UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 13, 2020

Mr. Kevin Falcon
Quality Engineering Manager
ASCO L.P.
1561 Columbia Hwy
Aiken, SC 29801

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF ASCO L.P. NO. 99901054/2020-201

Dear Mr. Falcon:

From March 9 through March 13, 2020, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at ASCO L.P.'s (hereafter referred to as ASCO) facility in Aiken, SC. The purpose of this limited-scope routine inspection was to assess ASCO's compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection specifically evaluated ASCO's implementation of the quality activities associated with the supply of safety-related valves for new plant construction and operating reactor projects for the U.S. nuclear power industry. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of ASCO's overall quality assurance (QA) or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC inspection team found that the implementation of your QA program met the applicable technical and regulatory requirements imposed on you by your customers or NRC licensees. No findings of significance were identified.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," the NRC will make available electronically for public inspection a copy of this letter and its enclosure through the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions concerning this matter, please contact Mr. Dong Park of my staff at (301) 415-0001.

Sincerely,

Kerri A. Kavanagh, Chief **/RA/**
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Docket No.: 99901054

EPID No.: I-2020-201-0028

Enclosures:
1. Inspection Report No. 99901054/2020-201
   and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF ASCO L.P. NO. 99901054/2020-201 Dated: April 13, 2020

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ADAMS Accession No.: ML20097J376 *via e-mail **NRR-106**

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DATE	04/8/2020	04/13/2020	

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT

Docket No.:	99901054
Report No.:	99901054/2020-201
Vendor:	ASCO L.P. 1561 Columbia Hwy Aiken, SC 55317
Vendor Contact:	Mr. Kevin Falcon Quality Engineering Manager Email: Kevin.Falcon@Emerson.com Office: (803) 641-9368
Nuclear Industry Activity:	ASCO L.P.'s scope of supply for the nuclear power plants (operating and under construction) includes manufacturing of safety-related solenoid valves.
Inspection Dates:	March 9 - 13, 2020
Inspectors:	Dong Park — NRR/DRO/IQVB, Team Leader Greg Galletti — NRR/DRO/IQVB Thomas Herrity — NRR/DRO/IQVB Yamir Diaz-Castillo — NRR/DRO/IQVB
Approved by:	Kerri A. Kavanagh, Chief Quality Assurance and Vendor Inspection Branch Division of Reactor Oversight Office of Nuclear Reactor Regulation

Enclosure

EXECUTIVE SUMMARY

ASCO L.P.
99901054/2020-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a routine vendor inspection at the ASCO L.P.'s (hereafter referred to as ASCO) facility in Aiken, SC, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC inspection team conducted the inspection on March 9 - 13, 2020. This was the second NRC inspection at ASCO's facility in Aiken, SC.

This technically-focused inspection specifically evaluated ASCO's implementation of quality activities associated with the design, manufacturing, and testing of safety-related solenoid valves provided to U.S. nuclear power plants (operating and under construction).

The following regulations served as the basis for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During this inspection, the NRC inspection team implemented Inspection Procedure (IP) 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017, IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017, and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

Specific activities observed by the NRC inspection team included:

- Pre-assembly inspection and verification of critical characteristics of a 125v direct current solenoid operated valve

- Receipt inspection process in support of the commercial-grade dedication (CGD) of the 125v alternate current (AC) solenoid operated valves

- Post assembly testing of the 125v AC solenoid operated valves

- Receipt inspection of a sample of cold rolled steel sleeves

- Calibration of an internal caliper

The NRC inspection team concluded that ASCO's QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that ASCO's personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with the requirements of 10 CFR Part 21. The NRC inspection team: (1) reviewed the 10 CFR Part 21 postings; (2) reviewed a sample of purchase orders (POs); and (3) verified that ASCO's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. No findings of significance were identified.

Design Control

The NRC inspection team reviewed ASCO's policies and procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. The NRC inspection team focused on the design review and design change processes to confirm design activities were performed consistent with NRC regulations and internal ASCO programs. No findings of significance were identified.

Commercial-Grade Dedication

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its CGD program to verify compliance with the requirements of Criterion III of Appendix B to 10 CFR Part 50. The NRC inspection team evaluated on-going CGD activities and reviewed completed CGD documentation including technical evaluations used to identify critical characteristics and acceptance criteria. No findings of significance were identified.

Supplier Oversight and Internal Audits

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its supplier oversight and internal audits programs to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of POs and confirmed that the POs contained the applicable technical and regulatory requirements. In addition, the NRC inspection team reviewed a sample of external and internal audit reports and confirmed that the external and internal audits were performed by qualified individuals using checklists and/or procedures, the checklists and/or procedures included an audit plan, documented objective evidence, audit results, and a review of audit results by responsible management. No findings of significance were identified.

Control of Measuring and Test Equipment

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its measuring and test equipment (M&TE) program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50. The NRC inspection team observed that M&TE was calibrated, labeled, tagged, handled, stored, or otherwise controlled to indicate the calibration status and its traceability to nationally recognized standards. In addition, the NRC inspection team confirmed that when M&TE is found to be out of calibration, ASCO initiates an M&TE Report Form (i.e.,

nonconformance report) and performs an evaluation to determine the extent of condition. No findings of significance were identified.

Nonconforming Material, Parts, or Components and Corrective Action

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its nonconforming materials, parts, or components and corrective action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspection team verified that the procedures contained sufficient guidance for evaluating non-conforming conditions and the procedures ensure that conditions are evaluated for possible corrective action or for 10 CFR Part 21 applicability. The NRC inspection team reviewed a sample of non-conforming material reports (NCMRs) and internal corrective action reports (ICARs) to verify that they demonstrate compliance with regulatory requirements and adherence to ASCO procedures.

The NRC inspection team also reviewed the corrective actions taken by ASCO to address Notice of Nonconformance (NON) 99901054/2016-201-01, contained in the errata to NRC inspection report No. 99901054/2016-201, dated October 4, 2016 (Agencywide Documents Access and Management System Accession No. ML16273A144). The NRC inspection team verified that ASCO had taken adequate corrective actions to address NON 99901054/2016-201. This NON is now closed.

No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

   a. Inspection Scope

   The NRC inspection team reviewed ASCO L.P.'s (hereafter referred to as ASCO) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of ASCO's purchase orders (POs) for compliance with the requirements of 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation," and 10 CFR 21.31, "Procurement documents." The NRC inspection team also verified that ASCO's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program.

   The NRC inspection team reviewed a sample of 10 CFR Part 21 evaluations performed within the past three years and confirmed that ASCO had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that ASCO's procedure direct notifications be performed in accordance with the requirements of 10 CFR 21.21, as applicable. ASCO provided sufficient documentation to support their engineering judgements regarding potential 10 CFR Part 21 reportability over the period of the past three years.

   The NRC inspection team also discussed the 10 CFR Part 21 program with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

   b. Observations and Findings

   No findings of significance were identified.

   c. Conclusion

   The NRC inspection team concluded that ASCO is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team also determined that ASCO is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

   a. Inspection Scope

   The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, "Design Control," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC inspection team reviewed ASCO's processes for performing design control, including design reviews and the design change processes, reviewed examples of valve design documentation, and discussed these processes and examples with ASCO's design engineering staff. The NRC inspection team confirmed that the design review process was conducted in accordance with ASCO's implementing procedures, and the results of design reviews were adequately documented. The NRC inspection team reviewed a sample of design change requests related to material or piece parts for a sample of legacy products and confirmed the design change process was effective in identifying the proposed changes and activities required to adequately evaluate and implement the changes.

The NRC inspection team verified that ASCO's design review process includes the purpose of each design review, method of conduct, agenda items, and documentation of the results. This process also identified phases of the design process where design reviews are conducted in accordance with ASCO's implementing procedures. Design changes resulting from design reviews are implemented through the engineering change review and notification process with the results of the design review being documented in the Design Review Release Record.

The NRC inspection team also discussed the design program with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed and the staff interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that ASCO is implementing its design control program in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that ASCO is implementing its policies and procedures associated with the design control program. No findings of significance were identified.

3. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of CGD plans, reports, and commercial-grade surveys of two commercial suppliers to assess the different elements of the CGD program. The NRC inspection team verified that the technical evaluations documented the criteria for the identification of item functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, the identification of verification methods, and justification of the sampling methodologies as applicable. Furthermore, the NRC inspection team reviewed the CGD packages, associated

drawings, and inspection reports for valve packages No. NPL8320A185E 125/DC WD Valve/Solenoid and No. NSL8316064 125/DC KD Valve/Solenoid. The NRC inspection team verified that: (1) the critical characteristics and acceptance methods were correctly specified; (2) the drawings and material specifications containing the associated acceptance criteria for each critical characteristic were referenced; and (3) the inspection reports adequately documented the acceptance of the critical characteristics to verify effective implementation of ASCO's CGD process. The NRC inspection team verified through observations of additional in-process inspections that the CGD activities as defined in ASCO's procedures include, but are not limited to: 100 percent pre-assembly individual part inspections, verification of proper cure date requirements, post-assembly testing, and post-testing inspection.

Pre-Assembly Inspection

The NRC inspection team observed in-process CGD inspection activities associated with nuclear work orders Nos. 22071825 and 22085330 for 125v direct current (DC) solenoid valves. The NRC inspection team confirmed ASCO's quality assurance (QA) inspectors were adequately following applicable procedures and documenting the inspection results.

Post-Inspection Assembly and Testing

The NRC inspection team observed in-process valve assembly and testing operations for nuclear work orders No. 22085330 for a 125v DC solenoid valve and No. 22085340 for a 120/60 alternate current (AC) solenoid valve. The NRC inspection team confirmed the assembly was performed in accordance with assembly and testing procedures AP-NP-228973, "NP & NS 8300 (P37) and TP-3-046, "NP8300 and NS8300," Revision AF, dated October 31, 2018, respectively. The NRC inspection team confirmed that assembly tools such as torque wrenches were calibrated and set to proper specifications in accordance with assembly drawing requirements.

The NRC inspection team confirmed that the assembler/tester was qualified to perform the assembly operations and had experience performing such activities. Testing was witnessed by a QA inspector in accordance with ASCO's CGD program.

The NRC inspection team reviewed a sample of completed test logs, including directly witnessing the testing on a sample of 125v AC and DC solenoid valves and confirmed the logs were completed per the requirements of the test procedure and all required information was adequately documented. The NRC inspection team reviewed a sample of post assembly/testing final inspection logs and witnessed post testing inspection activities to verify that the inspection activities were consistent with the shop work order and administrative controls. Configuration control measures were in place and used. The NRC inspection team confirmed the assembly area was free of foreign material and oils.

The NRC inspection team noted that ASCO performs CGD of calibration services for calibrations performed on-site, calibrations performed by commercial laboratories, and/or by qualifying commercial laboratories in accordance with the requirements of International Standard Organization (ISO)/International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories." For the sample of POs, commercial-grade surveys, and calibration

certificates associated with the CGD of calibration services, the NRC inspection team confirmed that: (1) the POs contained the appropriate technical and quality requirements; (2) critical characteristics for calibration services were adequately listed and verified; and (3) the calibration certificates were adequately reviewed during receipt inspection.

The NRC inspection team also discussed the CGD program with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that ASCO is implementing its CGD program in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team determined that ASCO is implementing its policies and procedures associated with the CGD program. No findings of significance were identified.

4. Supplier Oversight and Internal Audits

a. Inspection Scope

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its supplier oversight and internal audits programs to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of external and internal audits, and the most recent POs for these suppliers, as applicable. For the sample of POs reviewed, the NRC inspection team verified that the POs included, as appropriate: the scope of work, right of access to facilities, and extension of contractual requirements to sub-suppliers. The NRC inspection team also confirmed that the POs adequately invoked the applicable technical, regulatory, and quality requirements.

For a sample of external and internal audits reviewed, the NRC inspection team verified the audit reports included an audit plan, any findings identified, adequate documented objective evidence of compliance with the applicable requirements, and a review by ASCO's responsible management. In addition, the NRC inspection team also verified that the audits were performed by a qualified auditor, and in the case of the internal audits, that these audits were performed by personnel not having direct responsibilities in the areas being audited. Furthermore, the NRC inspection team reviewed a sample of training and qualification records of ASCO's lead auditors and confirmed that auditing personnel had completed all the required training and had maintained the applicable qualification and certification in accordance with ASCO's procedure No. QC-ER-142, "Lead Auditor Qualification," Revision G, dated November 7, 2019.

The NRC inspection team observed the receipt inspection of a sample of cold rolled steel sleeves and confirmed that the receipt inspection was performed in accordance with ASCO's procedure No. QC-ER-024, "Receiving Inspection," Revision U, dated September 22, 2015. In addition, the NRC inspection team reviewed the training and qualification record of the Quality Control (QC) Inspector who performed the receipt inspection and confirmed that the QC Inspector had completed all the required training and had maintained the applicable qualification and certification in accordance with ASCO's procedure No. QC-ER-80, "Training and Qualification of Q.A. Personnel," Revision E, dated December 1, 2009.

The NRC inspection team also discussed the supplier oversight and internal audits programs with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that ASCO is implementing its supplier oversight and internal audits programs in accordance with the regulatory requirements of Criterion IV, Criterion VII, and Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that ASCO is implementing its policies and procedures associated with the supplier oversight and internal audits programs. No findings of significance were identified.

5. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its control of measuring and test equipment (M&TE) program to verify compliance with the regulatory requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50.

For a sample of M&TE, the NRC inspection team determined that the M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The NRC inspection team also verified that the M&TE had been calibrated, adjusted, and maintained at prescribed intervals prior to use. In addition, the calibration records reviewed by the NRC inspection team indicated the as-found or as-left conditions, accuracy required, calibration results, calibration dates, and the due date for recalibration. Furthermore, the NRC inspection team also verified that the selected M&TE was calibrated using procedures traceable to known industry standards. The NRC inspection team confirmed that when M&TE equipment is found to be out of calibration, ASCO generates an M&TE Report Form (i.e., nonconformance report) to identify items that have been accepted using this equipment since the last valid calibration date and to perform an extent of condition review.

The NRC inspection team performed a walk-down of ASCO's laboratories to observe that M&TE were labeled, handled, and stored in a manner that indicated the calibration status of the instrument and ensured its traceability to calibration test data. The NRC inspection team observed the calibration of an internal caliper and confirmed that the calibration was performed in accordance with ASCO's procedure No. QC-CP-89, "Calibration of Internal Calipers," dated July 31, 2015 (no Revision No. available). The NRC inspection team observed the Calibration Specialist record the temperature and humidity as required by ASCO's procedure No. QC-ER-003, "Responsibilities of Gage Calibration Technician/Specialist (Management Calibration Program)," Revision AH, dated May 23, 2019. Furthermore, the NRC inspection team reviewed the training and qualification record of the Calibration Specialist who performed the calibration and confirmed that the Calibration Specialist had completed all the required training and had maintained the applicable qualification and certification in accordance with ASCO's procedure No. QC-ER-80.

The NRC inspection team also discussed the control of M&TE program with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that ASCO is implementing its control of M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that ASCO is implementing its policies and procedures associated with the control of M&TE program. No findings of significance were identified.

5. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed ASCO's policies and implementing procedures that govern the implementation of its nonconforming materials, parts, or components, and corrective action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed the current nonconformance procedures and verified they contained sufficient guidance for segregating, labeling, tracking, evaluating, reworking, and/or disposing of nonconforming materials, parts, and components. The procedures direct the proper creation of records for the material, part or component's condition and provide sufficient guidance that lead to a 10 CFR Part 21 evaluation, as applicable.

The NRC inspection team reviewed the implementation of ASCO's computer-based database system modules by a mock entry of a non-conforming condition. ASCO

personnel demonstrated the issue tracking and response capabilities of the new system that was implemented since the last NRC inspection in 2016. Nonconforming material condition reports (NMCRs) are not normally generated until the item is queued and segregated for final disposition. The NRC inspection team reviewed a sample of NMCRs associated with castings and machined components awaiting removal in the segregation area and confirmed that ASCO: (1) dispositioned the NMCRs in accordance with the applicable procedures, (2) documented an appropriate technical justification for the dispositions, and (3) took adequate corrective action regarding the nonconforming items to prevent recurrence. The NRC inspection team verified that the system generated reports and information accurately recorded the conditions of the material.

The NRC inspection team also reviewed a sample of internal corrective action reports (ICARs) to verify: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence, as applicable; (3) direction for review and approval by the responsible authority; (4) a description of the current status of the corrective actions; and (5) the follow-up actions taken to verify timely and effective implementation of the corrective actions. The NRC inspection team discussed the ICAR review process and verified ASCO personnel's understanding and desire to adhere to procedures assessing the conditions and assigning action items to address the conditions.

In addition, the NRC inspection team verified the implementation of the corrective actions taken in response to the Notice of Nonconformance (NON) documented in the errata to NRC's inspection report No. 99901054/2016-201, dated October 4, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16273A144).

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with ASCO's management and technical staff. The attachment to this inspection report lists the documents reviewed by the NRC inspection team.

b. Observations and Findings

Corrective Action Associated with NON 99901054/2016-201-01

Following the February 2016 inspection of ASCO, the NRC issued NON 99901054/2016-201-01 for ASCO's failure to adequately implemented its QA program in the area of CGD. Specifically, 1) ASCO failed to conduct commercial-grade surveys at the manufacturer of commercial elastomers that verify the critical characteristic for material identification; 2) ASCO failed to verify identified critical characteristics through inspection and testing for a nuclear coil kit and a nuclear O-ring, as established in their acceptance method plan; and 3) ASCO failed to provide the 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.

In its response dated September 27, 2016, (ADAMS Accession No. ML16273A277), ASCO stated it has addressed these issues through their corrective action program,

which included procedure revisions and extent of condition reviews. The NRC inspection team verified the actions ASCO had taken as explained below.

For issue (1), ASCO revised the supplier's commercial-grade surveys to ensure specific critical characteristics of a product are reviewed and the supplier's ability to ensure those characteristics is graded. ASCO revised procedure No. QC-ER-121, "Conducting Outside Quality Audits or Surveys," Revision AC, dated February 28, 2018, to document that critical characteristics are specified on commercial-grade survey checklists. The verification of raw materials was added to the critical characteristics for the survey of manufacturers. ASCO applied this revised process to all suppliers for their nuclear grade products, not just the elastomeric products identified in the NRC's inspection report No. 99901054/2016-201.

For issue (2), ASCO revised procedure No. QC-ER-096, "Commercial Grade Dedication of Nuclear Valves, Actuators, and Pressure/Temperature Switches, and Calibration Services," Revision AH, dated February 20, 2020, to eliminate the practice of selecting "Skip" for nuclear items. During the observation of pre-assembly inspections, the NRC inspection team verified that ASCO conducts positive material identification on associated critical characteristics. In addition, ASCO's inspector training was revised and all inspectors were retrained to this revised process.

For issue (3), ASCO revised procedure No. MP-I-026, "Sampling Plan for Product Acceptance," Revision AB, dated November 28, 2018, to adopt the sampling protocol from Electrical Power Research Institute Report No. TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," dated January 1999. ASCO implemented this procedure with the updated commercial-grade surveys of suppliers to create a sampling plan for components utilized in ASCO's nuclear grade products. Currently, ASCO does 100% sampling of all critical characteristics of piece-parts, including materials, used in the fabrication of basic components.

Based on review of the corrective actions, the NRC inspection team closed NON 99901054/2016-201-01.

c. Conclusion

The NRC inspection team concluded that ASCO is implementing its nonconforming materials, parts, or components and corrective action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that ASCO is effectively implementing its policies and procedures associated with the nonconforming materials, parts, or components and corrective action programs. No findings of significance were identified.

6. Entrance and Exit Meetings

On March 9, 2020, the NRC inspection team discussed the scope of the inspection with Mr. Mike Lenio, Director of Quality, Mr. Kevin Falcon, Quality Engineering Manager, and other members of ASCO's management and technical staff. On March 13, 2020, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Lenio, Mr. Falcon, and other members of ASCO's management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Mike Lenio	Director of Quality	ASCO L.P. (ASCO)	X	X	X
Kevin Falcon	Quality Engineering Manager	ASCO	X	X	X
Keith Gregory	Director of Operations	ASCO		X	
Bob Wilson	Product Engineer Manager	ASCO	X		
David B. DeWitte	Quality Assurance (QA) Supervisor	ASCO	X	X	
Bob Royer	Technical Services Supervisor	ASCO	X	X	X
Richard Thomas	Environmental Health and Safety (EHS) Manager	ASCO	X	X	
Deanna Mills	Supplier Quality Engineer	ASCO	X	X	
Brian Causey	Quality Engineer, Return Material	ASCO	X	X	X
Kevin Arthur	Supplier Quality Engineer	ASCO	X	X	X
Christina Holsomback	Supplier Quality Engineer	ASCO	X	X	
Natalie Zeitan	Assembly Manager	ASCO	X		
Todd Boggs	Assembly Manager	ASCO	X	X	
Steve Casadevall*	Nuclear Product, Engineering Manager	ASCO		X	X
Jeff Loprete*	Nuclear Product Engineer	ASCO		X	
Paul Cetrulo*	Technical Sales Nuclear	ASCO		X	
Marcus Tubman*	Materials Manger	ASCO		X	

Name	Title	Affiliation	Entrance	Exit	Interviewed
Todd Yanofchick*	Director Nuclear Engineering	ASCO		X	
Jian Zhou*	Nuclear Product Engineer	ASCO		X	
Randy Usry	Quality Engineer	ASCO			X
Robert Arnone	Senior Quality Engineer	ASCO			X
Donna Herron	QA Technician	ASCO			X
Brenda Johnson	Quality Control (QC) Inspector	ASCO			X
Jean Anderson	Calibration Specialist	ASCO			X
Paul Dischenes	QC Receiving Technician	ASCO			X
Susan Phillips	Nuclear Dedication Technician	ASCO			X
Linda Wessinger	Nuclear Dedication Technician	ASCO			X
Joyce Choly	Nuclear Assembly Supervisor	ASCO			X
Andrew Zamiela	QA Engineer	ASCO			X
Barbara Anderson	QA Administrative Assistant	ASCO			X
Kerri Kavanagh	Branch Chief	Nuclear Regulatory Commission (NRC)		X	
Dong Park	Team Leader	NRC	X	X	
Greg Galletti	Inspector	NRC	X		
Thomas Herrity	Inspector	NRC	X	X	
Yamir Diaz-Castillo	Inspector	NRC	X	X	

* Present via telephone

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

IP 43002, "Routine Inspections of Nuclear Vendors," dated January 27, 2017.

IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017.

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901054/2016-201-01	CLOSED	Notice of Nonconformance (NON)	Criterion III Criterion VII

4. DOCUMENTS REVIEWED

Design Control Documents

- EDP-111, "Qualification of Products for Safety Related Nuclear Power Plant Applications," Revision P, dated June 4, 2018
- EDP-129, "Reviewing Documents for Impact on the Performance of Nuclear Products," Revision P, dated June 4, 2018
- GBP-004, "ECR Quick Start Guide," Revision M, dated April 24, 2017
- GBP-005, "ECR User Guide (Detailed)," Revision J, dated February 17, 2016
- GBP-004, "ECN Quick Start User Guide," Revision D, dated September 28, 2017
- GBP-007, "ECN Central User Guide (Detailed)," Revision F, dated October 3, 2017
- NPD2.5-001, "New Product Development Process for Platform Products," Revision B, dated February 26, 2013
- Seismic Qualification Test Report No. K-505569-REP-0001 for the seismic qualification of ASCO solenoid valves, dated October 1, 2019
- Seismic Qualification Test Report No. K-115573-RA-0001, Revision 0, for the seismic qualification of ASCO solenoid valves, dated May 9, 2018

Design Review Process

- ECN 277890, "Engineering Change Notice – Design Review Nuclear – NT Scram Solenoid Pilot Valve LED," dated October 16, 2017

- DPR-VSI-111647, “Design Proposal Review Release – NT SSPV LED Upgrade,” dated August 14, 2017

- NPD2-005, “New Product Development Design Review Process (Portfolio and Customer Special Products,” dated October 26, 2009

- NPD2.5-009, “Development Process for Product Engineering Projects,” Revision A, dated February 4, 2013

- NPD2.5-010, “Three Gate Product Transfer and Localization Process,” Revision B, dated October 1, 2017

Commercial Grade Dedication

- EDP-177, “Determination of Critical Characteristics for Dedication Inspection (Nuclear Products),” Revision E, dated September 20, 2016

- MP-I-081, “Manufacturing Procedure for Nuclear Products – Procedure for Reporting Defects, Deviations, Noncompliance or Failure to Comply (Safety Related 10CFR – Part 21,” Revision V, dated February 2, 2018

- NUC-100109, “Product Eng. FMEA review minutes per EDP-177,” dated September 19, 2016

- ECN 268587, “Determination of Inspection Steps for Nuclear,” dated September 21, 2016

- NT8316, “Potential Failure Modes and Effects Analysis (Design FMEA),” dated September 19, 2016

- NPD2.5-007, “ASCO Global Codification,” Revision DA, dated March 2, 2020, 2013

- QC-ER-096, “Commercial Grade Dedication of Nuclear Valves, Actuators, and Pressure/Temperature Switches, and Calibration Services,” Revision AH, dated February 20, 2020

- QC-ER-109, “Responsibility of the QA Engineering Group,” Revision F, dated June 20, 1980

- QC-ER-227, “Use of Koslow Metal Alloy Sorter,” Revision B, dated June 6, 2018

Post Assembly Testing 125V Alternate Current Solenoid Valve

- AP-NP-228973, “NP & NS 8300 (P37)

- TP-1-035, “Testing Coils for Nuclear Valves & Kits,” Revision BA, dated February 26, 2008 – Hi Pot Test

- TP-3-046, “NP8300 and NS8300,” Revision AF, dated October 31, 2018

Sampling

- MP-I-026, “Sampling Plan for Product Acceptance,” Revision AB, dated November 28, 2018

Work Orders and Associated Process Inspection Worksheets

- 22071825, “125/DC KD Valve / Solenoid,” dated March 6, 2020
- 22085330, “125/DC DD Valve / Solenoid,” dated March 6, 2020
- 21860837, “125/DC WD Valve / Solenoid,” dated February 11, 2020
- 21824271, “125/DC KD Valve / Solenoid,” dated February 5, 2020
- 22085340, “120/60 DA Valve/ Solenoid,” dated March 4, 2020

Policies and Procedures

- MP-I-128, “Procedure for Handling Return of Nuclear Product,” Revision C, dated September 9, 2012
- MP-I-046, “Verification of Valve Contracts Requirements by Quality Assurance,” Revision N, dated February 2, 2020
- MP-I-128, “Procedure for Handling Return of Nuclear Product,” Revision C, dated September 5, 2012
- QC-ER-008, “Material Verification,” Revision AB, dated February 25, 2020
- QC-ER-057, “Procedure for Collection Plans,” Revision J, dated February 20, 2020
- QC-ER-079, “Procedure for Reporting and Executing Internal Corrective & Preventive Actions for Non-Conformances (I-CARS),” Revision R, dated February 20, 2020
- QC-ER-079, “Procedure for Reporting and Executing Internal Corrective & Preventive Actions for Non-Conformances (I-CARS),” Revision Q, dated September 10, 2018
- QC-ER-081, “Corrective & Preventive Actions for Government & Commercial Material,” Revision L, dated October 15, 2013
- QC-ER-121, “Conducting Outside Quality Audits or Surveys,” Revision AC, dated February 28, 2018
- QC-ER-038, “Inspection Guide for ASCO Rubber Components,” Revision C, dated June 21, 1967
- EDP-013, “Request for Engineering Investigation (E.I.) or Change,” Revision AG, dated November 15, 2019

- QC-ER-003, “Responsibilities of Gage Calibration Technician/Specialist (Management Calibration Program),” Revision AH, dated May 23, 2019

- QC-ER-024, “Receiving Inspection,” Revision U, dated September 22, 2015

- QC-ER-80, “Training and Qualification of Q.A. Personnel,” Revision E, dated December 1, 2009

- QC-ER-084, “Conducting Internal Quality Audits,” Revision BR, dated November 11, 2018

- QC-ER-142, “Lead Auditor Qualification,” Revision G, dated November 7, 2019

- QC-ER-168, “Calibration and Maintenance of Instrumentation,” Revision R, dated May 20, 2019

- QC-ER-217, “Measurement and Test Equipment (M&TE) Access System Procedure (Electronic),” Revision G, dated November 6, 2015

- QC-CP-89, “Calibration of Internal Calipers,” dated July 31, 2015 (no Revision No. available)

- VSP-16, “Procedure for Entering Customer Purchase Orders for Nuclear Safety Related Offerings,” Revision L, dated October 1, 2012

- ASCO’s Supplier Requirements Manual

- Manufacturing Procedure (MP) No. G-091, “Receipt, Marking, and Stocking of Raw Material,” Revision U, dated August 9, 2018

- PUR-001, “Supplier Evaluation and Audits,” Revision B, dated March 19, 2013

- PUR-002, “Adding Suppliers/Sub-Contractors,” Revision B, dated March 19, 2013

- PUR-003, “Approved Suppliers,” Revision C, dated March 19, 2013

- PUR-005, “Issuing Purchase Orders,” Revision B, dated March 19, 2013

Corrective Action Reports

- ICAR No. I-021516-01, dated February 15, 2016

- ICAR No. I-021516-02, dated February 15, 2016

- ICAR No. I-021516-03, dated February 15, 2016

- ICAR No. I-021516-04, dated February 15, 2016

- ICAR No. I-022216-05, dated February 22, 2016

- ICAR No. I-022216-06, dated February 22, 2016
- ICAR No. I-022216-07, dated February 22, 2016
- ICAR No. I-022216-08, dated February 22, 2016
- ICAR No. I-030216-09, dated March 2, 2016
- ICAR No. I-030216-10, dated March 2, 2016
- ICAR No. I-030216-11, dated March 2, 2016
- ICAR No. I-030216-12, dated March 2, 2016
- ICAR No. I-051616-01, dated May 16, 2016
- ICAR No. I-051616-02, dated May 16, 2016
- ICAR No. I-051616-03, dated May 16, 2016
- ICAR No. I-060718-03, dated June 13, 2018
- ICAR No. I-030420-01, dated March 4, 2020

Corrective Actions Opened During the NRC Inspection

- ICAR No. I-031320-01, dated March 13, 2020
- ICAR No. I-031320-02, dated March 13, 2020
- ICAR No. I-031320-03, dated March 13, 2020
- ICAR No. I-031320-04, dated March 13, 2020
- ICAR No. I-031320-05, dated March 13, 2020
- ICAR No. I-031320-06, dated March 13, 2020
- ICAR No. I-031320-07, dated March 13, 2020
- ICAR No. I-031320-08, dated March 13, 2020

Corrective Action Documents

- 652A, Corrective Action Report Log for Procedures and Systems (ICAR)
- Returned Material Packages dated December 30, 2019 and October 24, 2019, showing receipt, review, disposition/return to customer

- Non-conforming Material Report No. 7220
- Hold item, ticket No. 000302464, dated March 9, 2020 (in the casting scrap salvage area)
- 10 CFR Part 21 Meeting agenda log (spreadsheets) for 2016, 2017, 2018, 2019, and 2020

Purchase Orders, Audit Reports, and Commercial-Grade Surveys

- ASCO's Calibration Providers List
- External Audit Report of a supplier of testing services for an audit performed on August 6, 2019
- External Audit Report of a supplier of testing services for an audit performed on December 20, 2019
- Internal Audit Report, "Receiving Inspection," dated August 22, 2018
- Internal Audit Report, "Receiving Inspection," dated March 26, 2019
- Internal Audit Report, "Management," dated January 17, 2019
- Internal Audit Report, "Management," dated January 20, 2020
- Internal Audit Report, "Production Control Valve & Actuator," dated March 13, 2019
- Internal Audit Report, "Production Control Valve & Actuator," dated February 28, 2020
- Internal Audit Report, "Calibration Audit," dated October 3, 2018
- Internal Audit Report, "Product Engineering/Technical Services," dated February 18, 2019
- Internal Audit Report, "Navy Inspection/Nuclear Dedication Inspection," dated August 29, 2018
- Internal Audit Report, "Navy Inspection/Nuclear Dedication," dated April 30, 2019
- Internal Audit Report, "Management," dated January 17, 2019
- Internal Audit Report, "Management," dated January 30, 2020
- Purchase Order (PO) No. 4241004893 for an electrical connector assembly, Revision 1, dated August 2, 2019
- PO No. 4241006738 for an electrical connector assembly, Revision 2, dated September 10, 2019

- PO No. 810800 for seismic testing services, Revision 0, dated November 30, 2017
- PO No. 4241003427 for seismic testing services, Revision 2, dated July 9, 2019
- PO No. 4241009261 for calibration services, Revision 0, dated October 30, 2019
- PO No. 4241010486 for calibration services, Revision 0, dated November 26, 2019
- PO No. 937546 for calibration services, Revision 0, dated April 28, 2019
- PO No. 4241000635 for calibration services, Revision 0, dated May 6, 2019
- PO No. 4241004826 for calibration services, Revision 0, dated August 1, 2019
- PO No. 4241002297 for calibration services, Revision 0, dated June 14, 2019
- PO No. 864434 for calibration services, Revision 0, dated June 6, 2018
- PO No. 787914 for calibration services, Revision 0, dated September 13, 2017
- Commercial-Grade Survey of supplier No. 150002160, dated November 20, 2018
- Commercial-Grade Survey of supplier No. 150036573, dated August 26, 2015
- ASCO Receipt Traveler for a cold rolled steel sleeve associated with purchase order No. 99002545
- Drawing No. 099033, “Sleeve M-12 Solenoid,” Revision 8 (no date available)

Calibration Records and Certificates of Conformance

- ASCO’s Calibration Commercial Grade Checklist
- Calibration Work order for gage ID No. IDG-D11, dated March 11, 2020
- Certificate of Conformance/Compliance for PO No. 4241004893, dated October 31, 2019
- Certificate of Conformance/Compliance for PO No. 4241006738, dated November 26, 2019
- Certificate of Conformance for PO No. 810800 (no date provided)
- Certificate of Conformance for PO No. 4241003427 (no date provided)
- Certificate of Conformance for a cold rolled steel sleeve, dated March 6, 2020
- Certificate of Calibration No. 12052019-000050 for gage ID No. DI-08456, calibrated on December 5, 2019

- Certificate of Calibration No. 10092019-000001 for gage ID No. SC-7193, calibrated on October 9, 2019
- Certificate of Calibration No. 10192019-000023 for gage ID No. PGS-02, calibrated on October 19, 2019
- Certificate of Calibration No. 03112020-000025 for gage ID No. IDG-D11, calibrated on March 11, 2020
- Certificate of Calibration No. 02032020-000029 for gage ID No. DI-25, calibrated on February 2, 2020
- Certificate of Calibration No. 09232019-000029 for gage ID No. TQ-250 E, calibrated on September 23, 2019
- Certificate of Calibration No. 03062020-000017 for gage ID No. VTAT-8300-001, calibrated on March 6, 2020
- Certificate of Calibration No. 12272019-000009 for gage ID No. VTAT-027502-2, calibrated on December 27, 2019
- Certificate of Calibration No. 01142020-000053 for gage ID No. TQ-6988, calibrated on January 14, 2020
- Certificate of Calibration No. 1654680 for gage ID No. PR-407 A, calibrated on August 8, 2019
- Certificate of Calibration No. 1654674 for gage ID No. PR(I)-88, calibrated on August 8, 2019
- Certificate of Calibration No. 1645302 for gage ID No. PR(I)-502 A, calibrated on July 9, 2019
- Certificate of Calibration No. 1604774 for gage ID No. HP-25, calibrated on February 25, 2019
- Measuring and Test Equipment (M&TE) Report Form No. 5336 for gage ID No. SURF PL-950362, dated January 15, 2020
- M&TE Report Form No. 4717 for gage ID No. PR-575 B, dated January 9, 2019
- M&TE Report No. 5337 for gage ID No. SPR TEST-2A, dated January 15, 2020

Nonconformance Reports

- ERP NC Number: NC000300932
- ERP NC Number: NC000301994

Forms/Packages Reviewed

- 7220, 7220A, NMCR -Pilgrim & Oracle System
- 3712, Order Receipt Form
- 3877, RMA Evaluation/Repair Instructions
- 2663, In Process/Final Inspection Requirements
- VaQA652a, Internal Corrective/Preventive Action Report

Training and Qualification Records

- Lead auditor qualification records for Robert Arnone, Andrew Zamiela, Cecil Melendez, and Justin Miller
- Inspection Technician Qualification Records for Brenda Johnson
- Calibration Technician Qualification Records for Terry Nettles