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USA

October 21, 2020

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

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

References: 1) NRC Revised Notice of Nonconformance 99900105/2019-201-01.
2) NRC Revised Notice of Nonconformance 99900105/2019-201-02.
3) NRC Report No. 99900105/2019-201
4) NRC Independent Assessment of Nonconformances, 99900105/2019-201-01 AND -02

Fisher Controls International LLC ("Fisher") hereby responds to the aforementioned Revised Notices of Nonconformance (Reference 1 & 2), dated September 21, 2020 and received by Fisher on September 24, 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 Savvoir, and revised during the Independent Assessment of Nonconformances, 99900105/2019-201-01 AND -02 conducted by Christopher Miller.

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,

A handwritten signature in black ink, appearing to read 'Jacob Cies', with a large, stylized flourish extending from the end.

Jacob Cies
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.

IE09
NRR

Attachment 1
Reply to Revised NRC Notice of Nonconformance 99900105/2019-201-01
Docket Number 99900105
Inspection Report No 99900105/2019-201

This attachment 1 sets forth the reply of Fisher Controls International LLC ("Fisher") to the NRC's Revised Notice of Nonconformance dated September 21, 2020 relative to NRC Inspection Report 99900105/2019-201 (the "Inspection Report") dated January 8, 2020, Notice of Nonconformance 99900105/2019-201-01 (the "Nonconformance").

The Revised Notice of Nonconformance

The Revised 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."

Purchase Order 02385926, Rev. 6 (Florida Power & Light's Turkey Point Nuclear Plant), stated, in part, that the vendor shall certify the 546NS Electro-pneumatic Transducer is qualified in accordance with IEEE 344-1975 / 19872, "IEEE Recommended Practices for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations;" and, that the order was to be processed in accordance with Appendix B to 10 CFR Part 50.

Contrary to the above, as of November 8, 2019, Fisher Controls failed to conduct adequate testing to demonstrate suitable qualification testing of a prototype unit of the Type 546NS electro-pneumatic transducer under the most adverse design conditions as required in Florida Power & Light (FPL) Purchase Order 02385926, Rev. 6. Specifically, Fisher Controls failed to perform the operating basis earthquake and safe shutdown earthquake qualification testing in accordance with IEEE 344-1975/1987 standards to demonstrate that the Type 546NS electro-pneumatic transducers provided to FPL's Turkey Point Nuclear Plant could withstand the effects of site-specific earthquakes without the loss of capability to perform its intended safety function during and after a design basis seismic event.

Fisher's Response to the Notice of Nonconformance

Fisher is not contesting the Revised Nonconformance and has taken steps to address the issues identified in the Independent Assessment of Nonconformances. Fisher believes these changes represent an improvement to its quality assurance program.

I. Reason for the Notice of Nonconformance

Fisher certified the order to the procurement requirements per the purchase order and not the applicable testing listed in the qualification report, subsequently not meeting the IEEE 344-1975 / 1987 standards specified in the purchase order.

II. Corrective Steps Taken and Results Achieved

In response to Nonconformance 99900105/2019-201-01, Fisher has issued Corrective Action 1924 to address the procurement requirements. Fisher took the following steps:

Fisher Manufacturing Procedure 2Q12 "Nuclear Order Processing System – Determination of Project/Order Processing Requirements" was revised to include a requirement for all orders not requiring a mandatory Specification and Design Review, the Project Manager shall coordinate an internal alignment meeting with Application Engineering. The internal alignment meeting is to define and communicate order scope, schedule, objectives, specifications and requirements to the internal stakeholders who will have contribution to the execution of the order. The Technical Consultant Group will be asked for input as necessary.

Fisher Manufacturing Procedure 2Q12 - Form 1, "Nuclear/Safety Related Order Processing Instructions" was revised to include an internal alignment meeting selection.

Fisher Manufacturing Procedure 2Q11 - Form 2, "Nuclear Order Screening Process" was revised to give responsibility to Application Engineering for ensuring that all quoted exceptions have been acknowledged and accepted by the customer in the purchase order or customer document referring the purchase order. The Project Manager will only review the purchase order for complete acceptance of Fisher Quote. This form specifically details the checks required to verify that an order is complete and enterable.

Training of affected personnel was completed on October 7, 2020 and October 8, 2020.

A review of all 546 FQR Reports was completed on October 20, 2020 to ensure the purchase order requirements were met.

III. Corrective Steps That Will Be Taken

As noted above, all outstanding actions have been completed.

IV. Date Full Compliance Achieved

The steps to improve the process have been implemented and Fisher respectfully asserts that it is in full compliance as of the date of this reply.

Attachment 2
Reply to NRC Revised Notice of Nonconformance 99900105/2019-201-02
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 Revised Notice of Nonconformance dated September 21, 2020 relative to NRC Inspection Report 99900105/2019-201 (the "Inspection Report") dated January 8, 2020, Notice of Nonconformance 99900105/2019-201-02 (the "Nonconformance").

The Revised Notice of Nonconformance

The Revised 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."

Purchase Order 02385926, Rev. 6 (Florida Power & Light's Turkey Point Nuclear Plant), stated, in part, the vendor shall certify the 546NS Electro-pneumatic Transducer is qualified in accordance with IEEE 323-1974 / 1983, "Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations" (Harsh Environment); and, that the order was to be processed in accordance with 10CFR50, Appendix B Program.

Contrary to the above, as of November 8, 2019, Fisher Controls failed to conduct adequate testing to demonstrate suitable qualification of a prototype unit of the Type 546NS electro-pneumatic transducer under the most adverse design conditions as required in Florida Power & Light (FPL) Purchase Order 02385926, Rev. 6. In addition, Fisher Controls failed to appropriately perform testing in accordance with IEEE 323-1974/1983 standards to demonstrate that the 546NS electro-pneumatic transducers could perform their intended safety function. Specifically, Fisher Controls failed to:

1. Test the electro-pneumatic transducers in a configuration similar to how it would be used once installed in a system at the plant.
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. Document in the qualification report whether device maintenance was necessary or conducted during qualification testing.
5. Adequately calibrate the test specimen prior to baseline testing.
6. Evaluate how eight test anomalies affected the qualification of the electro-pneumatic transducers.

Fisher's Response to the Notice of Nonconformance

Fisher is not contesting the Revised Nonconformance and has taken steps to address the issues identified in the Independent Assessment of Nonconformances. Fisher believes these changes represent an improvement to its quality assurance program.

I. Reason for the Notice of Nonconformance

Fisher certified the order to the procurement requirements per the purchase order and not the applicable testing listed in the qualification report, subsequently not meeting the IEEE 323-1974 / 1983 standards specified in the purchase order.

II. Corrective Steps Taken and Results Achieved

In response to Nonconformance 99900105/2019-201-02, Fisher has issued Corrective Action 1925 to address the procurement requirements. Fisher took the following steps:

Fisher Manufacturing Procedure 2Q12 "Nuclear Order Processing System – Determination of Project/Order Processing Requirements" was revised to include a requirement for all orders not requiring a mandatory Specification and Design Review, the Project Manager shall coordinate an internal alignment meeting with Application Engineering. The internal alignment meeting is to define and communicate order scope, schedule, objectives, specifications and requirements to the internal stakeholders who will have contribution to the execution of the order. The Technical Consultant Group will be asked for input as necessary.

Fisher Manufacturing Procedure 2Q12 - Form 1, "Nuclear/Safety Related Order Processing Instructions" was revised to include an internal alignment meeting selection.

Fisher Manufacturing Procedure 2Q11 - Form 2, "Nuclear Order Screening Process" was revised to give responsibility to Application Engineering for ensuring that all quoted exceptions have been acknowledged and accepted by the customer in the purchase order or customer document referring the purchase order. The Project Manager will only review the purchase order for complete acceptance of Fisher Quote. This form specifically details the checks required to verify that an order is complete and enterable.

Training of affected personnel was completed on October 7, 2020 and October 8, 2020.

A review of all 546 FQR Reports was completed on October 20, 2020 to ensure the purchase order requirements were met.

In addition to Corrective Action 1925, Fisher has included responses to each of the (6) items for customer consideration. These responses are now included as an Appendix to all 546 FQR Reports. Additionally, for item 6, Fisher has evaluated each of the eight points discussed. The results of this evaluation are documented in the project file associated with the original device qualification.

III. Corrective Steps That Will Be Taken

As noted above, all outstanding actions have been completed.

IV. Date Full Compliance Achieved

Fisher respectfully asserts that it is in full compliance as of the date of this reply.