September 1, 2016

EA-16-141

Mr. Michael Lenio, Director of Quality
ASCO Valve, Inc.
1561 Columbia Hwy N
Aiken, SC 29801

SUBJECT: RESPONSE TO AND RE-CHARACTERIZATION OF ONE EXAMPLE OF DISPUTED NOTICE OF NONCONFORMANCE NO. 99901054/2016-201

Dear Mr. Lenio:

I am responding to your letter dated June 9, 2016, in which you disputed two examples of Nonconformance 99901054/2016-201-01 as identified in the Notice of Nonconformance (NON) attached to the Inspection Report 99901054/2016-201. The Nuclear Regulatory Commission (NRC) staff identified the subject nonconformance during an inspection conducted from February 8-12, 2016, at your ASCO facility in Aiken, SC. The nonconformance described three examples of ASCO not fully implementing its QA program in the area of commercial-grade dedication (CGD).

In your letter, you disputed that NON 99901054/2016-201-01, example one and a portion of example two related to part #G027502-001K occurred as stated. Regarding example one, the NRC described ASCO's failure to translate identified critical characteristics to an acceptance method plan, resulting in commercial-grade surveys performed without verification of the material identification critical characteristic for elastomers procured commercially. Your letter responded that ASCO performed receipt inspections and dedication inspections for elastomers consistent with your procedures, which you believe are adequate. Regarding example two, the NRC described ASCO's failure to verify identified critical characteristics established in a CGD testing acceptance plan. Your letter responded that ASCO had performed receipt and dedication inspections to dedicate a coil kit, but the original inspection record documenting this was not noted or observed during the NRC inspection.

The NRC staff has independently reviewed the information provided in your letter of June 9, 2016, and has concluded that the first disputed nonconformance example occurred as stated in the NON of April 15, 2016. The bases for the NRC conclusions regarding this matter are provided in the enclosure to this letter. Additionally, the NRC has concluded for the reasons presented in the enclosed evaluation that the second disputed nonconformance example should be re-characterized. This letter provides an update to the NON and the inspection record. We have no further questions or comments related to these two examples at this time and may review the implementation of your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained.

The NRC staff has also reviewed the corrective actions planned for NON 99901054/2016-201-01, example two, regarding part #022525-007-90 and example three and found them generally responsive to the NON. We have no further questions or comments related to those two examples at this time and may review the implementation of your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC site at http://www.nrc.gov/readingrm/adams.html.

Should you have any additional questions, please contact Edgardo Torres of my staff at 301-415-0705.

Sincerely,

/RA/ (BSmith for)

Michael C. Cheok, Director
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901054

Enclosure:
NRC Evaluation and Conclusion
for NON 99901054/2016-201-01

The NRC staff has also reviewed the corrective actions planned for NON 99901054/2016-201-01, example two, regarding part #022525-007-90 and example three and found them generally responsive to the NON. We have no further questions or comments related to those two examples at this time and may review the implementation of your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC site at http://www.nrc.gov/readingrm/adams.html.

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DISTRIBUTION:
ASakadales
KKavanagh
TJackson
Mike.lenio@emerson.com

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DATE	08/29/2016	08/31/2016	08/29/2016	08/31/2016
OFC	NRO/DCIP	OE/EB	NRO/DCIP	NRO/DCIP
NAME	TFrye*	TMarenchin*	BSmith	MCheok (BSmith for)
DATE	08/29/2016	08/31/2016	09/01/2016	09/01/2016

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NUCLEAR REGULATORY COMMISSION'S EVALUATION AND CONCLUSION

Statement of Nonconformance 99901054/2016-201-01

Criterion III, "Design Control," of Appendix B to Title 10 of the *Code of Federal Regulations* (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 safety-related functions of the structures, systems and components."

Criterion VII, "Control of Purchased Material, Equipment and Services," of Appendix B to 10 CFR Part 50, states, in part, that "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 February 12, 2016, ASCO failed to establish measures for the selection and review for suitability of application of materials and parts that are essential to the safety-related functions of components. In addition, ASCO failed to establish appropriate measures that included provisions for source evaluation, objective evidence of quality furnished by the contractor or subcontractor, and examination of products upon delivery. Specifically:

1. For commercial-grade dedication (CGD) of elastomers, ASCO failed to adequately translate identified critical characteristics to an acceptance method plan and therefore they were not verified. ASCO's commercial-grade surveys focused on general programmatic controls at the supplier, rather than on the control of critical characteristics for the elastomers being procured. Therefore, ASCO failed to identify and verify material critical characteristics in the commercial-grade surveys for the following examples:

    - PO 101504876 for four SB11AKR pressure switches and four TN10B42R pressure transducers called for a nuclear O-ring, which is made of Viton A type material. This material type is required for components that will be in service in a harsh environment, including exposure to radiation. These O-rings were procured from a distributor, who sourced them from a third party supplier.

    - PO 1015054413 for twenty-three NP 8316 3-way solenoid valves for Areva, a distributor for domestic nuclear plants, called for O-rings made of ethylene propylene. These O-rings were procured from a distributor, who sourced them from a third party supplier.

    - PO 4500834520 with PSEG Nuclear for an NPX8223G131 solenoid valve for Hope Creek called for a rubber disc. The valve disc was procured commercially from a supplier.

2. ASCO failed to verify the following identified critical characteristics: markings, inner diameter, outer diameter, length, turns, lead length, resistance, and the leads of a coil kit for Work Order A339448 (PO 1015038212), Coil MXX Nuclear as required by the commercial-grade dedication testing acceptance plan. In addition, ASCO failed to verify the material identification critical characteristic for an O-ring for Work Order 797668-15, by performing either a Fourier transform infrared spectroscopy (FTIR) or burn test, as required by the CGD receipt inspection acceptance plan.

3. ASCO failed to provide a documented technical basis for selection and use of sampling plans for CGD of commercial elastomers for the critical characteristic material identification by destructive testing as part of their acceptance method plan, when lot/batch control was not established through a commercial-grade survey. ASCO inspects only one item, independent of lot size, when performing destructive testing to verify material critical characteristics of the elastomers mentioned above, which is not in accordance with ASCO's procedure MP-I-026, "Sampling Plan for Product Acceptance," NRC regulatory guidance and Electric Power Research Institute (EPRI) industry standards.

Basis for Disputing the Nonconformance, Example 1

In its response to the NRC, ASCO stated that ASCO relies on material verification in the form of sampling and destructive testing at receipt inspection, not during commercial grade surveys, to verify critical characteristics. ASCO also stated that in doing so, ASCO is able to maintain traceability to compound number, cure date, lot and batch codes, and purchase order number.

NRC Evaluation of Vendor's Response to Example 1

An independent reviewer from the NRC staff has evaluated ASCO's response and has concluded that Nonconformance 99901054/2016-201-01, example 1, occurred as stated in our letter dated April 15, 2016. The independent reviewer's basis for this determination is as follows:

The independent reviewer considered the available regulatory guidance, the NRC inspection report, ASCO's response, and held discussions with the NRC inspection team. The NRC inspection team had noted multiple examples of ASCO inspecting one item, independent of lot size, when performing destructive testing to verify material critical characteristics for elastomers. The NRC inspection team had concluded that the above practice was not in accordance with ASCO's procedure MP-I-026, "Sampling Plan for Product Acceptance." The independent reviewer determined that the inspection team was correct in its assessment that ASCO had not established an adequate sampling plan during dedication, which would have been necessary to adequately justify the use of a sampling method. In addition, even if an adequate sampling plan had been used, ASCO would have also needed to provide objective evidence that lot homogeneity was controlled and traceability was maintained.

ASCO noted in its response letter that it did not rely on surveys for material verification. The inspection team and independent reviewer agreed that ASCO's surveys were not appropriate to verify lot/batch controls at the appropriate levels of the supply chain. Performed correctly, surveys can provide an acceptable method to maintain traceability and justify lot formation, which could then be used to justify the use of sampling, rather than 100% testing, as noted in the guidance documents referenced below.

In summary, ASCO had not provided objective evidence that lot formation was justified and that lot homogeneity could be verified, which would have supported use of a sampling plan. Even if the use of a sampling plan had been supported, ASCO had not established a plan that was adequate. The inspection team and the independent reviewer concluded that these practices do not conform to regulatory standards or EPRI industry standards. Therefore, the independent reviewer supports example 1 of NON 99901054/2016-201-1 that ASCO failed to adequately verify material as a critical characteristic.

Additional guidance on CGD can be found in an array of generic communications, guidance documents, and other communications. Most notably, the NRC conditionally endorsed Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)." In reviewing ASCO's letter, the independent reviewer also considered Revision 1 to EPRI NP-5652, and EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process." Also, the NRC inspection team used NRC Inspection Procedure (IP) 43004, "Inspection of Commercial-Grade Dedication Programs," to perform inspections. IP43004 provides guidance on verifying that traceability is maintained. IP43004, Appendix A, "Dedication Issues Basis for the Selection and Verification of Critical Characteristics," provides additional guidance on establishing lot/batch controls.

Specific Basis for Disputing the Nonconformance, Example 2

In response to the nonconformance, ASCO stated that they had performed receipt and dedication inspections to dedicate a coil kit, but the original inspection record documenting these inspections was not noted or observed during the NRC inspection.

NRC Evaluation of Vendor's Response to Example 2

In its response to the NRC, ASCO stated that the dedication inspection referenced in Nonconformance 99901054/2016-201-01, example 2, for part #G027502-001-K, had been previously completed. ASCO explained that, during the inspection, the objective evidence from this dedication inspection was not observed by the NRC inspectors. ASCO noted that it had provided the NRC inspection team with printed documents that did not include the inspection records from previously performed dedication activities.

During the NRC inspection, the NRC inspection team made multiple requests to ASCO staff for objective evidence demonstrating that the critical characteristics had been verified. However, ASCO staff was unable to provide documentation or justification for the apparent lack of verification of critical characteristics. ASCO also did not describe its process for documenting previous testing of critical characteristics as part of its dedication program.

The inspection team conducted an exit meeting with ASCO staff on February 12, 2016, and also conducted a re-exit phone call with ASCO staff on March 17, 2016. ASCO did not indicate at either of these opportunities that it had identified objective evidence to show that all critical characteristics for part #G027502-001-K had been adequately verified.

In its response to the nonconformance, ASCO stated that objective evidence of testing of the critical characteristics for the coil existed. ASCO noted that the coil had been previously tested, and therefore was suitable for use as a basic component. The NRC inspectors acknowledged that the record of testing is suitable for use in dedication. However, the NRC staff concluded that ASCO's dedication process failed to ensure that the records of dedication activities were available to demonstrate the suitability of application of materials and parts that are essential to the safety-related functions of components.

NRC Conclusion

An independent reviewer from the NRC staff has concluded that the first disputed nonconformance example occurred as stated in the NON of April 15, 2016. Based on the additional information you provided, an independent reviewer from the NRC staff has concluded that the second disputed nonconformance example should be re-characterized as follows:

Criterion III, "Design Control," 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 safety-related functions of the structures, systems and components."

Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50, states, in part, that "Sufficient records shall be maintained to furnish evidence of activities affecting quality. Records shall be identifiable and retrievable." Quality records are an important aspect of commercial-grade dedication activities, which are performed to provide reasonable assurance that an item will remain functional during and following design basis events at nuclear power plants. Documentation of these activities in quality records is the final step that provides this assurance.

Contrary to the above, as of February 12, 2016, ASCO failed to establish measures for the selection and review for suitability of application of materials and parts that are essential to the safety-related functions of components and failed to maintain identifiable and retrievable records to furnish evidence of activities affecting quality.

Specifically, ASCO's dedication process did not ensure that records of previously tested critical characteristics (i.e., markings, inner diameter, outer diameter, length, turns, lead length, resistance, and the leads) of a coil kit for Work Order A339448 (PO 1015038212), part #G027502-001-K, Coil MXX Nuclear, were retrievable and available to demonstrate the suitability of application of materials and parts that are essential to the safety-related functions of components.

The NRC staff has also reviewed ASCO's corrective actions, which include a procedure revision and extent of condition review, for this issue and found them generally acceptable to address the programmatic deficiencies that led to the nonconformance with Criteria III and XVII. ASCO's actions for subsequently verifying that dedication testing is adequately performed and documented can be credited as adequate corrective actions to address the specific example of a lack of timely objective evidence supporting the verification of part #G027502-001-K, Coil MXX Nuclear. We have no further questions or comments related to this example at this time and may review the implementation of your corrective actions during a future NRC staff inspection to determine whether full compliance has been achieved and maintained.