



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

November 13, 2020

Mr. Ethan Salsbury
Quality Manager
AMETEK Solidstate Controls
875 Dearborn Drive
Columbus, OH 43085

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
AMETEK SOLIDSTATE CONTROLS NO. 99901427/2020-201 AND NOTICE OF
NONCONFORMANCE

Dear Mr. Salsbury:

From September 28 through October 2, 2020, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the AMETEK Solidstate Controls' (hereafter referred to as Ametek) facility in Columbus, Ohio. The purpose of this limited-scope inspection was to assess Ametek'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 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 Ametek's implementation of the quality activities associated with the supply of Class 1E protection equipment, nuclear battery chargers, fusible panelboards, static inverters, terminal blocks, and commercial-grade dedication services to U.S. nuclear power plants. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of your 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 did not meet certain regulatory requirements imposed on you by your customers or NRC licensees. Specifically, the NRC inspection team determined that Ametek was not fully implementing its QA program in the area of corrective action. The NRC Inspection team identified three examples of Ametek's failure to ensure conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances were promptly identified and corrected. The specific finding and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not

include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without red action. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,

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

Docket No.: 99901427

EPID No.: I-2020-201-0141

Enclosures:

1. Notice of Nonconformance
2. Inspection Report No. 99901427/2020-201
and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF AMETEK SOLIDSTATE CONTROLS NO. 99901427/2020-201 AND NOTICE OF NONCONFORMANCE Dated: November 13, 2020

DISTRIBUTION:

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 Ethan.Salsbury@Ametek.com
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ADAMS Accession No.: ML20315A059 *via e-mail

NRR-106

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	AArmstrong*	YDiaz-Castillo*	DPark*
DATE	11/12/2020	11/12/2020	11/12/2020
OFFICE	NRR/DRO/IRAB	NRR/DRO/IQVB	
NAME	BHughes*	KKavanagh*	
DATE	11/12/2020	11/13/2020	

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NOTICE OF NONCONFORMANCE

Ametek Solidstate Controls
875 Dearborn Drive
Columbus, Ohio 43085

Docket No. 99901427
Report No. 2020-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Ametek Solidstate Controls' (hereafter referred to as Ametek) facility in Columbus, Ohio, from September 28, 2020 through October 2, 2020, Ametek did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon Ametek by its customers or NRC licensees.

- A. Criterion XVI, "Corrective Action," 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," states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected."

Ametek Procedure No. 01-090141, "Corrective Action," Revision M, dated November 11, 2014, provides for the identification and problem reporting, investigation of the problem for cause, reporting of the corrective actions, including the results of those actions, and evaluation of the effectiveness of the corrective action.

Contrary to the above, as of October 2, 2020, Ametek failed to assure that conditions adverse to quality were promptly identified and corrected. Specifically, the NRC inspection team identified three examples where Ametek failed to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected:

1. While testing the dissipation factor of capacitor No. 07-020139 as part of the commercial-grade dedication process, the NRC inspection team noted that the dissipation factor was tested at a frequency of 120 Hz. The technical evaluation of the capacitor identified the dissipation factor as a critical characteristic required to be tested at a frequency of 60 Hz. Ametek stated that it was tested at 120 Hz because the Inductance Capacitance Resistance (LCR) meter does not go below 120 Hz. Although this has been a known issue for years, Ametek failed to enter this condition into the Corrective Action Program (CAP) to evaluate its potential effect on the safety-function of the capacitor.
2. While reviewing the commercial-grade survey of a supplier used for testing of transformer impregnation resin, the NRC inspection team requested Ametek to provide the technical evaluation that identified the critical characteristics for the testing service. Ametek stated that it had never developed a technical evaluation even though they were aware of the issue. Ametek failed to enter this condition into the CAP to evaluate if it had identified the appropriate critical characteristics of the testing service.
3. Ametek initiated Corrective Action Report (CAR) No. 221 to document and address delays in the performance of external audits and commercial-grade surveys as a result of travel restrictions cause by the Coronavirus Disease 2019. Ametek closed

Enclosure

CAR No. 221 without implement compensatory measures for the inability to perform or delay external audits and commercial-grade surveys other than documenting that some approved suppliers would expire while Ametek was receiving safety-related materials and services from the suppliers.

This issue has been identified as Nonconformance 99901427/2020-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Quality Assurance and Vendor Inspection Branch, Division of Reactor Oversight, Office of Nuclear Reactor Regulation, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further noncompliance; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made electronically available for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible from the NRC's Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the Agency can make it available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information would create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If SGI is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Dated this the XX day of November 2020.

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

Docket No.: 99901427

Report No.: 99901427/2020-201

Vendor: Ametek Solidstate Controls
875 Dearborn Drive
Columbus, OH 43085

Vendor Contact: Mr. Ethan Salsbury
Quality Manager
875 Dearborn Drive
Columbus, OH 43085
Email: ethan.salsbury@Ametek.com

Nuclear Industry Activity: Ametek Solidstate Controls (hereafter referred to as Ametek) provides Class 1E protection equipment, nuclear battery chargers, fusible panelboards, static inverters, terminal blocks, and commercial-grade dedication services to U.S. nuclear power plants. Ametek manufactures analog based uninterruptable power supply (UPS) systems and has developed a new digital UPS system for U.S. nuclear power plants.

Inspection Dates: September 28 - October 2, 2020

Inspectors: Aaron Armstrong NRR/DRO/IQVB Team Leader
Yamir Diaz-Castillo NRR/DRO/IQVB
Dong Park NRR/DRO/IQVB Training

Approved: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

Ametek Solidstate Controls
99901427/2020-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a routine vendor inspection of Ametek Solidstate Controls' (hereafter referred to as Ametek) facility located in Columbus, OH, 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." In addition, the NRC inspection team verified Ametek's corrective actions initiated to address the Notice of Violation (NOV) and Notice of Nonconformances (NONs) identified during the past two NRC inspections performed in October 2013 and June 2017, respectively.

This technically focused inspection specifically evaluated Ametek's implementation of the quality activities associated with the supply of Class 1E protection equipment, nuclear battery chargers, fusible panelboards, static inverters, terminal blocks, and commercial-grade dedication services to U.S. nuclear power plants. Specific activities observed by the NRC inspection team included:

- Verification of the critical characteristics as part of the commercial-grade dedication of a relay and a capacitor.
- Demonstration of the receipt inspection process as part of the commercial-grade dedication of a wire.

These regulations served as the bases for the NRC inspection:

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

During the course of this inspection, the NRC inspection team implemented portions of 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; and IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated January 27, 2017.

With the exception of the nonconformance described below, the NRC inspection team concluded that Ametek'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 Ametek's personnel are implementing these policies effectively. The results of this inspection are summarized below.

Corrective Action

The NRC inspection team reviewed Ametek's policies and implementing procedures that govern the implementation of its corrective action program to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspection team evaluated Ametek's implementation and closure of the corrective actions taken in response to NOV 99901427/2013-201-01 and NON 99901427/2013-201-02, documented in the NRC's

inspection report No. 99901427/2013-201, dated October 2, 2013 (Agencywide Documents Access and Management System Accession (ADAMS) Accession No. ML13259A314). In addition, the NRC inspection team evaluated Ametek's implementation and closure of the corrective actions taken in response to NON 99901427/2017-201-01 and NON 99901427/2017-201-02, documented in the NRC's inspection report No. 99901427/2017-201, dated June 5, 2017 (ADAMS Accession No. ML ML17135A403). During this inspection, the NRC inspection team determined that Ametek's corrective actions were adequate to address NOV 99901427/2013-201-01, NON 99901427/2013-201-02, and NON 99901427/2017-201-01. Based on the review of the corrective actions, the NRC inspection team closed NOV 99901427/2013-201-01, NON 99901427/2013-201-02 and NON 99901427/2017-201-01. However, the NRC inspection team did not close NON 99901427/2017-201-02; therefore, this NON remains open. The enclosed report presents the results of the inspection.

In addition, the NRC inspection team reviewed Ametek's policies and implementing procedures that govern the implementation of its corrective action program to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. The NRC inspection team determined that Ametek was not fully implementing its QA program in the area of corrective action and identified three examples of Ametek's failure to ensure conditions adverse to quality were promptly identified and corrected. The NRC inspection team issued Nonconformance 99901427/2020-201-01 for Ametek's failure to implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50.

10 CFR Part 21

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

Commercial Grade Dedication of Replacement Parts and Components

The NRC inspection team reviewed Ametek's policies and implementing procedures that govern the implementation of its commercial-grade dedication program to verify compliance with the requirements of Criterion III, "Design Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team evaluated on-going commercial-grade dedication activities and reviewed completed documentation including the technical evaluations developed to identify the critical characteristics and the acceptance criteria. No findings of significance were identified.

Supplier Oversight and Internal Audits

The NRC inspection team reviewed Ametek'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 evaluated on-going supplier oversight activities and reviewed a sample of the most recent external audits, commercial-grade surveys, and POs from vendors on Ametek's "Nuclear Approved Vendor List." No findings of significance were identified.

REPORT DETAILS

1. Corrective Action

a. Inspection Scope

The NRC inspection team reviewed Ametek Solidstate Controls' (hereafter referred to as Ametek) policies and implementing procedures that govern the implementation of its corrective action program (CAP) to verify compliance with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Program 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."

Specifically, the NRC inspection team reviewed the implementation and closure of Ametek's response to Notice of Violation (NOV) 99901427/2013-201-01 and Notice of Nonconformance (NON) 99901427/2013-201-02 documented in the NRC's inspection report No. 99901427/2013-201, dated October 2, 2013 (Agencywide Documents and Access Management Systems (ADAMS) Accession No. ML13259A314). The NRC inspection team also evaluated Ametek's implementation and closure of the corrective actions taken in response to NON 99901427/2017-201-01 and NON 99901427/2017-201-02 documented in the NRC's inspection report No. 99901427/2017-201, dated June 5, 2017 (ADAMS Accession No. ML17135A403).

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

b. Observations and Findings

b.1 Corrective Action Associated with NOV 99901427/2013-201-01

Following the October 2013 inspection of Ametek, the NRC issued NON 99901427/2013-201-01 for Ametek's failure to report a defect associated with a substantial safety hazard as soon as practicable within 60 days of discovery or file an interim report to the NRC. Specifically, Ametek was notified of a deviation with Tyco/Potter & Brumfield relays on October 8, 2008. Ametek assessed the deviation and concluded that the issue was a substantial safety hazard, however: Ametek did not notify the NRC, affected licensees, and customers until 110 days later. Ametek established a work sheet (checklist) that will ensure Ametek completes the 10 CFR Part 21 evaluations within 60 day of discovery. The NRC inspection team concluded that Ametek's corrective actions in response to the NOV were adequate and therefore, NOV 99901427/2013-201-01 is now closed.

b.2 Corrective Action Associated with NON 99901427/2013-201-02

Following the October 2013 inspection of Ametek, the NRC issued NON 99901427/2013-201-02 for Ametek's failure to use a suitable testing program to verify the adequacy of the design of several battery chargers and inverters. Specifically, Ametek did not identify or test surge withstand capability as a critical characteristic for two battery chargers which required surge protection capability

per the customer specifications. Ametek also did not verify or validate the critical characteristic of synchronization testing which was outside of the acceptance criteria in eight out of nine battery chargers/inverters. Ametek provided justification for the battery chargers and inverters design adequacy with evaluations and adequate data from testing. Ametek also provided an evaluation, justification, and testing requirements to be implemented to verify and validate the synchronization testing critical characteristic which was outside of the acceptance criteria. The NRC inspection team concluded that Ametek's corrective actions in response to the NON were adequate and therefore, NON 99901427/2013-201-02 is now closed.

b.3 Corrective Action Associated with NON 99901427/2017-201-01

Following the October 2017 inspection of Ametek, the NRC issued NON 99901427/2017-201-01 for Ametek's failure to establish measures for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of systems, structures, and components. Specifically, Ametek failed to establish measures for ensuring that the seismically sensitive components (relays) utilized in production of uninterruptable power supply (UPS) units are bounded by previous qualification testing, and are the same in form, fit, and function as those that had previously undergone seismic qualification testing. Ametek provided a technical justification report which established the acceptance criteria for seismically sensitive components. The NRC inspection team concluded that Ametek's corrective actions in response to the NON were adequate and therefore, NON 99901427/2017-201-01 is now closed.

b.4 Corrective Action Associated with NON 99901427/2017-201-02

The NRC inspection team did not review the adequacy of the corrective actions taken in response to NON 99901427/2017-201-02 and did not determine if the actions taken in response to the NON were acceptable. The NRC inspection team determined that Nonconformance 99901427/2017-201-02 remains open.

b.5 Implementation of Ametek's Corrective Action Program

The NRC Inspection team identified three examples where Ametek failed to ensure conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances were promptly identified and corrected.

While observing the commercial-grade dedication of a capacitor, the NRC inspection team noted that Ametek's technical evaluation identified the capacitor's dissipation factor as a critical characteristic and required it to be tested at a 60 Hz frequency. During discussions with Ametek's staff, the NRC inspection team learned Ametek was testing the dissipation factor at a frequency of 120 Hz given that the Inductance Capacitance Resistance (LCR) meter would not go below 120 Hz. Ametek failed to enter this into the CAP to promptly identify and correct the known nonconformance. This issue is discussed further below in the commercial grade dedication section of this report and is the first example of Nonconformance 99901427/2020-201-01.

In addition, the NRC inspection team identified that Ametek failed to provide a technical evaluation for the testing of transformer impregnation resins. Ametek lacked objective evidence supporting the selection of the critical characteristics. Ametek's staff stated this was a known nonconforming condition, but failed to enter this issue into the CAP. This issue is discussed further below in the commercial-grade dedication section of this report and is the second example of Nonconformance 99901427/2020-201-01.

Furthermore, the NRC inspection team identified that Ametek initiated CAR No. 221 to document and address delays in the performance of external audits and commercial-grade survey resulting from travel restrictions caused by the Coronavirus Disease 2019 (COVID-19). Ametek closed CAR No. 221 without implement compensatory measures for the inability to perform or delay external audits and commercial-grade surveys during the COVID-19 pandemic. This issue is discussed below in the supplier oversight and internal audits section of this report and is the third example of Nonconformance 99901427/2020-201-01.

c. Conclusion

The NRC inspection team issued Nonconformance 99901427/2020-201-01 for Ametek's failure to implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Nonconformance 99901427/2020-201-01 cites Ametek's failure to ensure conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances were promptly identified and corrected. Specifically, Ametek failed to initiate corrective actions for known conditions adverse to quality, specifically: 1) failure to evaluate whether testing the dissipation factor of a capacitor at 120 Hz would have an impact on its safety function; 2) failure to provide a technical evaluation as part of the commercial-grade dedication of the testing service for the transformer impregnation resins; and 3) failure to implement compensatory measures for the inability to perform or delay external audits and commercial-grade surveys of suppliers during the COVID-19 pandemic.

2. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Ametek's policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with the regulatory requirements. The NRC inspection team also evaluated the 10 CFR Part 21 postings and a sample of Ametek'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." In addition, the NRC inspection team also verified that Ametek's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program. Furthermore, for a sample of 10 CFR Part 21 evaluations performed by Ametek, the NRC inspection team verified that Ametek had effectively implemented the requirements for evaluating deviations and failures to comply.

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

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that Ametek 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 Ametek is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

3. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed Ametek's policies and implementing procedures that govern the implementation of its commercial-grade dedication program to verify compliance with the regulatory requirements of Criterion III, "Design Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of commercial-grade dedication packages and commercial-grade surveys of several commercial vendors on Ametek's "Nuclear Approved Vendor List," Revision R, dated August 18, 2020. The sample of commercial-grade dedication packages included the following items: fuses, breakers, capacitors, relays, printed circuit boards, and diodes. The commercial-grade dedication packages included: 1) POs; 2) the technical evaluation for the identification and documentation of the basis and justification for the selection of the critical characteristics; 3) acceptance methods, and acceptance criteria; 4) receiving inspection records; and 5) Certificates of Conformance. The NRC inspection team also evaluated the criteria for the identification of safety functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, and the implementation of the verification methods to verify the effective execution of Ametek's commercial-grade dedication process. In addition, the NRC inspection team verified that commercial-grade surveys contained the objective evidence necessary to demonstrate adequate control of the critical characteristics by the commercial vendors.

The NRC inspection team also witnessed the verification of the critical characteristics as part of the commercial-grade dedication of a relay and a capacitor. The NRC inspection team verified that Ametek's Quality Assurance (QA) Technician was adequately following the applicable procedures and documenting the inspection results. In addition, the NRC inspection team confirmed that Ametek's QA Technician was using calibrated equipment to take the appropriate measurements.

The NRC inspection team also reviewed Ametek's measures established for the use of accreditation in lieu of performing commercial-grade surveys for the procurement of

calibration and testing services as part of the commercial-grade dedication process. The NRC inspection team confirmed that the POs contained the appropriate technical and quality requirements and the calibration certificates were adequately reviewed during receipt inspection.

The NRC inspection team also discussed the commercial-grade dedication program with Ametek's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

While observing the commercial-grade dedication of a capacitor, the NRC inspection team noted that the dissipation factor, which was identified as a critical characteristic in the technical evaluation, was required to be tested at a 60 Hz frequency. The NRC inspection team noted that the capacitor was being tested at 120 Hz. During discussions with Ametek's personnel, the NRC inspection team learned the dissipation factor was tested at 120 Hz due to limitations of the LCR meter since it does not go below 120 Hz. Even though this has been a known issue for years, Ametek did not enter this issue into the CAP to evaluate whether testing the dissipation factor at 120 Hz would have impact on the safety function of the capacitor. Ametek initiated Corrective Action Report (CAR) No. 239 to address this issue. This issue is the first example of Nonconformance 99901427/2020-201-01.

During the review of commercial-grade dedication packages, the NRC inspection team noted that for the commercial-grade dedication testing services of the transformer impregnation resins, there was no technical evaluation included for the testing service. During discussions with the Ametek's staff, the NRC inspection team learned that Ametek had not performed a technical evaluation or provided objective evidence for the supporting the chosen critical characteristics as well as being a known issue to Ametek. Although the NRC inspection team confirmed that the appropriate critical characteristics were chosen and verified during the commercial-grade survey of the testing supplier, Ametek failed to enter this issue into its CAP to promptly identify and correct this issue. Ametek initiated CAR No. 239 to address this issue. This issue has been identified as the second example of Nonconformance 99901427/2020-201-01.

c. Conclusion

With the exception of the examples to Nonconformance 99901427/2020-201-01 related to failure to initiate corrective actions, the NRC inspection team concluded that Ametek is implementing its commercial-grade dedication program in accordance with the regulatory requirements of Criterion III and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Ametek is implementing its policies and procedures associated with the commercial-grade dedication program.

4. Supplier Oversight and Internal Audits

a. Inspection Scope

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

The NRC inspection team reviewed a sample of the most recent external audits, commercial-grade surveys, and POs from suppliers on Ametek's "Nuclear Approved Vendor List," (ASL) Revision R, dated August 18, 2020. For a sample of external and internal audits reviewed, the NRC inspection team verified the audit reports included an audit plan, any findings identified, adequately documented objective evidence of compliance with the applicable requirements, and a review by 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 Ametek's lead auditors and confirmed that auditing personnel had completed all the required training in accordance with Ametek's procedure No. 01-090175, "Lead Auditor, Auditor, & Survey Leader Qualifications," Revision G, dated 07/25/2018. The NRC inspection team verified that Ametek prepared and approved plans that identify the audit scope and applicable checklist criteria before the initiation of the audit activity. The NRC inspection team confirmed the audit reports contained objective evidence of the review of the relevant QA criteria of Appendix B to 10 CFR Part 50.

For the sample of POs reviewed, the NRC inspection team verified that the POs included the scope of work and confirmed that the POs adequately invoked the applicable technical, regulatory, and quality requirements. The NRC inspection team also observed the receipt inspection process for a piece of wire associated with PO No. C27663. Specifically, the NRC inspection team observed the QA Technician verify the critical characteristics of the wire material as part of the commercial-grade dedication process. The NRC inspection team verified that Ametek's personnel adequately followed the applicable procedures and documented the inspection results. The receipt inspection examined objective evidence of the wire material by verifying attributes specified in procurement document and verified the identification and traceability of wire, strand count, and metered wire length using a properly calibrated cable length meter.

The NRC inspection team discussed the supplier oversight and internal audit program with Ametek's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

During the review of Ametek's ASL the NRC inspection team noted three suppliers with expired audits and surveys which were due in December 20, 2019, May 12, 2020, and May 17, 2020. The current System Management Procedure (SMP) No. 01-090065, "Supplier Approval," Revision T, dated July 31, 2018, states, in part, that "If an audit or survey is not performed within 90 days after the expiration date on the Nuclear Approved Vendor List (SMP No. 01-090069), the vendor shall be removed from the list until an audit or survey can

be completed.” Contrary to the procedure, the expired vendors remained on the approved vendor list although they were highlighted to indicate expiration. Ametek did not procure materials or services from the supplier which expired in December 20, 2019. Ametek initiated CAR No. 242 to address this issue.

With respect to the one expired audit and one expired commercial-grade survey due in May 12, 2020 and May 17, 2020, respectively, the materials received from these vendors occurred within 90 days of the expiration date. Although the two POs were issued outside the expiration of the audit and commercial-grade survey, the NRC inspection team confirmed the materials were awaiting disposition via the Material Review Board system in accordance with SMP No. 01-090130, “Control of Nonconforming Product,” Revision L, dated December 4, 2019. Ametek performed an extent of condition to verify that these materials and services did not leave the vendor facility.

The NRC inspection team noted that Ametek created CAR No. 221 to document and address delays in audit and commercial-grade surveys deadlines as a result of COVID-19 travel restrictions. The NRC inspection team identified that no action was taken other than recording the summary of the situation prior to the CAR being closed. Ametek closed CAR No. 221 without implement compensatory measures for the inability to perform or delay external audits and commercial-grade surveys. Based on discussions with the NRC inspection team, Ametek initiated CAR No. 237. This issue has been identified as the third example of Nonconformance 99901427/2020-201-01.

c. Conclusion

With the exception of the third example to Nonconformance 99901427/2020-201-01, the NRC inspection team concluded that Ametek 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 Ametek is implementing its policies and procedures associated with the supplier oversight and the internal audits program. No findings of significance were identified.

5. Entrance and Exit Meetings

On September 28, 2020, the NRC inspection team discussed the scope of the inspection with Mr. Ethan Salsbury, Ametek’s Director of Quality, and other members of Ametek’s management and technical staff. On October 2, 2020, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Ethan Salsbury, other members of Ametek ’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
Ethan Salsbury	Director of Quality	AMETEK Solidstate Controls (Ametek	X	X	X
Zachary Rumora	Manufacturing Engineer	Ametek	X	X	X
Patrick Williams	Vice-President, Business Unit Manager	Ametek	X	X	
Steve Wetta	Director of Engineering and Research and Development	Ametek	X	X	
Ben Gordon	Engineering Manager	Ametek	X	X	
Doug King	Project Engineer	Ametek	X	X	
Rebekah Needham	Project Engineer	Ametek	X	X	
Tim Kaiser	Quality and Environment, Health and Safety Coordinator	Ametek	X	X	
Devon Helfer	Quality Technician	Ametek		X	
Mark Stamper	Plant Manager	Ametek	X	X	X
Jeff Baker	Procurement Manager	Ametek	X	X	
Jordan Davis	Logistics Manager	Ametek	X	X	
Joanna Lin	Client Relations Manager	Ametek	X		
Aaron Armstrong	Inspection Team Leader	NRC	X	X	
Yamir Diaz- Castillo	Inspector	NRC	X	X	
Dong Park	Inspector	NRC	X	X	
Kerri Kavanagh	Branch Chief	NRC		X	

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
- Inspection Procedure 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
99901427/2013-201-01	Closed	NOV	10 CFR Part 21
99901427/2013-201-02	Closed	NON	Criterion III
99901427/2017-201-01	Closed	NON	Criterion III
99901427/2017-201-02	Discussed	NON	Criterion XVI
99901427/2020-201-01	Open	NON	Criterion XVI

4. DOCUMENTS REVIEWED

Policies and Procedures

- System Management Procedure (SMP) No. 01-090000, "Quality Policy Manual," Revision G, dated October 11, 2017
- Ametek Solidstate Controls' Quality Policy Manual, Revision G, dated October 11, 2017
- System Management Procedure (SMP) No. 01-090065, "Supplier Approval," Revision T, dated July 31, 2018
- SMP No. 01-090069, "Nuclear Approved Vendor List," Revision R, dated August 18, 2020
- SMP No. 01-090102, "Commercial Grade Dedication," Revision J, dated February 20, 2020
- SMP No. 01-090175, "Lead Auditor, Auditor, & Survey Leader Qualifications," Revision G, dated July 25, 2018
- SMP No. 01-160002, "Approved Part Number Request Procedure," Revision H, dated November 26, 2014
- SMP No. 01-161012, "Technical Evaluation - Commercial Grade Dedication," Revision C, dated January 18, 2018
- SMP No. 01-170143, "Sampling Plan Selection," Revision B, dated January 29, 2018
- SMP No. 01-090065, "Supplier Approval," Revision T, dated July 31, 2018
- SMP No. 01-090068, "Procurement Document Control," Revision H, dated September 10, 2016

- SMP No. 01-090069, "Nuclear Approved Vendor List," Revision R, dated August 18, 2020
- SMP No. 01-090101, "Receiving QA Inspection," Revision D, dated January 18, 2018
- SMP No. 01-090130, "Control of Nonconforming Product," Revision L, dated December 4, 2019
- SMP No. 01-090175, "Lead Auditor, Auditor, & Survey Leader Qualifications," Revision G, dated July 25, 2018
- SMP No. 01-090102, "Commercial Grade Dedication," Revision J, dated February 20, 2020
- MP No. 01-090102, "Failure Investigation/ Part 21 Reporting," Revision M, dated September 20, 2016
- Substantial Safety Hazard Determination form 02-190145, Revision B, April 19, 2017
- Ametek Solidstate Controls Report Number: 45-64000035-1, Revision C. dated April 16, 2019
- Sampling plan Evaluation Form 07-0740007-00-201-01, dated January 3, 2020
- Surge Withstand Testing Similarity Report CA110, date April 18, 2017
- Justification for Acceptance of Ametek SCI Job #C103552 Synchronization Test, date July 21, 2017

Design and Commercial-Grade Dedication Documents

- Commercial Grade Dedication Test Plan for the calibration of a digital multimeter, asset No. QA008, dated April 30, 2020
- Commercial Grade Dedication Test Plan for a digital multimeter, asset No. QA40, dated November 17, 2019
- Commercial Grade Dedication Test Plan for the calibration of a handheld capacitance meter, asset No. QA56, dated September 25, 2020
- Commercial Grade Dedication Test Plan for the calibration of an LCR meter, asset No. QA58, dated September 25, 2020
- Commercial Grade Dedication Test Plan for the calibration of a digital caliper, asset No. QA1007, dated March 28, 2020
- Commercial Grade Dedication Test Plan for a capacitor - AC CVT, part No. 07-020139, dated September 30, 2020
- Commercial Grade Dedication Test Plan for the calibration of a digital multimeter, asset No. QA39, dated September 16, 2020

- Commercial Grade Dedication Test Plan for the calibration of a digital scale, asset No. QA51, dated May 5, 2020
- Commercial Grade Dedication Test Plan for the calibration of an insulation tester, asset No. QA63, dated May 21, 2020
- Commercial Grade Dedication Test Plan for the calibration of a differential probe, asset No. QA 65, dated August 8, 2020
- Commercial Grade Dedication Test Plan for the calibration of a differential probe, asset No. QA66, dated September 2, 2020
- Commercial Grade Dedication Test Plan for the calibration of an oscilloscope, asset No. QA67, dated September 9, 2020
- Commercial Grade Dedication Test Plan for the calibration of a resistance tester, asset No. RD011, dated October 2, 2019
- Commercial Grade Dedication Test Plan for a relay, part No. 07-740001-00 (in-progress, no date available)
- Commercial Grade Dedication Test Plan for a fuse, part No. 07-752213-00, dated January 6, 2020
- Commercial Grade Dedication Test Plan for a breaker capacitor, part No. 70-110041-90, dated January 6, 2020
- Commercial Grade Dedication Test Plan for a capacitor - AC COMM, part No. 07-020401-00, dated February 21, 2020
- Commercial Grade Dedication Test Plan for a relay, part No. 07-740008-00, dated February 21, 2020
- Commercial Grade Dedication Test Plan for a printed circuit board, part No. 80-921902-90, dated March 4, 2020
- Commercial Grade Dedication Test Plan for a capacitor, part No. 03-040008-00, dated March 18, 2020
- Commercial Grade Dedication Test Plan for a diode, part No. 07-600503-00, dated March 18, 2020
- Commercial Grade Dedication Test Plan for a printed circuit board, part No. 80-9214031-90, dated March 18, 2020
- Drawing No. SKD16835, Revision 0, dated November 26, 2014
- Technical evaluation of a capacitor - AC CVT, Revision 2, dated November 2, 2017
- Technical evaluation of a relay, Revision 5, dated March 18, 2019

- Technical evaluation of a fuse, Revision 2, dated May 15, 2019
- Technical evaluation of sheet metal components, Revision 1, dated May 3, 2017
- Technical evaluation of a capacitor - AC COMM, Revision 2, dated November 2, 2017
- Technical evaluation of a printed circuit board with embedded software, Revision 1, dated February 22, 2019
- Technical evaluation of a capacitor (film type), Revision 2, dated May 31, 2017
- Technical evaluation of a diode, Revision 1, dated June 20, 2017
- Technical evaluation of a circuit breaker (non-electronic), Revision 5, dated March 3, 2020
- Technical evaluation for calibration services, Revision 1, dated August 17, 2018
- Sampling Plan Evaluation for the commercial-grade dedication of the relays, dated September 29, 2020
- Certificate of Conformance for a printed circuit board, Purchase Order (PO) No. 3501220710, Ametek job No. 46003134, dated March 4, 2020
- Certificate of Conformance for capacitors and relays, PO No. 3501220710, Ametek job No. 46003134, dated February 26, 2020
- Certificate of Conformance for breaker capacitors, PO No. 03104669, Ametek job No. 4600.3078, dated January 6, 2020
- Certificate of Conformance for diodes, capacitors, and printed circuit board, PO No. 03107594, Revision 1, Ametek job No. 46003176, dated March 25, 2020

Purchase Orders and Commercial-Grade Surveys

- PO No. C261500 Revision 0, dated September 24, 2019
- PO No. C276663 Revision 0, dated September 14, 2020
- PO No. C276974 Revision 0, dated September 21, 2020
- PO No. C271079, Revision 0, dated April 23, 2020
- PO No. C270134, Revision 1, dated March 18, 2020
- PO No. C269176, Revision 0, dated February 27, 2020
- PO No. C262313, Revision 0, dated October 8, 2019

- PO No. C263579, Revision 0, dated November 1, 2019
- PO No. C261199, Revision 0, dated September 18, 2019
- PO No. C276283 for the calibration of a handheld capacitance meter and an LCR meter, Revision 0, dated September 3, 2020
- PO No. C269176 for the calibration of a digital caliper, Revision 0, dated February 27, 2020
- PO No. C276123 for the calibration of a digital multimeter, Revision 0, dated August 31, 2020
- PO No. 271079 for the calibration of a digital scale, Revision 0, dated April 23, 2020
- PO No. C271557 for the calibration of an insulation tester, Revision 0, dated May 7, 2020
- PO No. C274436 for the calibration of a differential probe, Revision 0, dated July 27, 2020
- PO No. C275109 for the calibration of a differential probe and an oscilloscope, Revision 0, dated August 10, 2020
- PO No. C261199 for the calibration of a resistance tester, Revision 0, dated September 18, 2019
- PO No. C262313 for calibration services, Revision 0, dated October 8, 2019
- PO No. C270134 for calibration services, Revision 1, dated March 18, 2020
- Commercial-grade survey report of a supplier of molded case circuit breakers, dated October 4, 2018
- Commercial-grade survey report of a supplier of testing services, dated May 17, 2017
- Commercial-grade survey report of a supplier of sheet metal components and welded cabinets, dated April 30, 2019
- Commercial-grade survey report of a supplier of testing services (no date provided)

Calibration Documents

- Certificate of Calibration for a handheld capacitance meter, dated September 16, 2020
- Certificate of Calibration for an LCR meter, dated September 14, 2020
- Certificate of Calibration for a digital caliper, dated March 2, 2020
- Certificate of Calibration for a digital multimeter, dated September 11, 2020
- Certificate of Calibration for an insulation tester, dated May 21, 2020

- Certificate of Calibration for a differential probe, dated August 4, 2020
- Certificate of Calibration for a differential probe, dated August 20, 2020
- Certificate of Calibration for an oscilloscope, dated September 2, 2020
- Certificate of Calibration for a resistance tester, dated September 26, 2019
- Certificate of Calibration for a digital multimeter, dated April 5, 2020
- Certificate of Calibration for a cable length meter, dated October 28, 2019
- Out-of-Calibration Condition Analysis for asset No. QA51, dated May 5, 2020
- Out-of-Calibration Condition Analysis for asset No. QA008, dated April 30, 2020
- Out of Tolerance Notification for asset No. QA51, dated April 28, 2020

Corrective Action Reports Opened During the NRC Inspection

- Corrective Action Report (CAR) No. 238, opened on September 30, 2020
- CAR No. 239, opened on September 30, 2020
- CAR No. 240, opened on October 1, 2020
- CAR No. 237, opened on October 1, 2020
- CAR No. 241, opened on October 1, 2020
- CAR No. 242, opened on October 1, 2020

Training and Qualification Records

- Training and qualification record for Devon Helfer, Quality Technician
- EMCBC NQA-1 Lead Auditor Qualification Record for Ethan Salsbury, dated November 15, 2019
- EMCBC NQA-1 Lead Auditor Qualification Record for Brian Battin, dated November 04, 2016

Internal Audits

- Ametek Solidstate Controls, Inc. Audit Report Number 2020-02, July 13-15, 2020, dated July 23, 2020.

Corrective Actions

- CAR No. 109 created on September 28, 2017
- CAR No. 110, created on October 2, 2017
- CAR No. 221, created on June 23, 2020
- CAR No. 222, created on July 14, 2020
- CAR No. 223, created on July 14, 2020
- CAR No. 224, created on July 16, 2020
- CAR No. 225, created on July 16, 2020
- CAR No. 226, created on July 16, 2020
- CAR No. 227, created on July 16, 2020
- CAR No. 228, created on July 18, 2020

Audits

- Supplier audit report dated May 19, 2017
- Supplier audit report dated October 2, 2018
- Supplier audit report dated July 24, 2020
- Supplier audit report dated March 17, 2017