EMERSON.
Industrial Automation

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September 27, 2016

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

Subject: REPLY TO NOTICE OF NONCONFORMANCE
ASCO VALVE, INC., DOCKET NO. 99901054
VENDOR INSPECTION REPORT 99901054/2016-201

References: 1.) NRC Notice of Nonconformance 99901054/2016-201-01
2.) NRC Vendor Inspection Report No. 99901054/2016-201

ASCO Valve, Inc. (ASCO) provides in the Attachment 1 identified as hereto the written statement or explanation requested in the Notice of Nonconformance (Reference 1) dated April 15, 2016. Attachment 1 contains information that ASCO considers to be proprietary. Attachment 2 hereto is ASCO's Reply with the proprietary information redacted. Attachment 3 hereto is in response to the letter from Mr. Richard McIntyre dated July 5, 2016 Attachment 3 replaces the affidavit transmitted by my letter dated June 9, 2016, which includes ASCO's affidavit supporting its request for proprietary treatment of the redacted information. The Nonconformance was identified during the Nuclear Regulatory Commission's (NRC) inspection of ASCO's Aiken SC facility (Reference 2) conducted February 8th-12th, 2016 by Edgardo Torres (Inspection Leader), Laura Micewski, Raju Patel, and Louis Dumont.

Please contact me at (803) 641-9205 if you have questions or need to discuss this matter further.

ASCO self-identified that the letter needed to be corrected to include the proprietary legend that was inadvertently left off the pages of attachment 1.

Sincerely,

Michael G. Lenio
Director of Quality
ASCO Valve, Inc.

cc. Chief, Quality Vendor Inspection Branch-2
Division of Construction Inspection and Operational Programs
Office of New Reactors, USNRC

IE09
NRO

ASCO®

Attachment 3

AFFIDAVIT

Re: Request for Withholding from Public Disclosure per 10 C.F.R. 2.390

STATE OF SOUTH CAROLINA)
) ss
COUNTY OF AIKEN)

I, Michael G. Lenio, being duly sworn, hereby say and depose:

1. I am Director of Quality, ASCO Valve, Inc. ("ASCO") and as such I have been specifically delegated the function of reviewing company proprietary information sought to be withheld from public disclosure in connection with the nuclear safety related qualification of certain o-rings and am authorized to apply for its withholding on behalf of ASCO.

2. The information sought to be withheld is contained in the ASCO's Reply to Notice of Nonconformance 99901054/2016-201.

   The document contains information considered to be proprietary (Attachment 1). Proprietary material in the enclosed document is indicated by brackets [ ] or other similar markings as required by 10 C.F.R. 2.390(b)(1)(i)(B). A non-proprietary version of the document with specific proprietary information deleted (Attachment 2) is also being provided, as indicated in the transmittal letter.

   The information considered to be proprietary consists of information (compound numbers) identifying the materials used in o-rings that are referenced in the cited Notice of Nonconformance as well as the manufacturers supplying those compounds to ASCO.

3. I am making this affidavit in conformance with the provisions of 10 C.F.R. § 2.390 of the Commission's regulations and in conjunction with ASCO's application for withholding accompanying this Affidavit.

4. I have personal knowledge of the criteria and procedures utilized by ASCO in designating information as a trade secret, privileged, or as confidential commercial or financial information. Some examples of categories of information which fit into the definition of proprietary information are:

   a) Information which discloses process, method, or apparatus, including supporting data and analyses, where prevention of its use by ASCO's competitors without license or contract from ASCO constitutes a competitive economic advantage over other companies in the industry.
   b) Information, which if used by a competitor, would reduce his expenditure of resources or improve his competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
   c) Information which reveals cost or price information, production capacities, budget levels, or commercial strategies of ASCO, its customers, its partners, or its suppliers.

d) Information which reveals aspects of past, present, or future ASCO customer-funded development plans or programs, of potential commercial value to ASCO.
e) Information which discloses patentable subject matter for which it may be desirable to obtain patent protection.
f) Information obtained through ASCO actions which could reveal additional insights into nuclear safety-related equipment qualification processes and regulatory proceedings, and which are not otherwise readily obtainable by a competitor.

Information sought to be withheld is considered to be proprietary based on the reasons set forth in paragraphs 4(a),(b) and (f) above.

5. Disclosure of the information sought to be withheld would cause substantial harm to ASCO's competitive position as there are other competing companies who market or may seek to market nuclear-qualified o-rings. Competing firms could seek to use the manufacturers and compounds which ASCO has expended significant resources to qualify without compensating ASCO, thereby putting ASCO at a competitive disadvantage. Specifically, ASCO believes that publicly identifying the specific compounds used in ASCO's nuclear-qualified o-rings would allow potential competitors to avoid the costs that ASCO has incurred to qualify those compounds. Similarly, identifying the specific manufacturers that ASCO uses to supply those compounds would allow potential competitors to determine which of the multiple manufacturers of the o-ring material have the requisite quality programs to supply nuclear-qualified material, thus avoiding the costs which ASCO has incurred to make those determinations.

6. Pursuant to the provisions of paragraph (b)(4) of Section 2.390 of the Commission's regulations, the following is furnished for consideration by the Commission in determining whether the information sought to be withheld from public disclosure should be withheld.
   (i) The information sought to be withheld from public disclosure is owned and has been held in confidence by ASCO.
   (ii) The information is of a type customarily held in confidence by ASCO and not customarily disclosed to the public. ASCO has a rational basis for determining the types of information customarily held in confidence by it and, in that connection, utilizes a system to determine when and whether to hold certain types of information in confidence. The application of that system and the substance of that system constitute ASCO policy and provide the rational basis required.
   (iii) The information is being transmitted to the Commission in confidence and, under the provisions of 10 C.F.R. § 2.390, it is to be received in confidence ty the Commission.
   (iv) This information is not readily available in public sources.
   (v) Public disclosure of this proprietary information is likely to cause substantial harm to ASCO's competitive position, because it would enhance the ability of competitors to provide similar equipment without the investment made by ASCO to qualify that equipment at considerable expense to ASCO and has significant value.

7. The foregoing statements are true and correct to the best of my knowledge information, and belief.

Michael G. Lenio
Director of Quality
ASCO Valve, Inc.

Sworn to and subscribed before me

This 1st day of September, 2016

Heather B Riggs
Notary Public

Heather B Riggs
Notary Public South Carolina
My Commission Exp: 8-18-2025

HEATHER B RIGGS
NOTARY
My Comm. Expires
8-18-2025
PUBLIC
SOUTH CAROLINA

Nonconformance Item 2:

Nonconformance Item 2 states the following:

> 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), Part # G027502-001-K, 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, Part # 022525-007-90, by performing either a Fourier transform infrared spectroscopy (FTIR) or burn test, as required by the CGD receipt inspection acceptance plan.*

ASCO's Response to Item 2:

The Quality System provides the inspector with three options to record the result: 1.) Pass, 2.) Skip, and 3.) Fail. The "Skip" selection is commonly used to document inspected items that were previously dedicated. However, this selection does not facilitate an explicit reference to notes regarding the prior dedication inspection. In addition, when the inspection record is printed, as is the case during audits and inspections, the reference to the prior dedication is not included in the printed information. During the NRC inspection, the printed document was reviewed and the notes regarding prior dedication were missed as a result.

Regarding example one (PO 1015038212, Part # G027502-001-K): A notation of prior dedication inspection was included on the inspection record, but was not observed or noted during the NRC Inspection. The critical characteristics including markings, inner diameter, outer diameter, length, turns, lead length, resistance, and the leads were inspected at the dedication inspection and the material was put into stock in the nuclear stock room. This inspection dedicates the coil. Therefore, when pulled for a specific order, an additional inspection is not required.

When a previously dedicated component is selected for a work order, the dedication inspector documents the original inspection number that dedicated the component, and then selects one of the three available options. In this example, the previous inspection record was referenced, and the "skip" option was selected. ASCO has verified the inspection record does include a reference to the original dedication inspection but was not noted or observed during the NRC Inspection.

The review of the elements of example one in Item 2 described above indicates that ASCO performed receipt inspection and dedication inspections consistent with our procedures. Therefore, ASCO takes exception to the finding in this example. However, ASCO understands the concerns expressed by the NRC during the inspection and is implementing corrective actions as described below to address those specific concerns.

Regarding example two (Work Order 797668-15, Part # 022525-007-90): Parts were inspected as commercial product. Material verification was not performed at receipt inspection. There are instructions in the Operations Sheet to perform a material verification at receipt inspection. However, for this particular order, instructions given by the Quality Manager were misinterpreted to omit this step at receipt inspection. This instruction was provided on 10/1/15 to inspectors via e-mail. It should be noted that ASCO's MRP (Material Resource Planning) system designates all parts used in Nuclear products as "MP-I-094" parts. Once a part carries this designation, the designation cannot be removed, even if the part is no longer used for Nuclear products. This maintains the record integrity for legacy products. Operations Sheets are updated for parts that are no longer used in Nuclear products. Inspectors must use the Operations Sheets to ensure proper inspection and dedication is performed. There is a provision in ASCO Procedure MP-I-026 – "*Sampling Plan for Product Acceptance*" to allow for exceptions from the Operations Sheet if authorized by the Quality Manager or designee.

Corrective Actions:

- ASCO Procedure QC-ER-096 – "*Commercial Grade Dedication of Nuclear Valves, Actuators and Pressure / Temperature Switches, and Calibration Services*", has been revised to eliminate the practice of selecting "Skip" for nuclear items. Going forward, the items will be inspected and reference to the previous dedication inspection will be prominently noted.
- ASCO reviewed the extent of condition for all parts listed on o-ring drawings to ensure that the inspection Operations Sheets reflect the current revision level and all nuclear items are properly identified.
- ASCO determined that the instruction to the inspectors to skip certain parts inspections was given on 10/1/15. ASCO reviewed the extent of condition for dedication records from 10/1/14 to 2/26/16. The findings concluded that no parts designated for use in Nuclear products were inspected as commercial items from 10/1/14 to 10/1/15. After the instruction by the Quality Manager had been issued, in the period from 10/1/15 to 2/26/16, ten lots of parts designated for use in Nuclear products, including the part in example two, were inspected as commercial product. Parts from nine of these lots were still available. ASCO has sampled the stock from these nine lots and verified the correct material in accordance with ASCO Procedure QC-ER-008 – "*Material Verification*". It was determined that none of the material from the tenth lot was used in the production of a Nuclear product.

NRC Nonconformance Item 3:

Nonconformance Item 3 states the following:

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.*

ASCO's Response to Item 3:

The material verification of elastomeric components is destructive. ASCO Procedure EDP-177 – "*Determination of Critical Characteristics for Dedication Inspection (Nuclear Valves)*" did not properly identify sampling plans for parts requiring destructive testing to ensure a lot is homogenous per EPRI industry standards. In addition, ASCO Procedure MP-I-026 – "*Sampling Plan for Product Acceptance*" does not address sample size to be used for destructive testing. The practice has been to use one sample from the lot received for material verification. ASCO did not define a sampling plan as defined in EPRI 5652 Commercial Grade Dedication section D.2.9, Referencing EPRI report TR-017218-R1 sampling plans for destructive and non-destructive inspection methods.

Corrective Actions:

- ASCO Procedure EDP-177 – "*Determination of Critical Characteristics for Dedication Inspection (Nuclear Valves)*" section 4.A & 4.B has been revised to reference destructive and non-destructive testing as follows:

    a. Destructive type testing:
    Material verification is typically a destructive testing feature that is critical when listed as such in the FMEA document, therefore dedication inspection needs to verify that receiving inspection performed sufficient destructive type testing on the lot/batch being dedicated based on the criteria below:

        1. For custom parts direct from the manufacturer, a sampling plan of one piece per lot is allowed per EPRI report TR-017218-R1 section 2.4.4.1 as the lot is traceable to the production lot number.
        2. For O-rings, U-cups, and other commercially available parts traceable to a single manufacturer, verify that the sampling plan set forth under section 2.4.4.2 of EPRI report TR-017218-R1 is followed.

b. Non-destructive testing where the sample inspected during receipt inspection would show consistent results throughout the entire lot and/or batch. Where features and criteria can be expected to have similar consistent results, a sampling plan lower than 100% based on Section 2.3.4.1 of EPRI report TR-017218-R1 can be selected and approved as specified on the Operations Sheet.

- MP-I-026 – *"Sampling Plan for Product Acceptance"* will be revised to include Sampling Plan for both destructive and non-destructive testing. Corrective action completion date is August 10, 2016.

End of Attachment 1

Attachment 2

This Attachment sets forth ASCO Valve Inc.'s (ASCO's) written statement or explanation in response to the Notice of Nonconformance 99901054/2016-201-01, dated April 15, 2016 (the "Nonconformance").

Nonconformance Item 1:

Nonconformance Item 1 states the following:

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 Part # G039619-050-VI (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 [**********], who sourced them, from [**********].*

(ASCO NOTE: The correct PO referenced in the bullet point above is 1015045876)

• *PO 1015054413 for twenty-three NP 8316 3-way solenoid valves for Areva, a distributor for domestic nuclear plants, called for O-rings, Part # G089834-005-HT (O-ring nuclear), Part # G031325-002-HT (O-ring nuclear), and Part # G039619-005-HT (nuclear O-ring). All are made of ethylene propylene. These O-rings were procured from [**********], who sourced them from [**********].*

• *PO 4500834520 with PSEG Nuclear for an NPX8223G131 solenoid valve for Hope Creek called for a rubber disc, Part # G064355-007 (Disc nuclear). The valve disc was procured commercially from [**********].*

ASCO's Response to Item 1:

Based on ASCO's procedure for conducting commercial grade dedication, ASCO Procedure QC-ER-096 – "*Commercial Grade Dedication of Nuclear Valves, Actuators and Pressure / Temperature Switches, and Calibration Services*", critical characteristics are identified and translated into inspection criteria and verified during receipt and dedication inspection. 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. In doing so, ASCO is able to maintain traceability to compound number, cure date, lot and batch codes, and purchase order number.

Regarding example one (PO 1015045876, Part # G039619-050-VI): The referenced o-rings were verified to be Viton in accordance with ASCO Procedure QC-ER-008 – "*Material Verification*" at receipt inspection. In accordance with ASCO Procedure QC-ER-096 – "*Commercial Grade Dedication of Nuclear Valves, Actuators and Pressure / Temperature Switches, and Calibration Services*", material verification was performed and documented at receipt inspection. Then the batch/lot number and cure date were recorded in the dedication inspection record for traceability back to the receipt inspection record containing material verification. Notes from the receiving record and dedication record for the part in this example are summarized below:

Receiving Record INS-IC494574-01

- Part #: 039619-050-VI
- Cure Date: 1Q15
- Compound #: [**********]
- Batch/Lot #: UF207000/60219
- Manufacturer: [**********]
- Material Verification Test Result: FKM (Viton), self extinguishing, specific gravity=1.88, performed on 08/06/15

Dedication Record INT-FN425924-01

- Part #: G039619-050-VI
- Supplier: [**********]
- Purchase Order #: 592526
- Batch/Lot #: UF207000/60219
- Compound #: [**********]
- Cure Date: 1Q15

Regarding example two (PO 1015054413, Part # G089834-005-HT, G031325-002-HT, and G039619-005-HT): The referenced o-rings were verified to be ethylene propylene in accordance with ASCO Procedure QC-ER-008 – "*Material Verification*" at receipt inspection. Elastomeric materials are not verified at dedication inspection since this requires a destructive test. Therefore, in accordance with ASCO Procedure QC-ER-096 – "*Commercial Grade Dedication of Nuclear Valves, Actuators and Pressure / Temperature Switches, and Calibration Services*"; the cure date, compound number, lot and batch, and ASCO purchase order are recorded into the dedication inspection record to maintain traceability.

ASCO reviewed the receipt inspection records for these parts to verify that material testing was performed at receipt inspection. Notes from the receiving record for the parts in this example are summarized below:

ASCO Order #606405; Work Order # 425656

- Part #: G089834-005-HT
  - Supplied by: [**********]
  - Purchase Order #: 552291
  - Batch/Lot #: 201109080/50399
  - Compound #: [**********]
  - Cure Date: 3Q11
  - Material Verification Test Result EP (ethylene propylene) - Burns readily, Black Coarse Ash and subtle odor, does not swell in MEK (Methyl Ethyl Ketone), test performed on 3/23/15
- Part #: G031325-002-HT
  - Supplied by:[**********]
  - Purchase Order #: 592889
  - Batch/Lot #: 021407050163/60963
  - Compound #: [**********]
  - Cure Date: 3Q14
  - Material Verification Test Result - has very subtle odor, burns readily
- Part #: G039619-005-HT
  - Supplied by [**********]
  - Batch/Lot #: 021405100224/57573
  - Compound #: [**********]
  - Cure Date: 2Q14
  - Material Verification Test Result - FTIR (Fourier Transform Infrared Spectroscopy) test performed 9/18/15 Sample @ MP-I-026 S5 Plan

Regarding example three (PO 4500834520, Part # G064355-007): The referenced o-ring was purchased direct from the manufacturer, [**********]. The inspection record did include ASCO purchase order, material received, lot and batch numbers, compound number, and cure date. ASCO performed a commercial-grade survey at [**********]. However, the critical characteristics in the survey of [**********] did not include a review of their verification of raw material (resin) and validation of materials. Material Identification was identified as a critical characteristic, but was not adequately verified during the commercial grade survey.

ASCO reviewed the receipt inspection records for these parts to verify that material testing was performed at receipt inspection. Notes from the receiving record for the parts in this example are summarized below:

ASCO Order # 420397, Work Order # 193419

- Part #: G064355-007
- Supplied by [**********]
- Purchase Order #: 533736
  - Batch/Lot #: 201213520065
  - Compound #: [**********]
  - Cure Date: 2Q12
  - Material Verification Test Result: buna, combustible, swells in MEK specific gravity=1.297, test performed on 12/09/14
- Purchase Order #: 542607
  - Batch/Lot #: 201502120272
  - Compound #: [**********]
  - Cure Date: 1Q15
  - Material Verification Test Result: NITRILE/NBR, Combustible, Black Coarse Ash and high cyanogenic odor, Swells in MEK, test performed on 3/18/15 Sampled @ MP-I-026 S5 Plan

The review of the elements of Item 1 described above indicates that ASCO performed receipt inspections and dedication inspections consistent with our procedures which we believe are adequate. Therefore, ASCO takes exception to the finding in these examples. However, ASCO understands the concerns expressed by the NRC inspectors during the inspection and is implementing the following corrective actions to address those specific concerns:

Corrective actions:

- Commercial-grade surveys have been revised to include critical characteristics as acceptance criteria for all elastomers at both distributors and suppliers.
- The verification of raw materials has been added to the critical characteristics for the survey of elastomeric manufacturers.
- ASCO performed an extent of condition review of [**********] and identified 115 elastomeric parts used in nuclear products that are sourced from three manufacturers that supply elastomeric products to [**********]. ASCO plans to perform surveys at each of these suppliers using the revised survey that includes raw material verification by August 10, 2016.
- The extent of condition review also identified additional distributors of parts used for nuclear products. ASCO will review all items provided by suppliers through distribution, and will perform an evaluation as to the part's potential effect on the safety function of the basic component. Corrective action completion date is August 10, 2016.

Nonconformance Item 2:

Nonconformance Item 2 states the following:

> 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), Part # G027502-001-K, 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, Part # 022525-007-90, by performing either a Fourier transform infrared spectroscopy (FTIR) or burn test, as required by the CGD receipt inspection acceptance plan.*

ASCO's Response to Item 2:

The Quality System provides the inspector with three options to record the result: 1.) Pass, 2.) Skip, and 3.) Fail. The "Skip" selection is commonly used to document inspected items that were previously dedicated. However, this selection does not facilitate an explicit reference to notes regarding the prior dedication inspection. In addition, when the inspection record is printed, as is the case during audits and inspections, the reference to the prior dedication is not included in the printed information. During the NRC inspection, the printed document was reviewed and the notes regarding prior dedication were missed as a result.

Regarding example one (PO 1015038212, Part # G027502-001-K): A notation of prior dedication inspection was included on the inspection record, but was not observed or noted during the NRC Inspection. The critical characteristics including markings, inner diameter, outer diameter, length, turns, lead length, resistance, and the leads were inspected at the dedication inspection and the material was put into stock in the nuclear stock room. This inspection dedicates the coil. Therefore, when pulled for a specific order, an additional inspection is not required.

When a previously dedicated component is selected for a work order, the dedication inspector documents the original inspection number that dedicated the component, and then selects one of the three available options. In this example, the previous inspection record was referenced, and the "skip" option was selected. ASCO has verified the inspection record does include a reference to the original dedication inspection but was not noted or observed during the NRC Inspection.

The review of the elements of example one in Item 2 described above indicates that ASCO performed receipt inspection and dedication inspections consistent with our procedures. Therefore, ASCO takes exception to the finding in this example. However, ASCO understands the concerns expressed by the NRC during the inspection and is implementing corrective actions as described below to address those specific concerns.

Regarding example two (Work Order 797668-15, Part # 022525-007-90): Parts were inspected as commercial product. Material verification was not performed at receipt inspection. There are instructions in the Operations Sheet to perform a material verification at receipt inspection. However, for this particular order, instructions given by the Quality Manager were misinterpreted to omit this step at receipt inspection. This instruction was provided on 10/1/15 to inspectors via e-mail. It should be noted that ASCO's MRP (Material Resource Planning) system designates all parts used in Nuclear products as "MP-I-094" parts. Once a part carries this designation, the designation cannot be removed, even if the part is no longer used for Nuclear products. This maintains the record integrity for legacy products. Operations Sheets are updated for parts that are no longer used in Nuclear products. Inspectors must use the Operations Sheets to ensure proper inspection and dedication is performed. There is a provision in ASCO Procedure MP-I-026 – "*Sampling Plan for Product Acceptance*" to allow for exceptions from the Operations Sheet if authorized by the Quality Manager or designee.

Corrective Actions:

- ASCO Procedure QC-ER-096 – "*Commercial Grade Dedication of Nuclear Valves, Actuators and Pressure / Temperature Switches, and Calibration Services*", has been revised to eliminate the practice of selecting "Skip" for nuclear items. Going forward, the items will be inspected and reference to the previous dedication inspection will be prominently noted.
- ASCO reviewed the extent of condition for all parts listed on o-ring drawings to ensure that the inspection Operations Sheets reflect the current revision level and all nuclear items are properly identified.
- ASCO determined that the instruction to the inspectors to skip certain parts inspections was given on 10/1/15. ASCO reviewed the extent of condition for dedication records from 10/1/14 to 2/26/16. The findings concluded that no parts designated for use in Nuclear products were inspected as commercial items from 10/1/14 to 10/1/15. After the instruction by the Quality Manager had been issued, in the period from 10/1/15 to 2/26/16, ten lots of parts designated for use in Nuclear products, including the part in example two, were inspected as commercial product. Parts from nine of these lots were still available. ASCO has sampled the stock from these nine lots and verified the correct material in accordance with ASCO Procedure QC-ER-008 – "*Material Verification*". It was determined that none of the material from the tenth lot was used in the production of a Nuclear product.

NRC Nonconformance Item 3:

Nonconformance Item 3 states the following:

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.*

ASCO's Response to Item 3:

The material verification of elastomeric components is destructive. ASCO Procedure EDP-177 – "*Determination of Critical Characteristics for Dedication Inspection (Nuclear Valves)*" did not properly identify sampling plans for parts requiring destructive testing to ensure a lot is homogenous per EPRI industry standards. In addition, ASCO Procedure MP-I-026 – "*Sampling Plan for Product Acceptance*" does not address sample size to be used for destructive testing. The practice has been to use one sample from the lot received for material verification. ASCO did not define a sampling plan as defined in EPRI 5652 Commercial Grade Dedication section D.2.9, Referencing EPRI report TR-017218-R1 sampling plans for destructive and non-destructive inspection methods.

Corrective Actions:

- ASCO Procedure EDP-177 – "*Determination of Critical Characteristics for Dedication Inspection (Nuclear Valves)*" section 4.A & 4.B has been revised to reference destructive and non-destructive testing as follows:

    a. Destructive type testing:
    Material verification is typically a destructive testing feature that is critical when listed as such in the FMEA document, therefore dedication inspection needs to verify that receiving inspection performed sufficient destructive type testing on the lot/batch being dedicated based on the criteria below:

        1. For custom parts direct from the manufacturer, a sampling plan of one piece per lot is allowed per EPRI report TR-017218-R1 section 2.4.4.1 as the lot is traceable to the production lot number.
        2. For O-rings, U-cups, and other commercially available parts traceable to a single manufacturer, verify that the sampling plan set forth under section 2.4.4.2 of EPRI report TR-017218-R1 is followed.

b. Non-destructive testing where the sample inspected during receipt inspection would show consistent results throughout the entire lot and/or batch. Where features and criteria can be expected to have similar consistent results, a sampling plan lower than 100% based on Section 2.3.4.1 of EPRI report TR-017218-R1 can be selected and approved as specified on the Operations Sheet.

- MP-I-026 – "*Sampling Plan for Product Acceptance*" will be revised to include Sampling Plan for both destructive and non-destructive testing. Corrective action completion date is August 10, 2016.

End of Attachment 2