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United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-001

Subject: Reply to NRC Inspection Report No. 99900105/2011-201, Notice of Violation and Notice of Nonconformance

References: 1) NRC Notice of Violation Docket Number 99900105/2011-201-01
2) NRC Notice of Nonconformance Docket Number 99900105/2011-201-02
3) NRC Notice of Nonconformance Docket Number 99900105/2011-201-03
4) NRC Notice of Nonconformance Docket Number 99900105/2011-201-04
5) NRC Notice of Nonconformance Docket Number 99900105/2011-201-05
6) NRC Notice of Nonconformance Docket Number 99900105/2011-201-06
7) NRC Report 99900105/2011-201

Fisher Controls International LLC ("**Fisher Controls**") hereby responds to the aforementioned Notice of Violation and Notice of Nonconformance (Reference 1 through 6), dated September 13, 2011 and received by Fisher Controls on September 20, 2011. The violation and nonconformances were identified during the Nuclear Regulatory Commission's ("**NRC**") inspection (Reference 7) of Fisher Controls' Marshalltown, Iowa facility, conducted August 1-5, 2011, by inspectors Yamir Diaz-Castillo, Samantha Crane, Douglas Bollock, Paul Coco, Aixa Belen-Ojeda, Steven Downey, Tuan Le, and Robert Latta.

Attached, please find Fisher Controls' reply to References 1, 2, 3, 4, 5, and 6.

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)754-2026 if you have any questions or need to discuss this matter further.

Sincerely,

George Baitinger
Manager Quality
Fisher Controls International LLC

Attachments

cc: Juan Peralta, Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, United States Nuclear Regulatory Commission, Washington, DC 20555-0001



JE09

Attachment 1
Reply to NRC Notice of Violation
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 1 sets forth the reply of Fisher Controls International LLC (“**Fisher Controls**”) to the NRC’s Notice of Violation dated September 13, 2011, relative to NRC Inspection Report 99900105/2011-201 (the “**Inspection Report**”), Notice of Violation **99900105/2011-201-01** (the “**Notice of Violation**”).

The Notice of Violation

“Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21(a), “Notification of failure to comply or existence of a defect and its evaluation,” requires, in part, that “[e]ach individual, corporation, partnership, or other entity subject to the regulations in this part shall adopt appropriate procedures to -- (2) [e]nsure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted in writing to the Commission. . . within 60 days of discovery of the deviation or failure to comply.”

Section 8c of Fisher General Specification 15B76, “Reporting of Potential Defects and Noncompliance in Accordance with 10 CFR Part 21, US Code of Federal Regulations,” Revision D, dated June 2, 2011, states, in part, that “if an evaluation of the deviation cannot be completed within 60 days, an interim report must be submitted to the NRC by the Director, Quality-Valve Division.”

Contrary to the above, as of August 5, 2011, Fisher Controls International LLC did not complete an evaluation and failed to prepare and submit in writing to the Commission an interim report within 60 days of discovery of an identified deviation or failure to comply potentially associated with a substantial safety hazard. Specifically, Fisher Controls did not complete its evaluation, nor prepared and submitted an interim report to the Commission for an ongoing 10 CFR Part 21 evaluation initially identified on March 3, 2011.

This issue has been identified as Violation 99900105/2011-201-01.

This is a Severity Level IV violation (Section 6.5.d of the NRC Enforcement Policy).”

Fisher Controls’ Response to the Notice of Violation

By way of background, during a survey of Fisher Controls’ casting supplier, Brafe Engineering, LTD (“**Brafe**”), in March of 2011, Fisher Controls detected that weld rods procured by Brafe and intended for their use to fulfill nuclear orders may not meet the qualifications of ASME 2010 NCA_3800 as set forth in Fisher Controls’ procurement documentation, but rather, had been qualified on the basis of ISO 9001. As a result, Fisher Controls reviewed the Brafe items ordered and delivered since Fisher Controls’ last survey of Brafe in 2008, for evidence of deviation or non-compliance resulting from Brafe’s failure to qualify the weld rods per the technical requirements of Fisher Controls’ procurement documentation. None of the castings procured from Brafe required weld repair, therefore, no weld rod material was used by Brafe in these castings, and therefore there were no deviations or non-compliances.

Fisher Controls historically interpreted the term “discovery”, as used in 10 CFR Part 21, to mean the completion of documentation first identifying the existence of a deviation or failure to comply

potentially associated with a substantial safety hazard. In the situation referenced in the Notice of Violation, Fisher Controls' assessment of its applicable product inventory confirmed there was no product affected by a deviation or failure to comply; therefore, there was no "discovery" as Fisher Controls understood the term to be defined.

Thus, Fisher Controls' evaluation of whether a particular deviation or failure to comply created a substantial hazard would have begun to toll sixty (60) days from the date Fisher Controls documented the existence of non-certified product identified at Fisher Controls' facility, not from the time of the March, 2011 survey.

Understanding that circumstances can differ, in furtherance of substantiating Fisher Controls' good faith effort to comply with 10 CFR Part 21, the following NRC responses to questions concerning 10 CFR Part 21 appear to be consistent with Fisher Control's historic interpretation. See "NRC Responses to 10 CFR Part 21 and Fuel Cycle Facility Questions Received During the Vendor Workshop on New Reactor Construction in December 2008", dated July 15, 2009 (ADAMS #ML090930116) :

"Question 30:
When does a vendor identify deviations?"

Answer:
A vendor identifies deviations only after the basic component has been offered for use, i.e., shipped to a purchaser of a basic component. A departure from procurement specifications which the vendor identifies before the vendor offers the SSC for use as a basic component (i.e., before shipment to the purchaser) is not a deviation. Such departures should be addressed through the vendor's quality assurance program."

"Question 31:
With respect to "discovery," using an example of stainless steel versus carbon steel bolts: what if during inventory check it is found that there are two extra carbon steel bolts and two missing stainless steel bolts but the vendor does not know when the discrepancy occurred. The vendor reviews records and finds (one month later) that the stainless steel bolts were shipped to Springfield Nuclear. When does the discovery clock start: when they identified the discrepancy or when they determined that the two stainless steel bolts were shipped to Springfield Nuclear?"

Answer:
Discovery, as defined in § 21.3, is the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard. Therefore, the discovery occurs once the supplier documents that the incorrect bolts were shipped to Springfield Nuclear as basic components (i.e., safety-related SSCs)."

Fisher Controls is not contesting the Violation and has taken steps to address the Violation identified in the Inspection Report. While Fisher Controls believes its corrective action in response to the Notice of Violation represents an improvement to its quality assurance program, Fisher Controls respectfully contends that its program met the requirements of 10 CFR Part 21 prior to the implementation of this corrective action, as explained above.

I. Reason for the Notice of Violation

Fisher Controls historically interpreted the term "discovery", as used in 10 CFR Part 21, to mean the completion of documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard.

As explained above, Fisher Controls' review of the associated product revealed no evidence of the existence of a deviation or failure to comply; therefore, there was no "discovery" as Fisher Controls understood the term to be defined. Thus, the requirement to submit an Interim Report would not have been triggered by Fisher Controls' historic interpretation.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, the Inspectors made Fisher Controls aware of the NRC's expectation that Fisher Controls use the date of March 3, 2011, as the date of discovery, as this was the date in which Fisher Controls' survey of Brafе's operations revealed Brafе's failure to properly qualify weld rod.

In response to this expectation, Fisher Controls issued internal Corrective Action Request CAR 1505. Pursuant to the CAR, Fisher Controls took the following steps:

The actions included issuing an interim report to the NRC (NRC Event # 47123, Notification Date 08/04/2011). Please note: A follow-up interim report was issued by Fisher Controls to the NRC, dated August 23, 2011, confirming that no orders used the subject nonconforming material noted in the Notice of Violation and that no notification would be issued, per the requirements of 10CFR21.21(b), because a failure to comply condition did not exist.

Additionally, Fisher Controls employees making determinations of Part 21 compliance requirements were either involved in the implementation of CAR 1505 or were subsequently made aware of the Notice of Violation and CAR 1505. All such employees clearly understand the NRC's interpretation of what constitutes "discovery". Please also know that past and in-process potential Part 21 investigations were reviewed to confirm there were no other occurrences of missed sixty (60) day interim report requirements.

Further, Fisher Controls internal General Specification (FGS 15B76) was revised to clarify the requirement for an interim report when an investigation is not complete within sixty (60) days of discovery. This revision was completed during the course of the NRC Inspection (August 3, 2011) as reflected in Fisher Controls Engineering Change Request Notice No. 20112056.

On August 9, 2011, Fisher Controls internal Corrective Action Procedure (FMP 2K9) and the associated Request for Corrective Action (Form 2K9) were updated to require date of discovery be set forth in CAR.

Training of affected personnel was completed August 19, 2011.

III. Corrective Steps That Will Be Taken

As noted above, all outstanding actions have been completed. Additionally, going forward, Fisher Controls will continue to ensure that all welding consumables utilized by Brafе are purchased from an approved material organization. Last, all orders to be made at Brafе shall continue to be flagged and welding will not be performed until Brafе has correct weld rod available. All such consumables for nuclear work shall continue to be segregated and marked.

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.

Attachment 2
Reply to NRC Notice of Nonconformance A
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 2 sets forth the reply of Fisher Controls International LLC (“**Fisher Controls**”) to the NRC’s Notice of Nonconformance dated September 13, 2011 relative to NRC Inspection Report 99900105/2011-201 (the “**Inspection Report**”), Notice of Nonconformance **99900105/2011-201-02** (the “**Nonconformance-02**”).

The Notice of Nonconformance

The Notice of Nonconformance provides the following description of Nonconformance-02:

“Criterion III, “Design Control,” of Appendix B, “Quality Assurance Program 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 safety-related functions of the structures, systems, and components.”

Fisher Manufacturing Procedure (FMP) 2G19.3, “Material Verification Using Niton Alloy Analyzers,” Revision 8, dated November 14, 2005, states, in part, that “the test methods outlined in this procedure are intended to identify alloy materials and are not intended to establish the exact conformance of a material to a particular alloy specification.”

Contrary to the above, as of August 5, 2011, Fisher Controls failed to review for suitability of application materials that are essential to the safety-related functions of the structures, systems, and components. Specifically, Fisher Controls did not employ a suitable method to verify that a pin and a stud connection for a nuclear safety-related butterfly valve met the material specifications identified as critical characteristics in the associated dedication plans.

This issue has been identified as Nonconformance 99900105/2011-201-02.”

Fisher Controls’ Response to the Notice of Nonconformance

Fisher Controls is not contesting Nonconformance-02, but rather seeks to make the NRC aware of its good faith effort to comply with the requirements of Appendix B to 10 CFR Part 50 prior to the receipt of the Inspection Report.

Historically, Fisher Controls has made every attempt to obtain reasonable assurances that the methods used to identify critical characteristics in the associated dedication plans were suitable to the applicable safety-related function of the structure, system, part or component (“**Component(s)**”). It was Fisher Controls’ belief that its practice of using PMI and hardness tests to check the basic material constituents provided reasonable assurance that the Component in question was made of the material described in the purchase order or other procurement documentation for a given nuclear application. Fisher Controls has historically obtained all commercially dedicated Components from reliable, well-vetted sources – each of which were expected to have a quality assurance process that met or exceeded industry standards. Following a thorough review of its product records, Fisher Controls found no evidence of material-related problems with commercially dedicated parts supplied to it from such sources.

I. Reason for the Notice of Nonconformance

The dedication plans in question listed material as a critical characteristic. In order to inform the Fisher Controls inspector of the acceptance criteria for PMI, the material specification tied to the part number was displayed on the dedication plan. This was interpreted by the NRC inspector to mean that all of the requirements of the material specification were critical for the part to perform its intended safety function. As stated in Fisher Manufacturing Procedure 2G19.3, use of PMI is not intended to establish the exact conformance of a material to a particular alloy specification.

II. Corrective Steps Taken and Results Achieved

In response to Nonconformance-02, Fisher Controls issued internal Corrective Action Request CAR 1516. Pursuant to the CAR, Fisher Controls took the following steps:

A review of dedication plans has been implemented to clarify when all the requirements of a material specification are critical and require the use of Method 2, as defined by EPRI NP-5652 for verification. The critical characteristics of the material have been stated on the dedication plans to limit confusion. Inspectors have been trained to review all dedication plans to ensure that plans that list material specification as a critical characteristic, do not utilize PMI as a method to verify compliance to the specification.

For each item dedicated prior to October 6, 2011, that utilized PMI and listed the material specification on the dedication plan without clarification, Fisher Controls performed an engineering evaluation with the result that only some of the material characteristics were identified as critical. For all cases, the use of PMI was deemed to be adequate.

Training of affected personnel was completed October 5, 2011.

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.

Attachment 3
Reply to NRC Notice of Nonconformance B
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 3 sets forth the reply of Fisher Controls International LLC (“**Fisher Controls**”) to the NRC’s Notice of Nonconformance dated September 13, 2011 relative to NRC Inspection Report 99900105/2011-201 (the “**Inspection Report**”), Notice of Nonconformance **99900105/2011-201-03** (the “**Nonconformance-03**”).

The Notice of Nonconformance

The Notice of Nonconformance provides the following description of Nonconformance-03:

“Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50 states, in part, that “measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors.

FMP 2K47, “Supplier Qualification and Control,” Revision 2, dated June 3, 2010, states, in part, that “The nuclear buyer uses the ASL along with Purchasing Notes information in the supplier to ensure that proper requirements are passed on to the supplier by the Purchase Order (PO) or Purchase Order Appendix (POA). A POA should be attached to the PO in order to convey additional requirements to the supplier as applicable.

FMP 2K27, “Control of Commercial Grade Items to be Dedicated for Use in Nuclear Safety Related Applications,” Revision 15, dated October 15, 2010, states, in part, that “Commercial grade items which are to be produced and tested by the original equipment manufacturer may be purchased from the approved suppliers list (ASL) when the test is used as part of the dedication process. Procurement documents shall specify the required tests or controls as stated in the scope of qualification listed in the ASL.

Contrary to the above, as of August 5, 2011, Fisher Controls failed to impose the applicable requirements in procurement documents. Specifically, Fisher Controls failed to impose the requirements of Appendix B to 10 CFR Part 50 on two purchase orders for valve body forgings intended for use in a safety-related valve and failed to impose the required controls identified during a commercial grade survey that are necessary to verify the critical characteristics of a valve positioner.

This issue has been identified as Nonconformance 99900105/2011-201-03.”

Fisher Controls’ Response to the Nonconformance

Fisher Controls is not contesting Nonconformance-03 and has taken steps to address the issue identified in the Inspection Report. Fisher Controls believes these changes represent an improvement to its program.

I. Reason for the Notice of Nonconformance

Although the required language “10CFR Part 21 applies” was included on Fisher Controls’ purchase orders to Appendix B suppliers for safety-related items, the language “10 CFR Part 50 Appendix B” was not automatically included on such purchase orders.

Additionally, some items to be dedicated utilizing EPRI-5652 Method 2, that were not routed to the Nuclear Buyer and items procured without the required controls on the purchase order, including the valve positioner, were identified as nonconforming during dedication. Further, some purchase orders for items routed to the Nuclear Buyer did not impose all required controls necessary to verify critical characteristics of the commercial item.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, it was brought to Fisher Controls' attention that Fisher Controls failed to impose the requirements of Appendix B to 10 CFR Part 50 on two purchase orders for valve body forgings intended for use in a safety-related valve and that it had failed to impose the required controls identified during a commercial grade survey that are necessary to verify the critical characteristics of a valve positioner. In response to these observations, Fisher Controls issued internal Corrective Action Requests CAR1510 and 1511 on August 4, 2011. Pursuant to the CARs, Fisher Controls took the following steps:

The Approved Supplier List was updated to include the language "10CFR Part 50 Appendix B and 10CFR Part 21 apply" on purchase orders to Appendix B suppliers for safety-related items.

Items procured with only the language "10CFR Part 21 applies" on the purchase order were reviewed and found to meet the requirements of Appendix B to 10 CFR Part 50.

Items that were not routed to the Nuclear Buyer and items procured without the required controls on the purchase order, including the valve positioner, were identified as nonconforming during dedication. A change order was issued for the valve positioner to impose the required controls.

Planners and Nuclear Buyers were trained on the process for reviewing dedication plans for the purpose of identifying commercial items that will be dedicated utilizing Method 2. This process requires that affected purchase requisitions be forwarded to the Nuclear Buyer who will issue a purchase order that includes all required controls necessary to verify critical characteristics of the commercial item.

Training of affected personnel was completed 9/26/11.

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.

Attachment 4
Reply to NRC Notice of Nonconformance C
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 4 sets forth the reply of Fisher Controls International LLC ("**Fisher Controls**") to the NRC's Notice of Nonconformance dated September 13, 2011 relative to NRC Inspection Report 99900105/2011-201 (the "**Inspection Report**"), Notice of Nonconformance **99900105/2011-201-04** (the "**Nonconformance-04**").

The Notice of Nonconformance

The Notice of Nonconformance provides the following description of Nonconformance-04:

"Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Contrary to the above, as of August 5, 2011, Fisher Controls failed to provide objective evidence of quality by the contractor through commercial grade surveys. Specifically, Fisher Controls' commercial grade surveys of SIMCO Electronics and Honeywell Inc. did not verify the critical characteristics identified in the commercial grade survey checklist.

This issue has been identified as Nonconformance 99900105/2011-201-04."

Fisher Controls' Response to the Nonconformance

Fisher Controls is not contesting the Nonconformance-04 and has taken steps to address the issue identified in the Inspection Report.

I. Reason for the Notice of Nonconformance

Prior to the release of FMP2K43.1, on August 15, 2010, the Fisher Controls' checklist used in conjunction with commercial grade surveys of calibration service providers did not clearly identify critical characteristics to be verified. This created confusion with the Nuclear Lead Auditor and survey reviewer as to which questions required objective evidence of critical characteristic verification, resulting in a failure to document objective evidence to verify some critical characteristics.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, the Inspectors made Fisher Controls aware that the commercial grade surveys of SIMCO Electronics and Honeywell Inc. did not verify the critical characteristics identified in the corresponding commercial grade survey checklist. In response to this observation, Fisher Controls issued internal Corrective Action Request CAR 1507 on August 4, 2011. Pursuant to the CAR, Fisher Controls took the following steps:

Beginning August 15, 2010, Calibration Services Commercial Grade Survey, checklist FMP2K43.1, has been utilized and lists the critical characteristics that are required to be verified. A review by Fisher Controls Nuclear Lead Auditors was completed of all commercial grade surveys for calibration services performed prior to August 15, 2010. In addition to the

surveys for SIMCO Electronics and Honeywell Inc., identified in Nonconformance-04, a lack of objective evidence was found in the survey of MaxPro.

A new survey of SIMCO Electronics was completed August 16, 2011, with no adverse findings. A new survey of Honeywell Inc. was completed October 10, 2011 with no adverse findings. A new purchase order was issued to Honeywell Inc. to calibrate all equipment and the calibrations were completed on October 11, 2011 with no units out of calibration in the as-found condition. The survey of MaxPro was amended on October 11, 2011 to identify critical characteristics and document objective evidence to verify critical characteristics. Review of the objective evidence resulted in no adverse findings.

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).

Attachment 5
Reply to NRC Notice of Nonconformance D
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 5 sets forth the reply of Fisher Controls International LLC (“**Fisher Controls**”) to the NRC’s Notice of Nonconformance dated September 13, 2011 relative to NRC Inspection Report 99900105/2011-201 (the “**Inspection Report**”), Notice of Nonconformance **99900105/2011-201-05** (the “**Nonconformance-05**”).

The Nonconformance

The Notice of Nonconformance provides the following description of Nonconformance-05: “Criterion XVI, “Corrective Action,” of Appendix B to 10 CFR Part 50 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.

Contrary to the above, as of August 5, 2011, Fisher Controls failed to establish measures to evaluate significant conditions adverse to quality. Specifically, Fisher Controls considers all nonconformances, deviations, malfunctions, etc., as conditions adverse to quality and does not evaluate them to determine if any are significant conditions adverse to quality, which require (1) that the cause of the condition be determined, (2) corrective action be 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.

This issue has been identified as Nonconformance 99900105/2011-201-05.”

Fisher Controls’ Response to the Notice of Nonconformance

Fisher Controls is not contesting Nonconformance-05 and has taken steps to address the issue identified in the Inspection Report.

I. Reason for the Notice of Nonconformance

Fisher Controls’ Implementing Procedure FMP 2K9 did not clearly state which Corrective Action Requests were considered “Significant Condition Adverse To Quality”. Additionally, while the Corrective Action Request process did include all the quality requirements listed in 10 CFR Part 50 Appendix B, Requirement 16, these quality requirements were not clearly stated.

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 Request CAR 1509 on August 4, 2011. Pursuant to the CAR, Fisher Controls took the following steps:

Fisher Controls revised Corrective Action Procedure FMP2K9 to include an updated form differentiating between 'significant conditions adverse to quality' and 'conditions adverse to quality'. This process is now defined in procedure FMP2K9.

Fisher Controls also reviewed all open CAR's to confirm there were no significant conditions adverse to quality.

Training of affected employees was completed August 19, 2011.

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.

Attachment 6
Reply to NRC Notice of Nonconformance E
Docket Number 99900105
Inspection Report No. 99900105/2011-201

This Attachment 6 sets forth the reply of Fisher Controls International LLC (“**Fisher Controls**”) to the NRC’s Notice of Nonconformance dated September 13, 2011 relative to NRC Inspection Report 99900105/2011-201 (the “**Inspection Report**”), Notice of Nonconformance **99900105/2011-201-06** (the “**Nonconformance-06**”).

The Notice of Nonconformance

The Notice of Nonconformance provides the following description of Nonconformance-06:

“Criterion XVIII, “Audits,” of Appendix B to 10 CFR Part 50 states, in part, that ‘The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited.’

Subsection 19.2.1 of Fisher Controls’ Nuclear Quality Assurance Manual, Revision 8, dated October 4, 2010, states, in part, that “Auditors selected shall not have direct responsibilities in the area he/she is auditing.”

Contrary to the above, as of August 5, 2011, Fisher Controls failed to verify that audits were performed by personnel not having direct responsibilities in the areas being audited. Specifically, the NRC inspection team identified one internal audit in which the QA Manager, who has direct responsibility for the implementation of Fisher Controls’ QA program, participated in an internal audit as a member of the audit team and audited an area for which he has direct responsibility.

This issue has been identified as Nonconformance 99900105/2011-201-06.”

Fisher Controls’ Response to the Notice of Nonconformance

Fisher Controls is not contesting Nonconformance-06 and has taken steps to address the issue identified in the Inspection Report. Fisher Controls believes the changes it implemented to address Nonconformance-06 represent an improvement to its program.

I. Reason for the Notice of Nonconformance

Fisher Controls Quality Manager participated in the 2010 Internal Audit and reviewed work, performed by others, that was in his area of responsibility.

II. Corrective Steps Taken and Results Achieved

During the NRC Inspection, the Inspectors made Fisher Controls aware of the NRC’s observation that the Quality Manger’s participation in the internal audit did not meet the requirements of Appendix B to 10 CFR Part 50 and Fisher Controls Nuclear Quality Assurance Manual. In response to this observation, Fisher Controls issued internal Corrective Action Request CAR 1506 on August 3, 2011. Pursuant to the CAR, Fisher Controls took the following steps:

Fisher Controls revised implementing procedure FMP 2K41 to clarify a person cannot audit an area, or work performed, that is in his or her chain of command.

The 2011 internal audit performed March 3, 2011 through March 18, 2011, was reviewed and it was determined that all auditors involved were independent of the activities performed. No findings were identified during the 2011 internal audit in the areas in question.

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.