



SOLIDSTATE CONTROLS

Quality Assurance

875 Dearborn Drive, Columbus, OH 43085 U.S.A.

Telephone: 614-846-7500; Direct: 614-410-6293

E-mail: ethan.salsbury@ametek.com



December 11, 2020

U.S. Nuclear Regulatory Commission

Document Control Desk

Washington, DC 20555-0001

Subject: Ametek Solidstate Controls Response to NRC Inspection Nonconformances
99901427/2020-201-01

Reference: NRC Vendor Inspection Report 99901427/2020-201

Ametek Solidstate Controls Inc. (SCI) is providing the enclosed response to the subject Notice of Nonconformance issued during Nuclear Regulatory Commission Vendor Inspection 9901427/2020-201. Details regarding the corrective actions and their targeted completion dates are provided in the attachment to this letter.

Sincerely,

Ethan Salsbury



Response to Nonconformance 99901427/2020-201-01

Part 1: Incorrect Dissipation Factor Testing Frequency

Reason for Noncompliance

The testing device used to measure the dissipation factor of AC capacitors did not reach the specified frequency required on the dedication plan (60Hz). Prior to the NRC inspection, this discrepancy had not been escalated to engineering or quality management. This should have been escalated at the time of the test plan generation or testing after the implementation of the test plan or testing device. It is unclear as to why this was not brought to the attention of the engineering team or the quality management.

Corrective Steps Taken and Results Achieved

AMETEK contacted the capacitor manufacturer for information regarding the relationship between the dissipation factor acceptance criteria and the frequency at which capacitors are tested. Based on the information provided, the variance between the frequency used and the frequency specified was insignificant. Therefore, there is no action required for containment.

The dedication plan for the capacitor observed at the time of the inspection was corrected on October 7th, 2020. The revision incorporates comments from the manufacturer as a basis for changing the dissipation factor test frequency.

Extent of Condition Review

There is no impact on the performance of the capacitor based on correspondence with the manufacturer. AMETEK part numbers with a designated AC capacitor prefix require dissipation factor as an acceptance criteria. Effected dedication plans have been placed on hold or corrected as of December 3, 2020.

Corrective Steps to Avoid Noncompliance

- Review the corrective action procedure to incorporate best practices for escalating conditions adverse to quality
- Clearly define conditions that require corrective action initiation
- Conduct a training with all test, quality, and engineering personnel on the requirements for escalating conditions and generating a corrective action
- Further emphasize the "questioning culture" across the organization

Corrective Action Completion Date

The target completion date for the corrective action measures is January 29, 2021. Reference corrective action CAR-239.



Part 2: Testing Service Technical Evaluation

Reason for Noncompliance

A technical justification for commercial testing services was not created. AMETEK did not qualify testing services with a commercial grade dedication until May of 2017. The second test provider was approved in May of 2018. After a review of the dedication program around August of 2018, it was determined a technical evaluation for calibration services was required. At that time, an extent of condition evaluation should have indicated a need for a testing service technical justification. However, a corrective action was not issued for the lack of a calibration technical evaluation and an extent of condition was not evaluated.

Corrective Steps Taken and Results Achieved

A technical evaluation for testing services has been generated and approved as of November 30, 2020. This technical evaluation will be used going forward as a basis for commercial grade surveys of testing service providers.

The commercial grade surveys conducted in 2017 and 2018 did incorporate critical characteristics aligned with the testing services. Therefore, no additional containment action is required.

Extent of Condition Review

This condition applies to all testing service providers used by AMETEK. Currently, there are two commercial grade suppliers of testing services on the AMETEK nuclear approved vendor list. This technical evaluation will apply to these vendor surveys going forward. Previous surveys were conducted with critical characteristics aligned with this new technical evaluation.

Additionally, AMETEK reviewed the entire list of safety-related components and services which require dedication to verify all current parts within AMETEK's scope were included.

Corrective Steps to Avoid Noncompliance

- Review the corrective action procedure to incorporate best practices for identifying conditions adverse to quality
- Clearly define conditions that require corrective action initiation
- Conduct a training with all quality and engineering personnel on the requirements for initiating a corrective action
- A list of potential safety-related components and services exists that require a technical evaluation. Testing services was not incorporated on that list but has been added. The list will be re-evaluated to consider additional items and services that must be incorporated.

Corrective Action Completion Date

The target completion date for the corrective action measures is February 28, 2021. Reference corrective action CAR-240



Part 3: Extenuating Circumstances Corrective Action

Reason for Noncompliance

A valid justification was not established prior to receiving products from vendors who had expired from the Approved Supplier List. AMETEK issued a corrective action in June of 2020 to document the challenges presented by the COVID-19 pandemic. The corrective action did not have a specific permanent action, containment action, or preventative action. At the point of the initiation of the corrective action, the recommended path for justifying delays in audits/surveys was not available. Industry guidance was provided on August 29th, 2020. AMETEK should not have closed the corrective action prior to the release of industry guidance and should have incorporated additional measures to justify the continued usage of expired vendors.

Corrective Steps Taken and Results Achieved

AMETEK has generated a justification to allow usage of purchased parts from vendors who had expired on the approved vendor list during the ongoing pandemic. The justification was completed on November 19, 2020. Until the justification was complete, tangible products were held in MRB until disposition of return to stock was granted.

Extent of Condition Review

This condition applies to three vendors currently expired on the approved vendor list, however only two qualify for the additional grace period.

Two items were received on September 28th, 2020 and were transferred directly into the segregated MRB location. The items were not removed from MRB until the justification was completed for continued use on November 19th, 2020. No other tangible products were received before completion of required justification documentation.

At this point, there are no additional vendors expiring until 2021. However, it is anticipated that several more vendors will expire before travel restrictions are lifted. Additionally, the granted 25% grace period will likely also expire prior to the end of this pandemic. AMETEK will evaluate alternative options and approval methods for these instances.

Corrective Steps to Avoid Noncompliance

- A standard justification form for extending grace period has been created as of November 18, 2020.
- There are currently two vendors within the 25% grace period timeframe that required a justification for continued use. The justifications are complete.
- The Quality Management System has been updated to require at least two approvers for each corrective action. This will help ensure appropriate considerations are made prior to corrective action closure.
- Training on the corrective action will include reviewer guidance on properly scrutinizing corrective action with a questioning mindset and forward-looking perspective.
- A justification will be completed for vendors as necessary until survey/audit access can be obtained to facilities
- The approved vendor list will be updated to clarify vendor status and allow for comments in each instance.
- Update the supplier approval procedure to explain extenuating circumstances. This will be aligned with the issued industry guidance.

Corrective Action Completion Date

The target completion date for the corrective action measures is January 29, 2021. Reference corrective action CAR-237