Mr. Victor Montalbano  
Vice-President, Quality and Performance  
Framatome Inc.  
3315 Old Forest Road  
Lynchburg, VA 24501

SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION REPORT OF FRAMATOME, INC. NO. 99901300/2021-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Montalbano:

From November 15 through November 19, 2021, the U.S. Nuclear Regulatory Commission (NRC) staff conducted a limited scope routine vendor inspection at the Framatome, Inc.’s (hereafter referred to as Framatome) facility in Lynchburg, VA. The purpose of this limited-scope inspection was to assess Framatome’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 Framatome’s implementation of the quality activities associated with: (1) Arkansas Nuclear One’s radial peaking factor exceeding both the generic cycle independent criteria and the basic maneuvering acceptance criteria values, and (2) the digital instrumentation and control modernization project for Turkey Point Nuclear Generating Units 3 and 4. This NRC inspection report does not constitute NRC endorsement of Framatome’s overall quality assurance (QA) program.

During 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 Framatome was not fully implementing its QA program in the area of corrective action. The specific finding and references to the pertinent requirements are identified in the enclosures to this letter. In response to the enclosed notice of nonconformance (NON), Framatome should document the results of the extent of condition review for this finding and determine if there are any effects on other safety-related components.

Please provide a written statement or explanation within 30 days of this letter in accordance with the instructions specified in the enclosed NON. 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,” the NRC will make available electronically for public inspection a copy of this letter, its enclosure, and your response 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. To the extent possible, your response (and if applicable), should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that it can be made available to the public without redaction. 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 be 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 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.”

Sincerely,

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

Signed by Kavanagh, Kerri on 12/09/21

Docket No.: 99901300

EPID No.: I-2021-201-0063

Enclosures:
1. Notice of Nonconformance
2. Inspection Report No. 99901300/2021-201 and Attachment
SUBJECT: NUCLEAR REGULATORY COMMISSION VENDOR INSPECTION
REPORT OF
FRAMATOME, INC. NO. 99901300/2021-201 AND NOTICE OF
NONCONFORMANCE Dated: December 9, 2021

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NOTICE OF NONCONFORMANCE

Framatome, Inc.             Docket No. 99901300
3315 Old Forest Rd.     Report No. 2021-201
Lynchburg, VA 24501

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Framatome, Inc.'s (hereafter referred to as Framatome) facility in Lynchburg, VA, from November 15, 2021 through November 19, 2021, Framatome did not conduct certain activities in accordance with NRC requirements that were contractually imposed upon Framatome 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.”

Subsection 7.2.1 of Framatome’s procedure No. 1703-88, “US Fuel Corrective Action Program (Devonway ICAP),” Revision 1, dated March 2, 2020, states, in part, that “A CR [condition report] should be originated as soon as practical after an issue has been identified.”

Contrary to the above, as of November 19, 2021, Framatome failed to promptly identify and correct a condition adverse to quality associated with its Nodal Expansion Method Optimized (NEMO) core simulator computer code. Specifically, Framatome inadequately assessed potential causes of anomalies identified within NEMO. On May 10, 2021, Entergy Nuclear Operations, Inc. (hereafter referred to as Entergy - the licensee for Arkansas Nuclear One, Unit 1 (ANO-1)) notified Framatome that during a power distribution surveillance test at approximately 60-percent rated thermal power, a discrepancy was observed between the measured power in several fuel assemblies and the power predicted using NEMO. In response, Framatome provided Entergy revised surveillance acceptance criteria in reports dated May 11, 2021, May 17, 2021, and June 22, 2021. Entergy subsequently presented a draft apparent cause analysis to the NRC staff, with Framatome personnel in attendance, during a teleconference on June 28, 2021, indicating that NEMO modeling issues were a potential and likely significant contributor to the observed discrepancies. However, Framatome only opened Condition Report (CR) No. 2021-2275, “ANO-1 Cycle 30 Power Distribution Measurement Anomaly,” to address this issue as a track and trend CR on September 29, 2021. In addition, the CR did not adequately determine potential sources of the discrepancy associated with NEMO.

This issue has been identified as Nonconformance 99901300/2021-201-01.

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 full compliance will be achieved. Where good cause is shown, the NRC will consider extending the response time.

Because 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, which is accessible from the NRC’s Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or Safeguards Information (SGI) so that the NRC 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 9th day of December 2021.
Docket No.: 99901300
Report No.: 99901300/2021-201
Vendor: Framatome, Inc.
3315 Old Forest Road
Lynchburg, VA 24501
Vendor Contact: Mr. Victor Montalbano
Vice-President, Quality and Performance
Email: victor.montalbano@framatome.com
Phone: 434-832-3368

Nuclear Industry Activity: Framatome, Inc.’s scope of supply includes fuel design and fabrication, engineering services, and replacement of safety-related components for U.S. nuclear power plants.

Inspection Dates: November 15 - 19, 2021
Inspectors: Yamir Diaz-Castillo NRR/DRO/IQVB Team Leader
Greg Galletti NRR/DRO/IQVB
Frankie Vega NRR/DRO/IQVB Trainee
Benjamin Parks NRR/DSS/SFNB Technical Specialist
Jeremy Dean NRR/DSS/SFNB Technical Specialist

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation
The U.S. Nuclear Regulatory Commission (NRC) staff conducted a limited scope routine vendor inspection at the Framatome, Inc.'s (hereafter referred to as Framatome) facility in Lynchburg, VA, 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 inspection team conducted this inspection from November 15 through November 19, 2021. The last NRC inspection of this facility was conducted virtually in February 2021.

This technically-focused inspection specifically evaluated Framatome’s implementation of quality activities associated with: (1) Arkansas Nuclear One, Unit 1’s (ANO-1) radial peaking factor exceeding both the generic cycle independent criteria and the basic maneuvering acceptance criteria (BMAC) value, and (2) the digital instrumentation and control (DI&C) modernization project for Turkey Point Nuclear Generating (TPNG) Units 3 and 4. Specific activities observed by the NRC inspection team included:

- Walkthrough of the Tricon product test bed area for the TPNG Units 3 and 4 DI&C modernization project and receipt inspection areas

These regulations served as the bases for the NRC inspection:

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


With the exception of the nonconformance described below, the NRC inspection team concluded that Framatome’ QA policies and procedures comply with the applicable requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, and that Framatome personnel are implementing these policies and procedures effectively. The results of this inspection are summarized below.

Nonconforming Material, Parts, or Components and Corrective Action

The NRC inspection team reviewed Framatome’s policies and procedures that govern the implementation of Framatome’s nonconforming material, parts, or components and corrective action programs to verify compliance with the regulatory requirements in Criterion XV, “Nonconforming Materials, Parts or Components,” and Criterion XVI, “Corrective Action,” of
Appendix B to 10 CFR Part 50. The NRC inspection team reviewed a sample of nonconformance reports (NCRs) and condition reports (CRs) associated with the TPNG Units 3 and 4 DI&C modernization project. For the NCRs, the NRC inspection team confirmed that they were adequately documented, reviewed, tracked, and dispositioned. For the CRs, the NRC inspection team confirmed that they were adequately reviewed, implemented, and approved by appropriate personnel in a timely manner. No findings of significance were identified.

The NRC inspection team issued Nonconformance 99901300/2021-201-01 in association with Framatome’s failure to implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Nonconformance 99901300/2021-201-01 cites Framatome for failing to promptly identify and correct a condition adverse to quality associated with its Nodal Expansion Method Optimized (NEMO) core simulator computer code. Specifically, the NRC inspection team determined that Framatome inadequately assessed potential causes of the anomalies identified by ANO-1 within the NEMO code system identified during a power distribution surveillance test at approximately 60-percent rated thermal power. Framatome did not thoroughly evaluate potential deviations that may have been attributable to the NEMO code, such as by performing additional sensitivity studies or higher-order calculations to further investigate the sensitivity of the NEMO predictions to evolutionary design changes implemented at ANO-1.

Design Control

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its design control program to verify compliance with the requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed examples of work products developed for the TPNG Units 3 and 4 DI&C modernization project including documentation associated with the planning and requirements phases identified on the Master Configuration List. The NRC inspection team also reviewed cycle-specific design calculations supporting the event at ANO-1, as well as governing procedures and guidelines, and applicable licensing documents. No findings of significance were identified.

Commercial-Grade Dedication

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its commercial-grade dedication program to verify compliance with the requirements of Criterion III and Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed completed documentation including a sample of commercial-grade surveys and technical evaluations associated with the TPNG Units 3 and 4 DI&C modernization project. The NRC inspection team confirmed the commercial-grade surveys contained sufficient objective evidence of the control of the critical characteristics and the technical evaluations adequately identified the critical characteristics and the acceptance criteria of the items being dedicated. No findings of significance were identified.

Supplier Oversight

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its supplier oversight program to verify compliance with the
requirements of Criterion IV, “Procurement Document Control,” and Criterion VII of Appendix B to 10 CFR Part 50. The NRC inspection team evaluated on-going supplier oversight activities associated with TPNG Units 3 and 4 DI&C modernization project and reviewed a sample of the most recent external audits and purchase orders (POs) from vendors on Framatome’s Approved Supplier List. No findings of significance were identified.

10 CFR Part 21 Program

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with 10 CFR Part 21. The NRC inspection team: (1) reviewed the 10 CFR Part 21 postings; (2) reviewed a sample of POs; (3) verified that Framatome’s nonconformance and corrective action programs provide a link to the 10 CFR Part 21 program; and (4) reviewed a sample of 10 CFR Part 21 evaluations performed by Framatome. No findings of significance were identified.
REPORT DETAILS

1. Design Control

   a. Inspection Scope

   The NRC inspection team reviewed Framatome Inc.’s (hereafter referred to as Framatome) policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, “Design Control,” 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.” The NRC inspection team focused its review of Framatome’s design control process on: (1) the digital instrumentation and control (DI&C) modernization project for Turkey Point Nuclear Generating (TPNG) Units 3 and 4 and (2) the Arkansas Nuclear One, Unit 1 (ANO-1) event where the radial peaking factor exceeded both the generic cycle independent criteria and the Basic Maneuvering Acceptance Criteria (BMAC) values.

   Turkey Point Nuclear Generating Units 3 and 4 DI&C Modernization Project

   Planning (Conceptual) Phase Review

   The NRC inspection team reviewed a sample of quality procedures and instructions governing the development of DI&C project specific plans, and output documents required to implement the modernization project, including the: (1) Project Management Plan (PMP); (2) Project Quality Plan (PQP); (3) Master Configuration List (MCL) - Unit 3 and 4; (4) Software Quality Assurance Plan (SQAP); (5) Software Development Plan (SDP); (6) Software Configuration Management Plan (SCMP); (7) and the Software Verification and Validation Plan (SVVP). These plans were developed as part of the planning (conceptual) phase activities for the modernization project. The NRC inspection team verified that the project specific plans were developed in accordance with Framatome’s quality procedures and instructions, as applicable.

   The NRC inspection team also reviewed a sample of completed independent verification and validation (IV&V) task activities and discussed the role IV&V plays in the implementation of the modernization project. The NRC inspection team verified that IV&V had completed activities specified in the SVVP for the planning phase and provided objective evidence to support those activities such as formal reviews of several planning phase documents identified in the MCL including the PQP, SQAP, SCMP, SDP, and SVVP.

   Requirements Phase Review

   The NRC inspection team reviewed several requirements phase documents governing the control and development of project specific quality records, including those for developing and revising specifications and system descriptions, and control of IV&V engineering and design engineering interfaces. For the modernization project, the NRC inspection team noted that at the time of the inspection, only the qualified safety parameter display system (QSPDS) requirements phase documentation has been developed.
The NRC inspection team also reviewed a sample of system and software requirement specifications for the QSPDS. The NRC inspection team confirmed that: (1) the specifications were developed in accordance with the requirements phase procedures and instructions, and (2) the output specifications were developed in accordance with the applicable written instructions.

In addition, the NRC inspection team reviewed examples of the use of the Cradle software tool used to document the system and software requirements developed initially from the customer specification, and further decomposed from the system requirements specification (SyRS). The NRC inspection team reviewed the process used to identify and establish linkages between the requirements, the processes used by IV&V to establish both forward and backward requirements traceability, and discussed the process IV&V uses to perform the requirements phase task activities related to requirements traceability and acceptance.

Furthermore, the NRC inspection team reviewed the SVVP activities, sampled completed IV&V task activities and reports, and discussed the role of IV&V in the implementation of the modernization project. The NRC inspection team verified that IV&V had completed several required activities specified in the SVVP for the requirements phase and had documented their evaluation of the project activities in the QSPDS requirements phase summary report. The report described several key activities including:

1. Verification that the configuration management process was complete and accurate.
2. Performance of a security assessment (performed separately by Framatome’s cyber security group).
3. Development of the traceability analysis from the customers’ engineering procurement specification to the SyRS and software requirements specification (SRS).
4. Evaluation of the SyRS and SRS for correctness, consistency, completeness, and accuracy.
5. Preparation of the QSPDS requirements phase summary report.

ANO-1 Radial Peaking Factor Event

The NRC inspection team reviewed Framatome’s design control process for ANO-1’s radial peaking factor event including the applicable procedures and guidelines associated with ANO-1’s fuel design. The NRC inspection team also reviewed NRC-approved licensing topical reports that describe Framatome’s fuel cycle design analytic methods and the specific calculations supporting the design and operation of ANO-1 Cycles 27 through 30. In addition, the NRC inspection team reviewed Framatome’s calculations for the revised BMAC values and confirmed these calculations were done in accordance with Framatome’s design control procedures and within the applicable technical parameters. The NRC inspection team verified that the calculations were independently verified consistent with Framatome’s design control process.
The NRC inspection team also discussed the design control program with Framatome’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

ANO-1 Radial Peaking Factor Event

Framatome fabricates fuel, designs fuel cycles, and provides core monitoring software for Entergy Nuclear Operation’s (hereafter referred to as Entergy) ANO-1. Framatome designs fuel cycles using the NEMO computer code described in Topical Report BAW-10180-A, “NEMO - Nodal Expansion Method Optimized,” Revision 1, dated March 1993. In addition, Framatome uses outputs from the NEMO computer code to develop BMAC values, which Entergy uses to help monitor the local power distribution of the core at ANO-1 and assure that the fuel cycle design has been properly implemented and is operating in accordance with the design. The BMAC values reflect available power peaking margin at each core location beyond the limiting values assumed in the plant accident and transient analyses. Framatome issued Revision 1 of FS1-0051353, “ANO-1 Cycle 30 BMAC Summary Report,” on February 9, 2021, which was the first issuance of the BMAC report for ANO-1, Cycle 30.

Framatome fabricates fuel assemblies for use at ANO-1 that include stainless steel “filler” rods (SSRs), which replace ordinary, zirconium-alloy-clad, nuclear fuel rods in limited locations in select assemblies. These SSRs are installed in locations that are or will be subject to thermal hydraulic conditions that could increase the likelihood of a fretting failure of an ordinary fuel rod. When SSRs are used in a core design, they can cause incremental changes in the local and core-wide radial power distribution, and Framatome applies some modeling approximations within NEMO to account for this behavior.

On May 10, 2021, Entergy performed intermediate power level core power distribution testing at approximately 60-percent rated thermal power (RTP) and concluded that current BMAC values at 100-percent RTP would be insufficient to continue power ascension. Following this surveillance, Entergy requested Framatome to revise the ANO-1 Cycle 30 BMAC values to credit available margins to raise the BMAC values at 100-percent power, to accommodate the planned power ascension at ANO-1.

While performing the power distribution testing, Entergy measured the local assembly power in core location K-10 and observed that the measured power deviated from the power predicted in the fuel cycle design by 8.3-percent measured-to-predicted (M-P). Several other locations in core exhibited M-P deviations, but of lower magnitude. On May 11, 2021, at Entergy’s request, Framatome supplied FS1-0051353, “ANO-1 Cycle 30 BMAC Summary Report,” Revision 2, which credited additional sources of analytic margin, increased the BMAC values, and allowed Entergy to resume power ascension.

Entergy projected the fuel assembly power M-P agreement further into ANO-1 Cycle 30 operation and concluded that the newly revised BMAC values would be challenged early in the first half of the operating cycle due to adverse trends in M-P power comparisons. There was not sufficient analytic margin remaining to further adjust the BMAC values, such that other ways to increase the BMAC values were required. Upon request from Entergy, Framatome completed a third BMAC report, FS1-0051353, Revision 3, on May
17, 2021, which required the imposition of administrative limits on ANO-1 operating domain. The administrative limits would restrict the ANO-1 Cycle 30 positive imbalance setpoints by reducing them by 4-percent M-P.

Despite the issuance of Revision 3 of FS1-0051353, Entergy continued to observe adverse trending of the assembly power M-P agreement, and subsequently requested Framatome to prepare an additional revision to FS1-0051353. On June 22, 2021, Framatome issued FS1-0051353, Revision 4, to provide additional margin in the BMAC values to compensate for the adverse trending that Entergy continued to observe. In order to implement the new BMAC values, Entergy revised the ANO-1 Cycle 30 Core Operating Limits Report (COLR) and the Axial Shape Index (ASI) limits. Entergy then adjusted the Reactor Protection System (RPS) scram setpoints on ASI to match those in the revised ANO-1 Cycle 30 COLR. The revised COLR/ASI limits then supported the revised BMAC values. Framatome opened Condition Report (CR) 2021-2275, “ANO-1 Cycle 30 Power Distribution Measurement Anomaly,” as a track and trend CR on September 29, 2021 to continue monitoring this issue. A more detailed evaluation of Framatome’s CR-2021-2275, including the information that Entergy prepared to support an Apparent Cause Analysis (ACA), is documented in Section 2 below.

c. Conclusion

The NRC inspection team concluded that Framatome is implementing its design control program in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that Framatome is implementing its policies and procedures associated with the design control program. No findings of significance were identified.

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

a. Inspection Scope

The NRC inspection team reviewed Framatome’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 reviewed a sample of nonconformance reports (NCRs) associated with the TPNG Units 3 and 4 Di&C modernization project and confirmed that Framatome: (1) dispositioned the NCRs in accordance with the applicable procedures; (2) documented an appropriate technical justification for various dispositions; and (3) took adequate corrective action with regard to the nonconforming items. In addition, the NRC inspection team confirmed that the NCR process provides a link to the 10 CFR Part 21, “Reporting of Defects and Noncompliance,” program.

The NRC inspection team also reviewed a sample of CRs associated with the TPNG Units 3 and 4 Di&C modernization project and confirmed that the CRs provided: (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, as applicable, (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. In addition, the NRC inspection team confirmed that the CRs provide a link to the 10 CFR Part 21 program.

For ANO-1’s radial peaking factor event, Framatome did not initiate any NCRs and only opened CR-2021-2275.

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with Framatome’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 CR-2021-2275, the NRC inspection team noted that the CR did not adequately identify and investigate the potential causes of the deviations in the M-P power distribution event at ANO-1. Although the CR includes an ACA prepared by Entergy, which suggested that the modeling for SSRs could be the main contributor, Framatome attributed approximately 25-percent of the deviation to SSR modeling. Framatome’s analysis also identified other potential sources of error, but did not conclusively establish the causes of the error, nor the magnitude of each potential contributor. In addition, while CR-2021-2275 was opened on September 29, 2021, the NRC inspection team observed that Framatome had provided revisions to Entergy’s BMAC reports on May 11, May 17, and June 22, 2021. The May 17, 2021 revision required Entergy to implement an administrative limit to an allowable axial power imbalance, and the June 22, 2021, revision required the creation of a new COLR and implementation of revised reactor trip system setpoints.

Section 7.1 of Framatome’s Administrative Procedure No. 1703-88, “US Fuel Corrective Action Program (Devonway ICAP),” Revision 1, dated March 2, 2020, identifies 10 criteria under which a CR should be initiated. Subsection 7.2.1 of AP 1703-88 states, in part, that “A CR should be originated as soon as practical after an issue has been identified.” During discussions with Framatome staff, the NRC inspection team questioned why a CR had not been initiated sooner than September 2021. These discussions centered around Framatome’s belief that they had not deviated from technical and quality requirements stated in documents such as purchase orders (POs) or contracts. However, the NRC inspection team identified two additional criteria that applied to the discrepancy that Entergy observed at ANO-1. These criteria were: (1) there is uncertainty about compliance with requirements, and (2) there is a problem that may lead to noncompliance with requirements if not addressed.

Although the event occurred on May 10th, subsequent revisions to the BMAC reports occurred on May 11th, May 17th, and June 22nd. The initial revision allocated available sources of analytic target margin to allow the licensee to resume power ascension testing, however, the May 17th and June 22nd revisions required Entergy to take remedial measures at ANO-1. The May 17th BMAC revision required the implementation of administrative controls to reduce the allowable power imbalance, and the June 22nd revision required the customer to take corrective actions, including revising the Core Operating Limits Report and revising trip setpoints. Given that these BMAC report revisions were created to address continued, adverse trending of the M-P
agreement observed during power distribution surveillance testing, the NRC inspection team determined that the adverse trending created uncertainty about compliance with requirements, or could have led to non-compliance with requirements if not addressed.

In addition, Entergy briefed the NRC technical staff during a tele-conference on June 28, 2021, with Framatome staff also in attendance. Entergy’s briefing consisted of a discussion of their draft ACA. The draft ACA concluded that most, if not all, of the M-P discrepancy was being caused by Framatome modeling of SSRs. Although CR-2021-2275 indicates that Framatome’s modeling of SSRs is not the sole contributor to M-P deviation, the CR indicates that it is a likely contributor. The NRC inspection team also noted that Entergy’s ACA, and the additional documentation contained in the CR, which Framatome prepared, did not agree on the underlying causes of the adverse M-P power distribution comparisons. Because the CR was initiated as a track and trend CR, Framatome did not perform an adequate causal analysis. While several causes of the observed M-P deviations are operational issues, Framatome did not thoroughly evaluate potential deviations that may have been attributable to the NEMO code, such as by performing additional sensitivity studies or higher-order calculations to further investigate the sensitivity of the NEMO predictions to evolutionary design changes implemented at ANO-1, such as progressively higher loadings of SSRs and use of SSRs in fresh assemblies.

The NRC inspection team identified this issue as an example of Nonconformance 99901300/2021-201-01 for Framatome’s failure to promptly identify and correct a condition adverse to quality associated with its NEMO core simulator computer code.

c. Conclusion

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

The NRC inspection team issued Nonconformance 99901300/2021-201-01 in association with Framatome’s failure to implement the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Nonconformance 99901300/2021-201-01 cites Framatome for failing to promptly identify and correct a condition adverse to quality. Specifically, Framatome did not adequately determined potential sources of the discrepancy associated with the NEMO code system.

3. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed Framatome’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 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 surveys and commercial-grade dedication packages associated with the TPNG Units 3 and 4 DI&C modernization project. The sample of commercial-grade dedication packages included several items supporting the Tricon product (e.g., safety video display units, power supplies). 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 verified that the technical evaluations documented the criteria for the identification of item functions, credible failure mechanisms/modes, selection of critical characteristics and acceptance criteria, and the identification of verification methods. For the sample of commercial-grades surveys reviewed, the NRC inspection team confirmed that the 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 verified that the commercial-grade surveys were performed by qualified personnel.

The NRC inspection team also discussed the commercial-grade dedication program with Framatome’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 Framatome 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 Framatome is implementing its policies and procedures associated with the commercial-grade dedication program. No findings of significance were identified.

4. Supplier Oversight

a. Inspection Scope

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its supplier oversight program to verify compliance with the requirements of Criterion IV, “Procurement Document Control,” and Criterion VII of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed Framatome’s Approved Suppliers List, a sample of POs, supplier audits, and receipt inspection records associated with the TPNG Units 3 and 4 DI&C modernization project. 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 the suppliers’ 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.
The NRC inspection team verified that for the sample of receipt inspection records reviewed (e.g., receipt inspection reports, Certificates of Compliance), these records were (1) reviewed by Framatome for compliance with the requirements of the POs and (2) the records contained the applicable technical and regulatory information. In addition, the NRC inspection team performed a walk down of the receipt inspection and the Tricon product development areas, reviewed specific POs associated with several items awaiting inspection, and discussed these POs with Framatome’s staff.

For the sample of supplier audits reviewed, the NRC inspection team verified that the audit reports included an audit plan, any findings identified, adequate documented objective evidence of compliance with the applicable requirements, auditors’ qualifications, and a review by Framatome’s responsible management. The NRC inspection team also verified that the supplier audits were performed by qualified auditors. In addition, the NRC inspection team reviewed a sample of training and qualification records of Framatome’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 Framatome’s policies and procedures.

The NRC inspection team also discussed the supplier oversight program with Framatome’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 Framatome is implementing its supplier oversight program in accordance with the regulatory requirements of Criterion IV 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 Framatome is implementing its policies and procedures associated with the supplier oversight program. No findings of significance were identified.

5. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed Framatome’s policies and implementing procedures that govern the implementation of its 10 CFR Part 21 program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of Framatome’s 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 Framatome’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 Framatome, the NRC inspection team verified that Framatome had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, as applicable.
The NRC inspection team also discussed the 10 CFR Part 21 program with Framatome’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 Framatome 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 Framatome is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

6. Entrance and Exit Meetings

On November 15, 2021, the NRC inspection team discussed the scope of the inspection with Mr. Victor Montalbano, Framatome’s Vice-President of Quality and Performance, and other members of Framatome’s management and technical staff. On November 19, 2021, the NRC inspection team presented the inspection results and observations during an exit meeting with Mr. Montalbano and other members of Framatome’s management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals interviewed by the NRC inspection team.
# ATTACHMENT

## 1. ENTRANCE/EXIT MEETING ATTENDEES

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Affiliation</th>
<th>Entrance</th>
<th>Exit</th>
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<tbody>
<tr>
<td>Victor Montalbano</td>
<td>Vice-President (VP), Quality &amp; Performance</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Carl Fisher</td>
<td>VP, Instrumentation &amp; Control (I&amp;C) Unit</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Steven Lydzinski</td>
<td>VP, Fuel Design Engineering, North America</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Robert Freeman</td>
<td>VP, Fuels Contracts &amp; Services, North America</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Mark Harvey</td>
<td>Director, Quality Assurance (QA) &amp; Independent Validation &amp; Verification (IV&amp;V)</td>
<td>Framatome, Inc.</td>
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<td>Gary Peters</td>
<td>Director, Licensing &amp; Regulatory Affairs</td>
<td>Framatome, Inc.</td>
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<td>Gayle Elliott</td>
<td>Deputy Director, Licensing &amp; Regulatory Affairs</td>
<td>Framatome, Inc.</td>
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<td>Duane Newman</td>
<td>Manager, Quality Programs</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Al Pitts</td>
<td>Manager, QA</td>
<td>Framatome, Inc.</td>
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<td>Barb Scalia</td>
<td>Manager, I&amp;C Engineering &amp; Manufacturing</td>
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<td>Jeff Patton</td>
<td>Manager, I&amp;C Engineering &amp; Manufacturing</td>
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<tr>
<td>Paul Garcia</td>
<td>Manager, U.S. Fuels QA</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Pat McQuade</td>
<td>Manager, U.S. Corrective Action Program (CAP)</td>
<td>Framatome, Inc.</td>
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<td>Richie McKay</td>
<td>CAP Manager, I&amp;C</td>
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<tr>
<td>Brian Haibach</td>
<td>Manager, Fuel Core Design &amp; Safety Analysis</td>
<td>Framatome, Inc.</td>
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<td>Ron Legrand</td>
<td>Project Director</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Peter M. Suhocki</td>
<td>Team Leader, Babcock &amp; Wilcox Reload Design &amp; Analysis</td>
<td>Framatome, Inc.</td>
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<td>Brian Haynes</td>
<td>Chief Engineer, Turkey Point Project</td>
<td>Framatome, Inc.</td>
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<td>Bob Baxter</td>
<td>Supervisory &amp; Advisory Engineer</td>
<td>Framatome, Inc.</td>
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<td>Dwayne Fitts</td>
<td>Fuels Engineering Supervisor</td>
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<td>Morris Byram</td>
<td>Licensing &amp; Regulatory Affairs</td>
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<td>Eric Meerbach</td>
<td>Engineering Supervisor, I&amp;C</td>
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<td>Edward P. Michael</td>
<td>Principal Engineer, U.S. Fuels Neutronics</td>
<td>Framatome, Inc.</td>
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<tr>
<td>Sean Leengran</td>
<td>Principal Engineer, Fuels Neutronics</td>
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<td>Matthew DuShaw</td>
<td>Engineer, Thermal Hydraulics</td>
<td>Framatome, Inc.</td>
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<td>Amanda Gaines</td>
<td>Engineer IV, Fuel Thermal Hydraulics</td>
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<td>CJ Markum</td>
<td>Core Design &amp; Operations Support Engineer</td>
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<td>Russell Cox</td>
<td>Fuel Project Manager, Arkansas Nuclear Unit 1</td>
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<td>Jamey Laughlin</td>
<td>Quality Specialist</td>
<td>Framatome, Inc.</td>
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<td>Lee Williams</td>
<td>Project Engineer</td>
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<td>Ron Jaworowski</td>
<td>Senior Project Manager, I&amp;C</td>
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<td>Chris Ledoux</td>
<td>Project Manager, I&amp;C</td>
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<td>Bob Clark</td>
<td>Licensing</td>
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<td>Austin Johansen</td>
<td>Engineer</td>
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<td>Greg Hobson</td>
<td>Advisory Engineer</td>
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<tr>
<td>Yamir Diaz-Castillo</td>
<td>Inspection Team Leader</td>
<td>Nuclear Regulatory Commission (NRC)</td>
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<tr>
<td>Greg Galletti</td>
<td>Inspector</td>
<td>NRC</td>
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<tr>
<td>Frankie Vega</td>
<td>Inspector</td>
<td>NRC</td>
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<tr>
<td>Benjamin Parks</td>
<td>Technical Specialist</td>
<td>NRC</td>
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<tr>
<td>Jeremy Dean*</td>
<td>Technical Specialist</td>
<td>NRC</td>
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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**

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<th>Item Number</th>
<th>Status</th>
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<td>99901300/2021-201-01</td>
<td>Opened</td>
<td>Notice of Nonconformance</td>
<td>Criterion XVI, “Corrective Action”</td>
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4. **DOCUMENTS REVIEWED**

   **Policies and Procedures**
   - Framatome Inc. Quality Assurance Program Manual No. 56-9141754-011, Revision 11, dated May 10, 2021
   - Corporate Policy 0401, “Evaluation and Reporting per 10 CFR 21,” Revision 25, dated July 31, 2018
   - Administrative Procedure (AP) 0405-05, “Contract Variation Approval Request,” Revision 29, dated April 4, 2018
   - AP 0405-39, "I&C Design and Manufacturing under the Framatome 10CFR50 Appendix B Program," Revision 1, dated October 13, 2020
   - AP 0412-12, “Preparation, Processing, and Use of Licensing Documents,” Revision 38, dated November 9, 2020
   - AP 0412-55, “Developing and Revising Specifications and System Descriptions,” Revision 35, dated June 21, 2018
- AP 0412-76, “Commercial Grade Dedication,” Revision 17, dated October 14, 2021
- AP 0412-55, “Developing and Revising Specifications and Systems Descriptions,” Revision 35, dated June 21, 2018
- AP 0902-12, “Access Control Systems for Computers Running Engineering Application Software,” Revision 13, dated August 2, 2019
- AP 0902-13, “Production System Software and Hardware Changes,” Revision 10, dated March 31, 2020
- AP 0902-29, “Procurement of Engineering Applications Software,” Revision 15, dated June 29, 2021
- AP 1005-01, “Inspection and Material Control's Operation,” Revision 26, dated February 16, 2021
- AP 1212-21, “Purchase Requisition Requirements and Management,” Revision 11, dated October 21, 2020
- AP 1212-22, “Purchase Order Requirements and Management,” Revision 17, dated October 25, 2021
- AP 1703-88, “US Fuel Corrective Action Program (Devonway ICAP),” Revision 1, dated March 2, 2020
- AP 1705-03, “Quality Assurance Data Packages and Certificates of Conformance,” Revision 38, dated June 24, 2021
- AP 1708-08, “Quality Control Surveillance,” Revision 31, dated October 6, 2021
- AP 1710-04, “Quality Assurance/Quality Control Activities,” Revision 10, dated July 26, 2021
• AP 1717-06, “Corrective Action Program (CAP),” Revision 17, dated August 30, 2021

• AP 1719-22, “Quality Assurance Audits and Commercial Grade Surveys of Suppliers,” Revision 39, dated May 28, 2021

• AP 1719-23, “Qualification of Quality Assurance Audit Personnel,” Revision 29, dated February 20, 2019

• Engineering Information Record No. 51-9188123-006, “Dedication Plan for Commercial Grade Calibration Services,” Revision 6, dated September 3, 2021

• Fuel Standard Operating Procedure (FSOP)-02, “Fuel Controlled Documents Management,” Revision 15, dated February 2, 2021

• FSOP-07, “Design Analysis,” Revision 8, dated October 1, 2020

• Operating Instruction (OI) 2A826-9328874, “Triennial Audit/Survey 9 Month Extensions Due to Extenuating Circumstances,” Revision 0, dated May 12, 2021

• OI 2A926-9293054, “Control of Nonconforming Items,” Revision 1, dated September 18, 2020

• OI-9328874-F01, “9 Month Approved Suppliers List (ASL) Extension Review,” dated June 11, 2021

• OI-2A826-9293055, “Configuration Management,” Revision 3, dated June 25, 2021

• OI-1618-03, “Independent V&V Engineering/Design Engineering Interface,” Revision 3, dated October 9, 2009

Turkey Point Nuclear Generating Units 3 and 4 Digital Instrumentation and Control Modernization Project Specific Plans and Reports

• 2A826-9295109, “Requirements Traceability Matrix,” Revision 1, dated December 18, 2019

• 51-9330211-000, “Requirements Phase Summary Report - QSPDS,” Revision 0, dated June 11, 2021

• 09-9321605-000, “Software Quality Assurance Plan,” Revision 0, dated January 15, 2021

• 136-9321606-001, “Software Verification and Validation Plan,” Revision 1, dated May 20, 2021

• 56-9321451-004, “Project Quality Plan (PQP),” Revision 4, dated July 2021

• 105-5017274-010, “Projects Manual,” Revision 10, dated May 19, 2021
Arkansas Nuclear One, Unit 1 Event Radial Peaking Factor Event

- 47-9289270-000, “Core Operation Report: ANO-1 Cycle 27,” Revision 0 (no date provided)
- 47-9308900-000, “Core Operation Report: ANO-1 Cycle 28,” Revision 0 (no date provided)
- 47-933849-000, “Core Operation Report: ANO-1 Cycle 29,” Revision 0, dated August 30, 2021
- 51-1234001-01, “BAW-2149 Clarification,” Revision 1, dated October 15, 1996
- 103-3900-001, “Arkansas Nuclear One, Unit 1 - Cycle 30 Reload Report,” Revision 1, dated June 2021
- FS1-0037832, “Mark-B Maneuvering Analysis Guidelines,” Revision 1, dated January 11, 2019
- FS1-0049070, “ANO-1 Cycle 30 FFCD,” Revision 1, dated June 9, 2020
- FS1-0051334, “ANO-1 Cycle 30 Maneuvering Analysis,” Revision 4, dated June 17, 2021
Commercial-Grade Dedication Records

- Dedicated Parts Evaluation 910055-117, SVDU Server Assemblies (DPE-17), Revision 2, dated March 2017
- Dedicated Parts Evaluation 910055-118, SVDU Display Units (DPE-18), Revision 2, dated March 2017
- Dedicated Parts Evaluation 910055-107, Cable Assemblies for ETAs (DPE-07), Revision 8, dated March 2017
- Quality Control Inspection Report, ID T5.29-9336614-001, associated to Purchase Order (PO) 1021014114, dated September 24, 2021
- Quality Control Inspection Report, ID T5.29-9327269-000, associated to PO 1021001087, dated March 16, 2021

Purchase Orders, Audit Reports, and Commercial-Grade Surveys

- “9 Month Extension Review,” dated July 21, 2021
- PO 1021039096, Revision 0, dated October 11, 2021
- PO 1021013699, Revision 2, dated June 09, 2021
- PO 1021019677, Revision 1, dated June 03, 2021
- PO 1020046520, Revision 0, dated November 20, 2020
- PO 1021014114, Revision 8, dated September 27, 2021
- PO 1021001087, Revision 0, dated January 11, 2021
- Supplier audit report, Audit QA-AUD-1904, dated May 14, 2019
- Supplier audit report, Audit 681-1, dated May 2, 2018
- Commercial-Grade Survey Report, dated March 16, 2020

Nonconformance Reports

- Nonconformance Report (NCR) 2021-0060
- NCR-2021-0188
- NCR-2021-0205
Corrective Action Reports

- Condition Report (CR) 2019-2355
- CR-2020-0695
- CR-2020-0975
- CR-2020-1937
- CR-2020-2315
- CR-2021-0341
- CR-2021-0579
- CR-2021-1178
- CR-2021-1269
- CR-2021-1319
- CR-2021-1320
- CR-2021-1231
- CR-2021-1322
- CR-2021-1323
- CR-2021-1324
- CR-2021-1325
- CR-2021-1326
- CR-2021-1357
- CR-2021-2275

Corrective Action Reports Opened During the NRC Inspection

- CR-2121-2831

Training and Qualification Records

- Framatome, Inc.’s lead auditors training and qualification records