarizes the qualification testing performed and proposes to submit the existing FQR qualification package.

When those requests turn into orders, Fisher prepares the FQR using the existing language from FQR-55 and renumbers the document so that individual customers have unique report numbers (FQR-73, FQR-82, FQR-97, and others). The content of the reports is identical and clarifies (in FQR Purpose and Scope Section 1.2) the report is intended to be generic and:

> "useful for multiple nuclear service applications where the service conditions fall within the parameters and levels tested."

The Type 546 is used in many different applications and environments in a nuclear power plant. The intent with supplying the FQR to customers is to present the test data in a manner that enables each utility or plant to determine if the testing levels and results are appropriate for their chosen application. Rather than certifying a Type 546 meets a given application, Fisher presents the test data through the FQR to allow each individual plant to determine where and how the Type 546 could be used within their facility based on system requirements.

Attachment 2
Reply to NRC Notice of Nonconformance 99900105/2019-201-01
Docket Number 99900105
Inspection Report No 99900105/2019-201

This attachment 2 sets forth the reply of Fisher Controls International LLC ("Fisher") to the NRC's Notice of Nonconformance dated January 8, 2020 relative to NRC Inspection Report 99900105/2019-201 (the "Inspection Report"), Notice of Nonconformance 99900105/2019-201-01 (the "Nonconformance").

The Notice of Nonconformance 99900105/2019-201-01
The Notice of Nonconformance provides the following description:

> "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 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 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 failed to perform 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."

The below statements need to be taken in consideration with the opening statement (Attachment 1).

Fisher's Response to the Notice of Nonconformance - Part 1 of 3

Fisher is contesting the Nonconformance with the following clarifications.

The following addresses the first concern raised in the Design Control – Seismic Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The first concern provides the following description:

> "Fisher 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."

Reason for the contesting of the Notice of Nonconformance

Section 3 describes earthquake behavior and the response of equipment during an earthquake. Section 3 of IEEE 344-1975 does not discuss biaxial testing. Section 6 of IEEE 344-1975 permits single-axis testing which was presented to and approved by the customer in the original qualification package.

Fisher's Response to the Notice of Nonconformance - Part 2 of 3

The following addresses the second concern raised in the Design Control – Seismic Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The second concern provides the following description:

> "Fisher 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."

Reason for the contesting of the Notice of Nonconformance

Thermodyne Report 4F-3-1-2 documents all testing performed as a part of the original qualification program. This report is summarized in its entirety in the referenced FQR's supplied to customers. Each FQR is a complete, thorough, and accurate summary of the test program. The FQR is written in generic format intended as a way to present the test sequence and results to the customer. It is then up to the discretion of the customer to determine if the testing meets the requirements for a specific plant application and system.

Per the Table of Contents of the FQR, the FQR covers:

- Purpose and Scope
- Identification of Test Equipment
- Equipment Specification/Objectives
- Qualification Program
- Maintenance Requirements
- Safety-function Identification
- Environmental Test Procedure
- Test Results Summary
- Conclusions

The FQR also contains several attachments including (but not limited to) Environmental and Functional Test Procedures, Aging Calculations, Test Item Identification, Test Arrangements and Setups, and Test Equipment Calibration Data.

Fisher's Response to the Notice of Nonconformance - Part 3 of 3

The following addresses the third concern raised in the Design Control – Seismic Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The third concern provides the following description:

> "Fisher 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."

Reason for the contesting of the Notice of Nonconformance

Section 9 "Experience" paragraph 9.1 – Introduction states, "Qualification of the aforementioned equipment types may be accomplished by justifying their similarity with the previously qualified equipment or with equipment that has been exposed to other more severe environments." Section 9 was added in the 1987 Edition of IEEE 344 as another means to demonstrate qualification of a device. Section 4 "Seismic Qualification Approach" lists four general categories for qualification methods. As per Section 4: "The methods are grouped into four general categories that

1) Predict the equipment's performance by analysis
2) Test the equipment under simulated seismic conditions
3) Qualify the equipment by a combination of test and analysis
4) Qualify the equipment through the use of experience data

Each of the preceding methods, or other justifiable methods, may be adequate to verify the ability of the equipment to meet seismic qualification requirements."

This Fisher qualification program uses option 2 in lieu of experience data.

In summary, the Fisher Qualification Report (FQR) prepared for the Type 546 is an accurate representation of the testing that was conducted as part of the initial Type 546 qualification program. This test program was designed for a particular customer application with the testing and results summarized in the FQRs available to other customers. The intent of the FQR is not to demonstrate full compliance to a standard or a specific customer application. The purpose of the FQR is to present the test sequence and results to customers and allow them to determine where in their plant the Type 546 could be used.

Based on the above discussion, Fisher does not believe any further actions are necessary.

Attachment 3
Reply to NRC Notice of Nonconformance 99900105/2019-201-02
Docket Number 99900105
Inspection Report No 99900105/2019-201

This attachment 3 sets forth the reply of Fisher Controls International LLC ("Fisher") to the NRC's Notice of Nonconformance dated January 8, 2020 relative to NRC Inspection Report 99900105/2019-201 (the "Inspection Report"), Notice of Nonconformance 99900105/2019-201-02 (the "Nonconformance").

The Notice of Nonconformance 99900105/2019-201-02
The Notice of Nonconformance provides the following description:

> "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 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 electropneumatic transducers.
>
> This issue has been identified as Nonconformance 99900105/2019-201-02."

Fisher's Response to the Notice of Nonconformance – Part 1 of 7

Fisher is contesting the Nonconformance with the following clarifications.

The following addresses item 1; Item 1 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E 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."
>
> Specifically, the following addresses the first concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The first concern provides the following description:
>
> > "The NRC inspection team noted that Fisher 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 1 E Equipment for Nuclear Power Generating Stations."
> >
> > Fisher failed to demonstrate and consider interfaces using a connected air operated valve or pneumatic positioner."

Reason for the contesting of the Notice of Nonconformance

Section 5.4 Combined Methods, states, "...where size, application, time, or other limitations preclude the use of a type test on the complete equipment assembly, type testing of components supplemented by analysis may be used in the qualification process." The interfaces for the Type 546NS I/P transducer are:

1) 4 to 20mA input signal
2) Supply air connection (5psi higher than upper range limit of output signal)
3) 3 to 15psig air output
4) Mounting

During the testing program conducted at Thermodyne the Device Under Test (DUT) connections supplying the input signal and the supply air, and the connection for the output air were similar to those that would be used in a plant. The DUT was mounted directly to a shake table using mounting bracket 35A4153 which was the standard seismic bracket used to mount a Type 546 to an actuator as discussed in Section 4.5 of the FQR.

During the entirety of the testing, the Type 546 output was connected to a 100in3 volume tank with a pressure gauge between the Type 546 output and the volume tank input. This volume tank is approximately the size of a Fisher Type 657 Size 40 actuator casing.

Fisher's Response to the Notice of Nonconformance – Part 2 of 7

The following addresses item 2; Item 2 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E Equipment for Nuclear Power Generating Stations":
>
> > 2. Demonstrate that qualification testing was performed with service conditions and equipment specification considering a 10-50mA direct current design input."
>
> Specifically, the following addresses the second concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The second concern provides the following description:
>
> > "Fisher did not demonstrate, identify or evaluate a 10mA - 50mA DC design input."

Reason for the contesting of the Notice of Nonconformance

The 10mA-50mA version of the Type 546 is mechanically similar to the 4mA-20mA version that was tested. Construction materials are the same between the two versions. The differences between the two devices are as follows:

- The 10mA-50mA version contains a different bellows assembly with a higher spring rate. This higher spring rate is less susceptible to seismic input than the bellows in the 4mA-20mA construction.

- The 10mA-50mA version contains fewer coil windings in order to incorporate the differing signal input and pressure output. The wires are the same material and similar configuration to the 4mA-20mA construction.

These differences have no impact on overall device qualification.

Fisher's Response to the Notice of Nonconformance – Part 3 of 7

The following addresses the third concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The third concern provides the following description:

> "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."

Reason for the contesting of the Notice of Nonconformance

During seismic testing, signal input was changed at each frequency tested per the below table. It would be expected that a plant could be operating at any of the given pressure inputs at any time. The testing showed that the device output psi corresponded to the mA input signal at all of the tested frequencies. Additionally, functional testing with a modulated input signal (similar to the baseline functional

test) was performed during the LOCA/MSLB testing. This is referenced in Attachment F to the FQR.

Frequency (Hz)	Input Signal (mA)	Output Signal (psi)
3	12	9
5	16	12
7	20	15
9	16	12
11	12	9
14	8	6
17	6	4.5
20	4	3
25	6	4.5
32	8	6
40	12	9

Fisher's Response to the Notice of Nonconformance – Part 4 of 7

The following addresses item 3; Item 3 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E Equipment for Nuclear Power Generating Stations":
>
> > 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."
>
> Specifically, the following addresses the fourth concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The fourth concern provides the following description:
>
> > "Fisher 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)."

Reason for the contesting of the Notice of Nonconformance

The Activation Energy used in this testing is based on previous Fisher testing conducted under Fisher Lab Report 1685-3-11. Based on the results of that testing, an Activation Energy of [redacted] is considered conservative for EPDM components.

The nylon bobbin is a static component in this assembly. Dynamic components such as the EPDM/Nomex diaphragm have a functional requirement for continued operation. Material degradation of the nylon bobbin would be inconsequential.

Fisher's Response to the Notice of Nonconformance – Part 5 of 7

The following addresses item 4; Item 4 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E Equipment for Nuclear Power Generating Stations":
>
> > 4. Identify and evaluate the required maintenance during the aging portion of the qualification testing for the relay and feedback bellows replacement."
>
> Specifically, the following addresses the fifth concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The fifth concern provides the following description:
>
> > "Fisher 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."

Reason for the contesting of the Notice of Nonconformance

Section 5.0 of the FQR, titled *Maintenance Requirements* provides recommendations for maintenance of the Type 546. Reference is made to the Instruction Manual which is publicly available online. During qualification testing, no device maintenance was necessary or conducted.

Fisher's Response to the Notice of Nonconformance – Part 6 of 7

The following addresses item 5; Item 5 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E Equipment for Nuclear Power Generating Stations":
>
> > 5. Adequately calibrate the test specimen prior to baseline testing."
>
> Specifically, the following addresses the sixth concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The sixth concern provides the following description:
>
> > "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)"

Reason for the contesting of the Notice of Nonconformance

Prior to any qualification testing, the Type 546 was subjected to baseline functional testing in order to establish a starting point for device performance. The results of this baseline functional testing are documented in the FQR. These results show the Type 546 performed as expected, within published performance criteria, prior to the start of any qualification testing.

Fisher's Response to the Notice of Nonconformance – Part 7 of 7

The following addresses item 6; Item 6 provides the following description:

> "Fisher failed to meet the requirements listed below in accordance with the 1983 Edition of IEEE standard No. 323, "Standard for Qualifying Class 1 E Equipment for Nuclear Power Generating Stations":
>
> > 6. Evaluate how eight test anomalies affected the qualification of the electropneumatic transducers."
>
> Specifically, the following addresses the seventh concern raised in the Design Control – Environmental Qualification portion of the Report Details section of NCR Report No. 99900105/2019-201; The seventh concern provides the following description:
>
> > "Thermodyne's EQ Test Report No. 4F-3-1-2 identified eight test anomalies and Fisher Controls did not open any nonconformances or corrective actions to evaluate how the anomalies affected the qualification of the 546NS electropneumatic transducers or determine if the anomalies could invalidate the qualification."

Reason for the contesting of the Notice of Nonconformance

The Thermodyne Test Report does not identify any test anomalies.

The "eight test anomalies" discussed in the NRC report are a reference to a post-test evaluation of the overall test program. After all testing was completed and documented, Fisher prepared an independent document listing eight points of consideration for future testing. Fisher has confirmed with a 40+year Fisher employee familiar with this test program that this document was prepared by Fisher at the conclusion of the test program. This document is titled *Critique – Report 4F-3-1-2, Rev. 0 (For Planning Future 546 I/P Test Programs).* These points do not have an impact on device qualification and are instead suggestions for additional items to consider during any future test program.

In summary, the Fisher Qualification Report (FQR) prepared for the Type 546 is an accurate representation of the testing that was conducted as part of the initial Type 546 qualification program. This test program was designed for a particular customer application with the testing and results summarized in the FQRs available to other customers. The intent of the FQR is not to demonstrate full compliance to a standard or a specific customer application. The purpose of the FQR is to present the test sequence and results to customers and allow them to determine where in their plant the Type 546 could be used.

Based on the above discussion, Fisher does not believe any further actions are necessary.