



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

November 17, 2021

Mr. Martin Kurr
Quality Assurance Manager
Fairbanks Morse Engine
701 White Ave,
Beloit, WI 53511

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT
OF FAIRBANKS MORSE ENGINE, NO.99901378/2021-201

Dear Mr. Kurr:

From September 20 through September 24, 2021, the U.S. Nuclear Regulatory Commission (NRC) and the French Nuclear Safety Authority (ASN) conducted a parallel inspection at the Fairbanks Morse Engine (hereafter referred to as FME) facility in Beloit, WI. The purpose of this limited-scope routine inspection was to assess FME's compliance with provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically focused inspection specifically evaluated FME's implementation of the quality activities associated with the design, fabrication, and testing of safety-related emergency diesel generators and parts being supplied 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 FME's overall quality assurance (QA) or 10 CFR Part 21 programs.

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

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

If you have any questions concerning this matter, please contact Mr. Aaron Armstrong of my staff at (301) 415-8396.

Sincerely,

Kerri A. Kavanagh Digitally signed by Kerri A.
Kavanagh
Date: 2021.11.17 10:13:08 -05'00'

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

Docket No.: 99901378

EPID No.: I-2021-201-0044

Enclosures:

1. Inspection Report No. 99901378/2021-201 and Attachment

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF
FAIRBANKS MORSE ENGINE, NO. 99901378/2021-201 Dated: November 17, 2021

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DATE	11/1/2021	11/1/2021	11/1/2021
OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB	
NAME	AArmstrong	KKavanagh	
DATE	11/1/2021	11/3/2021	

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

Docket No.: 99901378

Report No.: 99901378/2021-201

Vendor: Fairbanks Morse Engine
701 White Ave,
Beloit, WI 53511

Vendor Contact: Mr. Martin Kurr
Quality Assurance Manager
Email: Martin.Kurr@fairbanksmorse.com
Office: 608.364.8247

Nuclear Industry Activity: Fairbanks Morse Engine (hereafter referred to as FME) is the original equipment manufacturer for emergency diesel generators that provide critical standby power for nuclear power plants. Fairbanks Morse Engine also supplies commercial-grade replacement parts that have been dedicated as basic components to maintain these engines.

Inspection Dates: September 20 - 24, 2021

NRC Inspectors:	Aaron Armstrong	NRR/DRO/IQVB	Team Leader
	Paul Prescott	NRR/DRO/IQVB	Remote
	Odunayo Ayegbusi	NRR/DRO/IQVB	
	Greg Galletti	NRR/DRO/IQVB	

ASN Inspectors:	Jeremy Hubert	French Regulatory Authority
	Benoit Fourche	French Regulatory Authority
	Xavier Tiret	French Regulatory Authority

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

Enclosure

EXECUTIVE SUMMARY

Fairbanks Morse
Engine
99901378/2021-201

The U.S. Nuclear Regulatory Commission (NRC) and the French Nuclear Safety Authority (ASN) conducted a parallel inspection at the Fairbanks Morse Engine (hereafter referred to as FME) facility in Beloit, WI, to verify that it had implemented an adequate quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC and ASN inspection team conducted the inspection on September 20 - 24, 2021. This was the second NRC inspection at FME's facility in Beloit, WI.

This technically-focused inspection specifically evaluated FME's implementation of quality activities associated with the design, manufacturing, and testing of safety-related emergency diesel generators and replacement parts provided to U.S. nuclear power plants for operating reactors.

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

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

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

The NRC inspection team observed the following specific activities:

- Commercial grade dedication of part 14789, "Spring, Duo-Check Check Valve," using BF5377E, "Nuclear Spare/Replacement Part Engineering Design Review, Revision 1 and BF5378B, "Critical Characteristic Verification Record," Revision 1 for the Duo-Check Check Valve Spring.
- Commercial grade dedication of part 16102034, "Extension, Spider," using BF5377E, "Nuclear Spare/Replacement Part Engineering Design Review, Revision 1 and BF5378B, "Critical Characteristic Verification Record," Revision 1 for the Spider Extension.

The NRC inspection team concluded that FME'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 FME's personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

10 CFR Part 21 Program

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

Commercial-Grade Dedication

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

Supplier Oversight and Internal Audits

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

Identification and Control of Materials, Parts, and Components

The NRC inspection team reviewed FME's policies and implementing procedures that govern the implementation of its material, parts, and components control program to verify compliance with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components," of Appendix B to 10 CFR Part 50. The NRC inspection team observed receipt, fabrication, and storage activities associated with on-going production orders and reviewed a sample of completed shop work orders to confirm FME personnel were performing material control activities in accordance with the policies and procedures established for those activities. No findings of significance were identified.

Nonconforming Material, Parts, or Components and Corrective Action

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

guidance for evaluating non-conforming conditions and the procedures ensure that conditions are evaluated for possible corrective action or for 10 CFR Part 21 applicability. The NRC inspection team reviewed a sample of non-conforming reports (NCRs), corrective action reports (CARs) and supplier corrective actions (SCAs) to verify that they demonstrate compliance with regulatory requirements and adherence to FME's procedures. In addition, the NRC inspection team reviewed the implementation and closure of the corrective actions opened to address the Notice of Violations and Notice of Nonconformance documented in the NRC's inspection report No. 99901378/2008-201, dated October 9, 2008. No findings of significance were identified.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

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

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

The NRC inspection team also discussed the 10 CFR Part 21 program with FME'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 FME 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 FME is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed FME's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify compliance with the regulatory requirements of Criterion III, "Design Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of

Appendix B to 10 CFR Part 50. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

a.1 Commercial Grade Dedication

The NRC inspection team reviewed the CGD methodology for safety-related replacement diesel engine components, including the development of critical characteristics (CCs), technical evaluations, failure modes and effects analyses, acceptance criteria methods, sampling methodology, checklists, survey reports, and associated purchase orders. The NRC inspection team reviewed the CGD process for several various diesel engine component. Components reviewed included, but were not limited to a circulating water pump, synchronizing control switch, electronic speed switch, digital governor reference unit, pump motor, and relief valve. The NRC inspection team evaluated a sample of technical evaluations and concluded that the technical evaluations in the dedication methodology appropriately identified the CCs necessary to provide reasonable assurance that the item or service would ensure the component would perform its intended safety function.

a.2 Commercial-Grade Surveys

The NRC inspection team reviewed FME's Approved Suppliers List (ASL) and selected a sample of suppliers to review the methodology of conducting and documenting surveys. The NRC inspection team reviewed FME's process of selecting and approving commercial suppliers and service providers. The NRC inspection team verified that FME had prepared and approved plans that identify the scope and applicable CCs to be verified before initiation of the survey.

b. Observations and Findings

The NRC inspection team noted in FME's engineering design review of a circulating water pump that the CC selection portion identified a functional test be performed to verify performance. No acceptance criteria were given for the functional test. The NRC inspection team reviewed Engineering Instruction 4418FM, "Testing of Water Pumps." No acceptance criteria were provided. The associated pump test log was reviewed, and the test results were provided; however, no associated acceptance criteria was given. The associated circulating water pump curves were requested. The NRC inspection team noted that the test results recorded in the pump test log were slightly below the nominal performance curve values at the test parameters. FME initiated corrective action Process Deviation Report (PDR) 1030 to review the functional test results and determine if the safety function (i.e., deliver required minimum flow to maintain required jacket water temperature) is met and to revise the test procedure to provide acceptance criteria.

The NRC inspection team noted in FME's engineering design review of a crankcase vacuum pump motor that the CC selection portion identified an electrical performance test be conducted. No acceptance criteria were given for the performance test. The associated record document BF5378B, "Critical Characteristic Verification Record," was reviewed. The only electrical test was a verification that all motor leads were isolated with respect to ground. FME initiated PDR 1031 to revise the BF5378B critical characteristic verification form to include verification of an electrical performance test.

The NRC inspection team noted that similar CGD process issues were identified in a Nuclear Procurement Issues Corporation (NUPIC) audit identified in PDR 926 dated March 5, 2020. FME has identified the extent of condition that required a full review of the CGD program. FME has developed a list of affected CGD documents that must be reviewed and verified for potential updates or enhancements and is committed to completing this work by December 1, 2022. The NRC inspection team notified FME that verification of the adequacy of this corrective action will be evaluated at subsequent to the completion date of the proposed corrective action.

c. Conclusion

The NRC inspection team concluded that FME is implementing its CGD 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 and activities observed, the NRC inspection team determined that FME is implementing its policies and procedures associated with the CGD program. No findings of significance were identified.

3. Supplier Oversight and Internal Audits

a. Inspection Scope

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

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

For a sample of external and internal audits reviewed, the NRC inspection team verified the audit reports included an audit plan, any findings identified, adequate documented objective evidence of compliance with the applicable requirements, and a review by FME's responsible management. In addition, the NRC inspection team also verified that the audits were performed by a qualified auditor, and in the case of the internal audits, that these audits were performed by personnel not having direct responsibilities in the areas being audited. Furthermore, the NRC inspection team reviewed a sample of training and qualification records of FME's lead auditors and confirmed that auditing personnel had completed all the required training and had maintained the applicable qualification and certification in accordance with FME's procedures. The NRC inspection team also discussed the supplier oversight and internal audits programs with FME'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 a sample of internal audit reports, the NRC inspection team noted that a corrective action to PDR 927 was to perform a monthly audit steering committee meeting; subsequently, this new process was added to FME procedure SP 781.45, "Internal and External Audits." Also, the NRC inspection team noted several inconsistencies in the internal audit reports and checklists. Some examples include not issuing CARs for checklist items that did not meet the requirement and a checklist not being fully completed with a checkmark as to meeting or not meeting the requirement. FME initiated PDR Nos. 1035 and 1033 respectively to address these issues. The NRC inspection team determined these issues to be minor because the inconsistencies did not impact the overall results of the internal audits.

c. Conclusion

The NRC inspection team concluded that FME is implementing its supplier oversight and internal audit 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 FME is implementing its policies and procedures associated with the supplier oversight and internal audit programs. No findings of significance were identified.

4. Identification and Control of Materials, Parts, and Components

a. Inspection Scope

The NRC inspection team reviewed FME's policies and implementing procedures that govern the implementation of its material control program to verify compliance with the regulatory requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components," of Appendix B to 10 CFR Part 50.

The NRC inspection team witnessed on-going shop activities related to product receipt and acceptance and verified that FME staff adequately performed intake activities including, material identification, assignment of unique certification numbers to orders,

and determining additional routing of materials necessary for formal receipt inspection, material certification, and entry into inventory.

The NRC inspection team also reviewed in-process fabrication activities in accordance with shop work orders and reviewed both material staging areas and nonconforming material segregation areas to verify material identification control methods including stamping, tagging, and pen markings. The NRC inspection team reviewed a sample of in-process and completed discrete job router documentation and confirmed material identification for each process step was adequately documented in accordance with procedures governing those activities.

The NRC inspection team discussed material identification methods with quality control inspectors, quality assurance personnel, and fabrication/craft personnel and confirmed

understanding of identification and control of materials. 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 FME is implementing its materials, parts, and components control program in accordance with the regulatory requirements of Criterion VIII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FME is implementing its policies and procedures associated with the materials, parts, and components control program. No findings of significance were identified.

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

a. Inspection Scope

The NRC inspection team reviewed FME's policies and implementing procedures that govern the control of nonconformances and corrective action to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

The NRC inspection team determined that FME's processes and procedures provide for the identification, documentation, segregation, evaluation, and disposition of nonconforming items. These processes also apply the principles of rework/repair, scrap, return to vendor (RTV), or "use as-is." The NRC inspection team also reviewed that FME's nonconformance process provides guidance to evaluate nonconformances for reportability under FME's 10 CFR Part 21 program. The nonconformance process is also linked to the corrective action program.

The NRC inspection team observed FME's assembly floor and verified that nonconforming materials were properly identified, marked, and segregated, when practical, to ensure that they were not reintroduced into the production processes.

The NRC inspection team reviewed the implementation of FME's new computer database system. FME personnel demonstrated the issue tracking and response capabilities of the system that was implemented after the last NRC inspection in 2008. The NRC inspection team reviewed a sample of non-conforming reports (NCRs) associated with the production of safety-related valves and confirmed that FME: (1) dispositioned the NCRs in accordance with the applicable procedures; (2) documented an appropriate technical justification for the dispositions; and (3) took adequate corrective action regarding the nonconforming items to prevent recurrence. The NRC inspection team reviewed that the system generated reports and accurately recorded the conditions of the material. The NRC inspection team also reviewed a sample of CARs and confirmed: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence; (3) direction for review and approval by

the responsible authority; (4) a description of the current status of the corrective actions; and (5) the follow-up actions taken to verify timely and effective implementation of the corrective actions.

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with FME'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 a sample of CARs, the NRC inspection team noted that some CARs were open longer than the 6 months allowed by FME procedure SP700.10, "Corrective and Preventive Action." Also, FME did not document the extent of condition for CARs written in response to customer complaints because FME's electronic CAR system does not offer it as an option. Finally, the CARs did not have enough information to determine the root cause and corrective actions without recourse to the originator of the CAR. The NRC inspection team determined these issues were programmatic in nature and therefore not more than minor. To address these issues, FME initiated PDR Nos. 1032, 1034 and 1036, respectively.

b.1 Corrective Action Associated with NOV 99901378/2008-201-01

Following the September 2008 inspection of FME, the NRC issued Notice of Violation (NOV) 99901378/2008-201-01 for FME's failure to establish an adequate procedure to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard. Specifically, FME did not identify and evaluate potential Part 21 deviations in accordance with Standard Practice 714.00. Also, FME failed to perform an adequate evaluation for determining 10 CFR Part 21 reportability. The evaluation failed to address whether the delamination of cylinder #8 would have prevented the EDG from performing its safety function as a basic component, as described in 10 CFR 21.3.

In response NOV 99901378/2008-201-01, FME initiated CAR Nos. 2173 and 2174 to address these issues. The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions, including the review of CAR Nos. 2173 and 2174. The NRC inspection team reviewed and confirmed that engineering reports, procedures and forms were revised and implemented appropriately, and FME implemented a Part 21 screening criteria in the electronic NCR system. In addition, the NRC inspection team reviewed the training log and confirmed that the applicable engineering and QA staff were trained. The NRC inspection team also reviewed a sample of recent POs during the inspection. The NRC inspection team did not identify any issues with FME's implementation of its Part 21 program. The NRC inspection team determined that FME's corrective actions were adequate to address the NOV. Based on the review of the corrective actions, the NRC inspection team closed NOV 99901378/2008-201-01.

b.2 Corrective Action Associated with NOV 99901378/2008-201-02

The NRC issued NOV 99901378/2008-201-02 for FME's failure to invoke the provisions of 10 CFR Part 21 in Purchase Order 1102554, to Nuclear Logistics

Incorporated for safety-related seismic testing services.

In response to NOV 99901378/2008- 201-02, FME initiated CAR No. 2175 to address these issues. The NRC inspection team reviewed SP645.00, SP645.10, SP645.20, and SP725.00 that provided the objective evidence for the completion of the corrective actions, including the review of CAR No. 2175. The NRC inspection team confirmed that the purchase order was revised and issued; and that FME procedures were updated to ensure that Part 21 requirements are included in the PO documents. In addition, the NRC inspection team reviewed the training log and confirmed that the applicable engineering and QA staff were trained. Furthermore, during its review of a sample of recent purchase orders during the inspection, the NRC inspection team did not identify any issues with FME invoking Part 21 in its purchase orders. The NRC inspection team determined that FME's corrective actions were adequate to address the NOV. Based on the review of the corrective actions, the NRC inspection team closed NOV 99901378/2008-201-02.

b.3 Corrective Action Associated with NON 99901378/2008-201-03

Following the September 2008 inspection of FME, the NRC issued Notice of Nonconformance (NON) 99901378/2008-201-03 for FME's failure to perform a survey to provide objective evidence that a functional test was performed by Crane Engineering on FME order 40059058 for a North Anna jacket water pump. No independent tests, analyses, or inspections were performed by FME to substantiate information from the non-audited supplier.

In its responses to NON 99901378/2008-201-03, FME initiated CAR No. 2176 to address these issues. FME revised Quality Engineering Instruction (QEI) 011, "Supplier Evaluation, Approval and Monitoring," to ensure FME will adequately audit sub-suppliers and add the sub-suppliers to the ASL database. In addition, FME audited Crane Pumps and Systems and two separate sub-suppliers are now being tracked independently in the FME database. The NRC inspection team reviewed the documentation that provided the objective evidence for the completion of the corrective actions, including the review of CAR No. 2176. Furthermore, the NRC inspection team reviewed the training log and confirmed that the applicable staff were trained. The NRC inspection team reviewed a sample of recent supplier surveys during this inspection and did not identify any issues with FME's supplier survey program. The NRC inspection team determined that FME's corrective actions were adequate to address the NON. Based on the review of the corrective actions, the NRC inspection team closed NON 99901378/2008-201-03.

c. Conclusion

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

6. Entrance and Exit Meetings

On September 21, 2021, the NRC inspection team discussed the scope of the inspection with Mr. Martin Kurr FME's Quality Assurance Manager, Glenn Miller FME's Vice President of Operations, and other members of FME's management and technical staff. On September 24, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Kurr and other members of FME'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
Aaron Armstrong	Inspection Team Leader	NRC	X	X	
Odunayo Ayegbusi	Inspector	NRC	X	X	
Greg Galletti	Inspector	NRC			
Paul Prescott	Inspector	NRC	*	*	
Kerri Kavanagh	Branch Chief	NRC		X	
Martin Kurr	Quality Assurance Manager	FME	X	X	
Glenn Miller	VP Operation	FME	*	*	
Ursula Johnson	Director Quality	FME	*	X	
Sue Garry	Eng. Services Admin	FME	*	*	
Dominic Thomson	Quality Assurance Supervisor	FME	*	*	
Jerry Mayhew	Design Supervisor	FME	*	*	
Jessica Piper-Anderson	Sr. Quality Tech	FME	X	X	
Mike Youakim	Engineering Design Manager	FME	*	*	
John Rath	Engineering Manager	FME	*	*	
Jon Tichenor	Sr. Quality Eng	FME	X	X	
Joe Dobogai	Quality Eng	FME	X	*	
Dominic Dedolph	Quality Manager, External	FME	X	X	
Sean Acheson	Test Tech	FME	X	X	
Mike Dubois	Quality Tech	FME	X	X	
Jeanne Conway	Sr. Quality Eng	FME	X	X	
Joe Francis	Sr. Analytical Eng	FME	X	X	
Frank Aboujaoude	Engineering Director	FME	*	X	
George Selburg	Sr. Analytical Eng	FME	*	*	
Norm Treager	Sr. System Eng	FME	X	*	
Xavier Tiret	Inspector	ASN		X	
Geoffrey Triquet	Inspector	EDF		X	
Benoit Fourche	Inspector	ASN		X	
Jeremy Hubert	Inspector	ASN		X	
Frederick Stewart	QA inspection	FME			X
Keith Sherfinski	QA inspection	FME			X

* Present via telephone or computer

2. INSPECTION PROCEDURES USED

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

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

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

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
99901378/2008-201-01	CLOSED	Notice of Violation (NOV)	Part 21.21
99901378/2008-201-02	CLOSED	NOV	Part 21.31
99901378/2008-201-03	CLOSED	Notice of Nonconformance (NON)	Criterion VII

4. DOCUMENTS REVIEWED

Part 21 Evaluation

- Part 21 Evaluations package 17-01 with Attachments, "16501949*00 and all other OP liners shipped to Nuclear customers," dated July 3, 2017
- Part 21 Evaluations package 20-01 with Attachments, "1 Unknown tightness of cam thrust lock nut assembly," dated January 31, 2020
- Part 21 Evaluations package 18-01 with Attachments, "Speed Control Module 2301A, S/N 20230943 failed the bench test," dated June 20, 2018

Commercial Grade Dedication

- Sales Order (SO) No. 40125500, "Pump Fresh Water," Certificate of Conformance (CoC), dated February 12, 2021
- BF5378D "Critical Characteristic Verification Record," for Part No. 16610751, "Pump Circulating Water Assembly"
- Order No. 1734185, "Discrete Job Routing," for Pump, Fresh Water Service, 91/4" Impeller
- QC Instruction, "Certification of Hydro Test," Revision C, dated January 2018
- FME Pump Test Log for Order No. 1734815
- BF5377G, "Engineering Design Review Sheet," Revision 0, for Item No. 16610751
- SO No. 40131105, "Switch," CoC dated June 8, 2012
- BF5378E "Critical Characteristic Verification Record," for Part No. 01708703, "Control Switch Synchronizing"
- BF5377G "Engineering Design Review Sheet," for Item No. 01708703, Control Switch Synchronizing
- SO No. 40129891, "Switch, Speed Electronic," CoC dated July 22, 2012
- BF5378B, "Critical Characteristic Verification Record," for Part No. 11916985
- Procedure, "Factory Set-up (Use with P12620880 Speed Switch Assembly)," Revision 0, dated October 9, 2017

- BF5377G “Engineering Design Review Sheet,” for Assembly Speed Switch
- Test Surveillance Procedure (TSP) 6438, “Digital Reference Unit,” Revision L, dated October 20, 2020
- BF 5377E “Engineering Design Review Sheet,” for Item No. 12996949, “Speed Controller,”
- SO No. 40127676, “Governor, (Repaired) and Digital Reference Unit,” CoC dated July 22, 2021
- Investigative Report No. 1163041, “Replacement of Aluminum Electrolytic Capacitors dated August 25, 2020
- BF5378B, “Critical Characteristic Verification Record,” for Part No. 12996949
- Test Surveillance Procedure (TSP) 6438, “Digital Reference Unit,” Revision L, dated October 20, 2020
- SO No. 40131354, “Valve, Relief,” CoC dated May 27, 2021
- BF5378E, “Critical Characteristic Verification Record,” for Lube Oil Pump Relief Valve
- BF5371G, “Engineering Design Review Sheet,” for Lube Oil Pump Relief Valve
- SO No. 40131025, “Motor, Pump,” CoC dated July 26, 2021
- BF5377E, “Engineering Design Review Sheet,” for Pump, Crankcase Vacuum – Motor Only, 1 Horsepower
- BF5378B “Critical Characteristic Verification Record,” for Electric Motor, Crankcase Vacuum Pump for Part No. 11907526 – Motor
- SO No. 40130033, “Digital Reference Unit,” CoC dated April 6, 2021
- BF5378B, “Critical Characteristic Verification Record,” for Woodward Part No. 9903-439
- TSP 6438, “Digital Reference Unit,” Revision L, dated June 17, 2020
- BF537B, “Critical Characteristic Verification Record,” for Digital Reference Unit Vendor CoC No. 5561411
- SO No. 40129464, “Thermo Assembly,” CoC dated November 25, 2020
- BF5378C, “Critical Characteristic Verification Record,” for Thermostatic Element
- BF5377G, “Engineering Design Review Sheet,” for Thermo Assembly
- SO No. 70011097, “Blower Assembly, Repaired,” CoC dated November 24, 2020
- BF5378B, “Critical Characteristic Verification Record,” for Blower Assembly
- Quality Control Instruction, “OP Blower Record 8-1/8 Roots Type Blower,” No. 2102QC10
- As-Found Blower Inspection Sheet for Serial Number R4474, dated November 7, 2020
- Blower Inspection and Build Report for Serial Number R4474, dated November 21, 2020
- SO No. 40130768, “Actuator,” CoC dated April 20, 2021
- BF5378E, “Critical Characteristic Verification Record,” for Actuator, Pneumatic Reverse Acting
- BF5377G, “Engineering Design Review Sheet,” for Actuator, Pneumatic Reverse Acting
- SO No. 40108030, “Valve Assembly,” CoC dated April 18, 2016
- BF5377E, “Engineering Design Review Sheet,” for Delivery Valve Assembly
- SO No.40129865, “Pump Set,” CoC dated January 21, 2012
- BF5378E, “Critical Characteristic Verification Record,” for Pump Set, Lube Oil Circulating
- BF5377G, “Engineering Design Review Sheet,” for Pump Set, Lube Oil Circulating
- SO No. 40133451, “Coupling,” CoC dated 8/26/21
- BF5378B, “Critical Characteristic Verification Record,” for Coupling
- BF5377C, “Engineering Design Review Sheet,” for Coupling Style 38

Surveys

- Fasteners and manufacturer of custom fasteners and machined parts supplier survey conducted by third-party contractor, dated January 17, 2019
- Pump manufacturing and testing supplier survey conducted by third-party contractor, dated September 10, 2021
- Iron Castings supplier survey conducted by FME, dated August 26, 2021
- Bearing and bearing testing supplier survey conducted by third-party contractor, dated October 11, 2019
- Die forgings and extruded forgings supplier survey conducted by FME dated October 11, 2019
- Pump supplier survey conducted by third-party contractor, dated September 14, 2019
- Generator related power conversion and control equipment supplier survey conducted by third-party contractor, dated October 2, 2019
- Crankshaft manufacturing supplier survey conducted by third-party contractor, dated June 1, 2017

Policies and Procedures

- Standard Practice (SP)-790.00, "Nuclear Unique Items (10 CFR 50 Appendix B)," New Issue, dated April 2021
- SP 714.00, "Procedure on Reporting of Defects & Noncompliance To NRC," dated March 2010
- SP 750.00, "Commercial Grade Dedication (CGD)," dated April 2020CP-Q-05, "Preparing and Processing the Non-Conformance Report," Revision 8, dated December 21, 2020
- SP 781.45, "Internal and External Audits," dated April 2021
- SP 700.10, "Corrective and Preventive Action," dated June 2009
- SP 700.10, "Corrective and Preventive Action," dated December 2019
- SP 630.20, "Nonconforming Material Control," dated June 2009
- SP 630.20, "Nonconforming Material Control," dated April 2021
- SP 714.00, "Procedure on Reporting of Defects & Noncompliance to NRC," dated November 2008
- SP 714.00, "Procedure on Reporting of Defects & Noncompliance to NRC," dated March 2010
- SP 725.00, "Procurement of ASME Section III Components, Parts and Material," dated June 2009
- SP 750.00, "Commercial Grade Item Dedication Program," dated March 2009
- SP 781.40, "Auditor Qualification," dated December 2011
- BF4876J, Corrective Action Request
- BF4876K, Corrective Action Request
- BF4876M, Corrective Action Request
- BF5388D, "Substantial Safety Hazard Evaluation 10 CFR 21"
- QEI-011V, "Supplier, Evaluation, Approval, Monitoring, and Improvement," dated February 2009
- SP660.20, "Receipt and Acceptance of Purchased Product & Services," dated August 2021
- SP325.20, "Identification and Traceability," dated November 2020
- SP525.20, "Control of Production and Service Provision," dated August 2020

Corrective Action Reports (CARs)

- PDR 964

- PDR 973
- PDR 991
- PDR 926
- PDR 929
- PDR 928
- PDR 925
- PDR 924
- PDR 921
- PDR 927
- PDR 931
- PDR 933
- PDR 930
- CAR 3145
- CAR 2214
- CAR 3020
- CAR 2890
- CAR 2191

Corrective Actions Opened During the NRC Inspection

- PDR 1030
- PDR 1031
- PDR 1032
- PDR 1033
- PDR 1034
- PDR 1035
- PDR 1036

Purchase Orders, Audit Reports, and Commercial-Grade Surveys

- PO No. 1197012, dated December 19, 2019
- Section 08 – Approved Audit Plan, Checklist and Report, dated September 20, 2021
- Section 04 – Approved Audit Plan, Checklist and Report, dated August 19, 2021
- Section 16 – Approved Audit Plan, Checklist and Report, dated July 20, 2021
- Section 01 – Approved Audit Plan, Checklist and Report, dated October 20, 2020
- Section 02 – Approved Audit Plan, Checklist and Report, dated December 22, 2020
- Section 10 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 07 – Approved Audit Plan, Checklist and Report, dated July 30, 2020
- Section 13 – Approved Audit Plan, Checklist and Report, dated January 29, 2021
- Section 14 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 11 – Approved Audit Plan, Checklist and Report, dated August 7, 2020
- Section 03, 05, 12 – Approved Audit Plan, Checklist and Report, dated April 27, 2020
- Section 09 – Approved Audit Plan, Checklist and Report, dated August 7, 2020
- Section 15 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 7.1 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 20 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 18 – Approved Audit Plan, Checklist and Report, dated January 15, 2021
- Section 04, 06, 7.1, 08, 09, 13, 16, 17, 19 – Approved Audit Plan, Checklist and Report, dated February 5, 2020
- Section 17 – Approved Audit Plan, Checklist and Report, dated December 22, 2020

Nonconformance Reports(NCR)

- NCR 228897
- NCR 229031
- NCR 229436
- NCR 229488
- NCR 229529
- NCR 229543
- NCR 229937
- NCR 230682
- NCR 230698
- NCR 231108
- NCR 231697
- NCR 231699
- NCR 231821
- NCR 232116
- NCR 232329
- NRC 232399
- NRC 232445

Training and Qualification Records

- Auditor qualification records for two FME auditors
- FME Inspector Training Records for inspectors interviewed
- FME Vision Test Records for inspectors interviewed