



7/2/15 Original
JH
Gubli 2
Sunsi complete

Fisher Controls International LLC
301 South First Ave.
P.O. Box 190
Marshalltown, Iowa 50158-0190
USA

June 15, 2015

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

Subject: Reply to NRC Inspection Report No. 99900105/2015-201, Notice of Nonconformance

References: 1) NRC Notice of Nonconformance 99900105/2015-201-01.
2) NRC Report No. 99900105/2015-201

Fisher Controls International LLC ("Fisher Controls") hereby responds to the aforementioned Notice of Nonconformance (Reference 1), dated May 22, 2015 and received by Fisher Controls on May 29, 2015. The nonconformance was identified during the Nuclear Regulatory Commission's ("NRC") inspection (Reference 2) of Fisher Controls' Marshalltown, Iowa facility, conducted April 13-17, 2015 by inspectors Aixa Belen-Ojeda, Jonathan Ortega-Luciano, Raju Patel, Paul Prescott, Andrea Keim, and Jason Christensen

Attached, please find Fisher Controls' reply to the Notice of Nonconformance (Reference 1).

Fisher Controls 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)754-2249 if you have any questions or need to discuss this matter further.

Sincerely,

Ben Ahrens
Manager, Quality
Fisher Controls International LLC

Attachments

cc: Edward H. Roach, Chief, Mechanical Vendor Inspection Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.



IE09
NRO

Attachment 1
Reply to NRC Notice of Nonconformance 99900105/2015-201-01
Docket Number 99900105
Inspection Report No 99900105/2015-201

This attachment 1 sets forth the reply of Fisher Controls International LLC ("Fisher Controls") to the NRC's Notice of Nonconformance dated May 22, 2015 relative to NRC Inspection Report 99900105/2015-201 (the "Inspection Report"), Notice of Nonconformance 99900105/2015-201-01 (the "Nonconformance").

The Notice of Nonconformance

The Notice of Nonconformance provides the following description:

"Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Processing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states that: "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Section 17.1.4 of Fisher Controls "ASME Section III, Division 1 Nuclear Quality Assurance Manual," Revision 13 dated November 15, 2014, states that "The department Manager or supplier responsible for the nonconformity shall determine and implement the corrective action required, both immediate and to preclude recurrence, and shall report such action on the corrective action request (CAR) form. The corrective action shall define the cause of the nonconformity, action taken to prevent reoccurrence, and schedule of corrective action implementation to the Manager Quality."

Contrary to the above, as of April 17, 2015, Fisher Controls failed to ensure that conditions adverse to quality were promptly identified and corrected, and also failed to ensure that significant conditions adverse to quality were corrected to preclude repetition.

Specifically:

1. Fisher Controls failed to provide adequate corrective action in response to NRC 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 in Appendix B to 10 CFR Part 50. The NRC inspection team verified that Fisher Controls had implemented the corrective action for NON 99900105/2011-201-05 as documented in a letter from Fisher Controls to the NRC dated October 12, 2011. The NRC inspection team determined that the revision made to FMP 2K9, "Procedure for Corrective Action," Revision 25 dated April 1, 2015, as part of the corrective action, was inadequate because the procedure did not provide a process to differentiate between a significant condition adverse to quality and a condition adverse to quality. Specifically, this revision did not include adequate instructions to allow the user to identify when a significant conditions adverse to quality has occurred and to ensure that; (1) the cause of the significant condition is determined; (2) corrective action are taken to preclude repetition; and (3) that appropriate levels

of management be notified of the significant condition adverse to quality, the cause of the condition, and the corrective action taken to preclude repetition.

2. Fisher Controls failed to ensure that the corrective actions taken for CAR 1551 dated April 9, 2012, related to a significant condition adverse to quality, were sufficient to preclude repetition. CAR 1551 was generated as a result of Fisher Controls' failure to include the thrust plate and the thrust plate cap screw, which are considered essential-to-function, as part of the dedication plan for a Type 9500 Butterfly valve. As part of the corrective actions, Fisher Controls revised the dedication plans only for the Type 9500 Butterfly valve design. However, the NRC inspection team identified that Fisher Controls issued CAR 1570 on October 12, 2012 and CAR 1644 on August 30, 2013, for their failure to dedicate essential-to-function commercial parts that were procured for a Type 9200 Butterfly valve and for valve actuators respectively. The NRC inspection team determined that the corrective actions taken by Fisher Controls as part of CAR 1551 were not adequate to ensure that the significant conditions adverse to quality, in the area of commercial grade dedication, were corrected to preclude repetition. The potential impact for the inadequate commercial grade dedication could impede the ability of the valves to perform their intended safety function.

3. Fisher Controls failed to ensure that the corrective actions taken for CAR 1697 dated June 30, 2014, were adequate. CAR 1697 was generated as a result of a supplier service request documenting that Fisher Controls provided the wrong elastomer material as required by Entergy procurement order (PO) 10383263 for pressure regulator FS67CFR-239. Fisher Controls was required by the PO to provide the pressure regulator with a Nitrile elastomer, instead it was provided with a Viton elastomer. During the investigation, Fisher Controls identified that the 'Material List', used by Engineering to select the correct material to withstand radiation capabilities, was incorrect. The 'Material List' generated by Fisher Controls' engineers listed Viton as having higher radiation capabilities than Nitrile, but those numbers were reversed when the list was created. The NRC inspection team identified that Fisher Controls did not generate corrective actions to maintain configuration controls for a reference 'Materials List' that is essential for maintaining original design configuration.

This issue has been identified as Nonconformance 99900105/2015-201-01."

Fisher Controls' Response to the Notice of Nonconformance – Part 1 of 3

Fisher Controls is not contesting the Nonconformance and has taken steps to address the issues identified in the Inspection Report. Fisher Controls believes these changes represent an improvement to its program and are designed to prevent reoccurrence.

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

"1. Fisher Controls failed to provide adequate corrective action in response to NRC 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 in Appendix B to 10 CFR Part 50. The NRC inspection team verified that Fisher Controls had implemented the corrective action for NON 99900105/2011-201-05 as documented in a letter from Fisher Controls to the NRC dated October 12, 2011. The NRC inspection team determined that the revision made to FMP 2K9, "Procedure for Corrective Action," Revision 25 dated April 1, 2015, as part of the corrective action, was

inadequate because the procedure did not provide a process to differentiate between a significant condition adverse to quality and a condition adverse to quality. Specifically, this revision did not include adequate instructions to allow the user to identify when a significant conditions adverse to quality has occurred and to ensure that; (1) the cause of the significant condition is determined; (2) corrective action are taken to preclude repetition; and (3) that appropriate levels of management be notified of the significant condition adverse to quality, the cause of the condition, and the corrective action taken to preclude repetition."

I. Reason for the Notice of Nonconformance

Fisher Controls' Implementing Procedure FMP 2K9 did not clearly differentiate between a 'Significant Condition Adverse to Quality' and a "Condition Adverse to Quality". Further, while the CAR process did include all the quality requirements listed in 10 CFR Part 50 Appendix B, Requirement 16, there was no differentiation between the processing requirements for a Significant Condition Adverse to Quality and that of a Condition Adverse to Quality.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, the Inspectors made Fisher Controls aware of the NRC's expectation that it is necessary to differentiate 'Significant Conditions Adverse to Quality' from 'Conditions Adverse to Quality'. In response to this expectation, Fisher Controls issued internal Corrective Action Report 1744 on April 16, 2015. Pursuant to this CAR, Fisher Controls took the following Steps:

Fisher Controls revised Corrective Action Procedure FMP2K9 to include a clear definition of Significant Condition Adverse to Quality, along with a differentiated processing requirement from that of a Condition Adverse to Quality. Specifically, a Significant Condition Adverse to Quality requires that a Fisher Controls 8D evaluation be performed to assure the cause of the condition is determined, proper actions are developed to eliminate the root cause, and corrective actions are put in place to preclude repetition. Additionally, Corrective Action Procedure FMP2K9 was revised to ensure that appropriate levels of management are notified.

III. Corrective Steps That Will Be Taken

All outstanding actions have been completed.

IV. Date Full Compliance Achieved

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

Fisher Controls' Response to the Notice of Nonconformance – Part 2 of 3

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

"2. Fisher Controls failed to ensure that the corrective actions taken for CAR 1551 dated April 9, 2012, related to a significant condition adverse to quality, were sufficient to preclude repetition. CAR 1551 was generated as a result of Fisher Controls' failure to include the thrust plate and the thrust plate cap screw, which are considered essential-to-function, as part of the dedication plan for a

Type 9500 Butterfly valve. As part of the corrective actions, Fisher Controls revised the dedication plans only for the Type 9500 Butterfly valve design. However, the NRC inspection team identified that Fisher Controls issued CAR 1570 on October 12, 2012 and CAR 1644 on August 30, 2013, for their failure to dedicate essential-to-function commercial parts that were procured for a Type 9200 Butterfly valve and for valve actuators respectively. The NRC inspection team determined that the corrective actions taken by Fisher Controls as part of CAR 1551 were not adequate to ensure that the significant conditions adverse to quality, in the area of commercial grade dedication, were corrected to preclude repetition. The potential impact for the inadequate commercial grade dedication could impede the ability of the valves to perform their intended safety function."

I. Reason for the Notice of Nonconformance

Fisher Controls' Implementing Procedure FMP 2K9 did not clearly define a process to determine the extent of condition of a 'Condition Adverse to Quality' or that of a 'Significant Condition Adverse to Quality'.

II. Corrective Steps Taken and Results Achieved

Pursuant to Fisher Controls internal CAR 1745 issued April 16, 2015 Fisher Controls revised Corrective Action Procedure FMP2K9 to include a Corrective Action Review Board process that shall be initiated for each Significant Condition Adverse to Quality prior to the closure of the Corrective Action. This Review Board will consist of appropriate levels of management and subject matter experts, and is charged with determining the extent of condition and subsequent actions necessary for adequate containment of the Significant Condition Adverse to Quality.

Fisher Controls also reviewed all Corrective Actions related to Significant Conditions Adverse to Quality and 10CFR Part 21 that were identified since the last NRC inspection (August 2011) using the Corrective Action Review Board process to confirm the extent of condition was properly identified.

III. Corrective Steps That Will Be Taken

All outstanding actions have been completed.

IV. Date Full Compliance Achieved

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

Fisher Controls' Response to the Notice of Nonconformance – Part 3 of 3

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

"3. Fisher Controls failed to ensure that the corrective actions taken for CAR 1697 dated June 30, 2014, were adequate. CAR 1697 was generated as a result of a supplier service request documenting that Fisher Controls provided the wrong elastomer material as required by Entergy procurement order (PO) 10383263 for pressure regulator FS67CFR-239. Fisher Controls was required by the PO to provide the pressure regulator with a Nitrile elastomer, instead it was provided with a Viton elastomer. During the investigation, Fisher Controls

identified that the 'Material List', used by Engineering to select the correct material to withstand radiation capabilities, was incorrect. The 'Material List' generated by Fisher Controls' engineers listed Viton as having higher radiation capabilities than Nitrile, but those numbers were reversed when the list was created. The NRC inspection team identified that Fisher Controls did not generate corrective actions to maintain configuration controls for a reference 'Materials List' that is essential for maintaining original design configuration."

I. Reason for the Notice of Nonconformance

Specifically with regard to the Entergy PO 10383263 for pressure regulator FS67CFR-239 investigated in Fisher Control CAR 1697: The design package identified both Nitrile and Viton as being suitable materials. The selection of the Viton material was based on the customer's stated environmental conditions and was offered as an enhancement to Nitrile. The customer reviewed and accepted this material based on suitability for their service prior to Fisher Controls' fulfillment of the order.

To address the issue of the radiation resistance data contained within the 'Materials List': The 'Materials List' discussed during the inspection is a reference library maintained exclusively by Fisher Controls' Materials Engineering group and is a resource that is independent from design control. Design configuration control, including suitable material selection, is handled by the product design packages and supported by internal standards as well as published industry standards. The information contained within the 'Material List' had no basis on the selection of the Viton material supplied to Entergy; however, the finding raised an issue that elastomer radiation capabilities were not maintained in a revision-controlled document.

II. Corrective Steps Taken and Results Achieved

Pursuant to Fisher Controls' internal CAR 1697 issued June 30, 2014 Fisher Controls Materials Engineering verified that no other errors were present in the 'Materials List' in regards to elastomer radiation capabilities. Fisher Controls also verified that radiation capabilities are the only characteristic in the 'Materials List' that is used for Nuclear product design configuration.

III. Corrective Steps That Will Be Taken

Pursuant to Fisher Controls internal CAR 1752 issued June 12, 2015, an engineering standard is being written that will contain the radiation capabilities of all elastomers used in nuclear applications by Fisher Controls. Review and approval, as well as approval of revisions, will be controlled per the Nuclear Quality Assurance Manual.

IV. Date Full Compliance Achieved

Fisher Controls will complete the outstanding corrective action steps to be taken by August 3rd, 2015.