



Lynn Skarin
Quality Assurance Manager
Pentair Valves & Controls US LP
Anderson Greenwood Crosby
55 Cabot Boulevard
Mansfield, MA 02048
Tele: 508-594-4450
Fax: 508-594-4279

REPLY TO A NOTICE OF NONCONFORMANCE

February 3, 2017

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN : Document Control Desk

Subject: Reply to Notice of Nonconformance
NRC Inspection Report No. 99901431/2016-201
Nonconformance 99901431/2016-201-01

Dear Sir,

Pursuant to the instructions in the Notice of Nonconformance, our response is herein provided.

Nonconformance 00001431/2016-201-01:

Nonconformance 99901431/2016-201-01 is the failure of Pentair to promptly identify and correct conditions adverse to quality. Specifically, Pentair closed its Corrective Action Reports (CARs) 665, 666, and 709 without adequately implementing the corrective actions to address the findings in the 2013 NRC Inspection Report 99901431/2013-201.

Reason for the noncompliance

The root cause for the above noncompliance was poor administration of the follow up responses sent to the NRC after the initial REPLY TO A NONCONFORMANCE was submitted. In most cases, CARs resulting from internal conditions adverse to quality or resulting from audit findings are closed upon verification of the implementation of corrective action without any further action required. Instances where Pentair is required to provide additional or revised corrective action plans are rare. Pentair had provided the NRC with the "Reply to Request for Clarification and Additional Information" four months following the initial reply and failed to update the original CARs to document the revised Planned Corrective Actions. If the follow up replies had been administered properly, the applicable CARs should have been reopened or new CARs generated to address the revised and/or additional corrective actions proposed. These open CARs would have then been tracked and monitored by the Corrective Action Board (CAB) for status and to identify the need for follow-up actions.

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Reason for the noncompliance (continued)

Three of the original six Pentair Corrective Action Requests (CAR) associated with the Notice of Nonconformance issued within NRC Report No 99901431/2013-201 were found to have been effectively implemented and closed out accordingly. The specific reason for noncompliance for each of the remaining three CARs is addressed below.

- 1) With regards to CAR 665 (Nonconformance 99901431/2013-201-06) pertaining to the temperature and humidity control for weld rod ovens, all of Pentair's responses and proposed planned corrective actions to the NRC focused on the temperature control of the ovens only with no mention of humidity control. Pentair contacted Phoenix International, the manufacturer of our on-site weld rod ovens who advised that humidity controls on the ovens are not necessary. When operated at the recommended drying temperatures, the weld oven removes any moisture absorbed by the weld rods through the baking process. Any moisture that accumulates within the oven exits through the oven vents. Pentair took immediate corrective action to purchase and install a calibrated temperature gage on the weld rod oven and closed CAR 655 on 9/26/2013. Pentair's response to the NRC addressed the resolution of the nonconformance regarding weld oven temperature controls but overlooked providing a valid explanation to why humidity controls were not necessary.
- 2) With regards to CAR 666 (Nonconformance 99901431/2013-201-04), the original response Pentair provided on September 20, 2013 to the Notice of Nonconformance 99901431/2013-201-04 stated that the planned corrective action was to a) locate and label all Neolube 1 bottles with a Tag stating "For Navy Use Only," b) train all assembly personnel regarding use of Neolube 1 which is currently only used for Navy products and c) train manufacturing supervisor to monitor and label all new incoming shipments of Neolube 1 prior to disbursement. Pentair took immediate corrective action to implement the above steps and closed out CAR 666 on 9/17/2013 prior to Pentair providing the formal response to the NRC for the REPLY TO A NOTICE OF NONCONFORMANCE.

A Request for Additional Clarification and Information was then received from the NRC in November of 2013 and Pentair's follow up response in December of 2013 stated an additional planned corrective action to revise a number of internal assembly and cleaning procedures. Pentair failed to update the original CAR 666, or issue a new CAR to record the additional planned corrective actions noted in the reply. Since there was no open CAR tracking the status of the planned resolutions, no subsequent follow up took place by the Corrective Action Board (CAB) to ensure that the referenced procedures were revised.

- 3) In the case of CAR 709 (Nonconformance 99901431/2013-201-05), the original planned corrective action stated that Pentair would apply Method 3 of EPRI NP-5652 to verify the supplier's capability to control material traceability to a heat number, production lot number or batch number. Pentair revised our Vendor Audit Schedule to include the Commercial Grade

Survey's for three suppliers of elastomeric items. Once the revised Vendor Audit Schedule was issued, Pentair prematurely closed the CAR based on the revised audit schedule and did not conduct proper verification that the audits were completed. Similarly as noted above, since there was no open CAR tracking the status of the planned resolution, no subsequent follow up took place by the Corrective Action Board (CAB) to ensure that the audits were completed.

Corrective steps that have been taken and results achieved

In response to this Notice of Nonconformance, Pentair has initiated CAR 1017 to address Pentair's overall Corrective Action program. An extent of condition review will be conducted for all CAR's associated with Pentair's Section III, 10CFR50 Appendix B Manual QC-110 dating back to 2013 timeframe. There are approximately 300 Corrective Action Requests that will be reviewed to assure that the planned corrective action addresses all aspects of the nonconformance as well as verification that the correction action was fully implemented.

In addition, new Corrective Action Requests CAR 976, 974, and 978 have been initiated for each of the nonconformances associated with the three original CARs referenced above.

- 1) New Corrective Action Request 976 has been initiated to document the technical justification for humidity control which was not originally addressed in CAR 665 for Nonconformance 99901431/2013-201-06. As mentioned above, Phoenix International was contacted and advised that humidity control on the weld rod ovens is not required. Back up correspondence and documentation from the vendor is maintained on file under new CAR 976. No further action is required.
- 2) New Corrective Action Request 974 has been initiated to document the additional planned corrective action stated within Pentair's Reply to Notice of Nonconformance dated March 24, 2014 which was not originally addressed in CAR 666 for Nonconformance 99901431/2013-201-04. Within that response, Pentair had noted that Engineering identified 40 cleaning procedures and 17 assembly procedures to be revised in order to clarify the use of Neolube for Nuclear applications. This CAR will remain in open status until 1) all identified procedures have been revised and 2) all of the Engineering and assembly personnel have been trained accordingly. All backup documentation and training records will be maintained on file under new CAR 974.
- 3) New Corrective Action Request 978 has been initiated to address the lack of implementation of corrective action on original CAR 709 for Nonconformance 99901431/2013-201-05. The original planned corrective action under CAR 709 stated that Pentair would apply Method 3 of EPRI NP-5652 to verify the supplier's capability to control material traceability to a heat number, production lot number or batch number. Pentair will conduct commercial grade survey's of its supplier's of elastomeric parts to verify the supplier's quality program is capable of appropriate

control of required critical characteristics, including material traceability and adequacy of Certificates of Conformance or Certified Material Test Reports.

Corrective steps that will be taken to avoid future noncompliance

To avoid issues in the future with Planned Corrective Actions not being properly verified for full implementation prior to closure, Departmental Operating Instruction DOI QA-48-3055 "Corrective Action Board" will be revised to address leaving CARs in open status for the purpose of tracking the resolution and include instructions on the requirements needed for closure of a Corrective Action Request.

Completion of the above Corrective Actions for CARs 974, 976 and 978 will preclude any future noncompliance.

Date when corrective action will be achieved

Corrective Action Request 976: closed. No further action is required.

Corrective Action Request 974: Estimated Completion – March 31, 2017

Corrective Action Request 978: Estimated Completion – May 31, 2017

Corrective Action Request 1017: 1) Revision of DOI QA-48-3055: March 3, 2017
 2) Extent of Condition review of CARs: March 31, 2017

If you should have any questions please feel free to contact me at (508) 594-4450 or by email: lynn.skarin@pentair.com

Regards,



Lynn A. Skarin
Quality Assurance Manager

Cc: John Burke, Chief
Quality Assurance Vendor Inspection Branch-2
Division of Construction Inspection and Operational Programs
Office of New Reactors