



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

June 22, 2021

Ms. Cheryl A. Gayheart
Regulatory Affairs Director
Southern Nuclear Operating Co., Inc.
3535 Colonnade Parkway
Birmingham, AL 35243

SUBJECT: EDWIN I. HATCH NUCLEAR PLANT, UNITS 1 AND 2; JOSEPH M. FARLEY NUCLEAR PLANT, UNITS 1 AND 2; VOGTLE ELECTRIC GENERATING PLANT, UNITS 1 AND 2; AND ASSOCIATED INDEPENDENT SPENT FUEL STORAGE FACILITIES – REDUCTION IN COMMITMENT TO THE QUALITY ASSURANCE TOPICAL REPORT (EPID L-2021-LLQ-0002) [COVID-19]

Dear Ms. Gayheart:

By letter dated May 7, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21127A184), as supplemented by letter dated May 26, 2021 (ADAMS Accession No. ML21147A077), Southern Nuclear Operating Company, Inc. (SNC) submitted a request for the U.S. Nuclear Regulatory Commission (NRC) approval of a change to the Quality Assurance Topical Report (QATR) that results in a reduction of commitment in accordance with the requirements of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR), Section 50.54(a)(4) for Edwin I. Hatch Nuclear Plant, Units 1 and 2; Joseph M. Farley Nuclear Plant, Units 1 and 2; and Vogtle Electric Generating Plant, Units 1 and 2, as well as the associated independent spent fuel storage facilities (SNC Fleet). The proposed change would revise the QATR to expand the allowances for performing fully remote and provisional remote audits and commercial-grade surveys during times of extenuating circumstances (e.g., pandemics) in SNC's QATR.

Specifically, SNC's submittal requested to implement guidance found in the Electric Power Research Institute's Technical Report 3002020796, "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," April 2021 to add the option to perform fully remote and provisional remote assessments during periods of exigent conditions (e.g., pandemics).

The NRC staff has completed its review of SNC's submittal. Based on the enclosed safety evaluation, the NRC staff concludes that there is reasonable assurance that the SNC Fleet QATR will continue to meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. Therefore, the NRC staff concludes that the proposed changes to SNC's Fleet QATR to perform fully and remote audits and commercial-grade survey during exigent conditions is acceptable.

If you have any questions, please contact me at (301) 415-3100 or via email at John.Lamb@nrc.gov.

Sincerely,

/RA/

John G. Lamb, Sr. Project Manager
Plant Licensing Branch II-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket Nos. 50-321, 50-366, 50-348,
50-364, 50-424, 50-425,
71-333, 71-521, 71-726,
72-036, 72-042, and 72-1039

cc: Listserv

SUBJECT: EDWIN I. HATCH NUCLEAR PLANT, UNITS 1 AND 2; JOSEPH M. FARLEY NUCLEAR PLANT, UNITS 1 AND 2; VOGTLE ELECTRIC GENERATING PLANT, UNITS 1 AND 2; AND ASSOCIATED INDEPENDENT SPENT FUEL STORAGE FACILITIES – REDUCTION IN COMMITMENT TO THE QUALITY ASSURANCE TOPICAL REPORT (EPID L-2021-LLQ-0002) [COVID-19] DATED JUNE 22, 2021

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UNITED STATES
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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

REQUEST FOR CHANGE TO THE QUALITY ASSURANCE TOPICAL REPORT

EDWIN I. HATCH NUCLEAR PLANT, UNITS 1 AND 2

JOSEPH M. FARLEY NUCLEAR PLANT, UNITS 1 AND 2

VOGTLE ELECTRIC GENERATING PLANT, UNITS 1 AND 2

SOUTHERN NUCLEAR OPERATING COMPANY

DOCKET NOS. 50-321, 50-348, 50-424, 50-366, 50-364, 50-425, 71-333, 71-521, 71-726,
72-036, 72-042, AND 72-1039

1.0 INTRODUCTION

By letters dated May 7, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21127A184), and supplemented by letter dated and May 26, 2021 (ADAMS Accession No. ML21147A077), Southern Nuclear Operating Company (SNC, the licensee) requested approval of a proposed change to the SNC Quality Assurance Topical Report (QATR) that results in a reduction of commitment to the previously accepted quality assurance (QA) program in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.54(a)(4).

Specifically, SNC's submittal requested to implement guidance in the Electric Power Research Institute's (EPRI's) Technical Report (TR) 3002020796, "Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions," for performing fully remote and provisional remote assessments. EPRI TR 3002020796 was developed by the industry to provide an option within a licensee's or vendor's QA program for remote performance when a vendor assessment is required. The proposed change provides guidance for the application of video and other real-time communication technologies for the successful performance of remote vendor assessments. SNC's proposed use of this method of vendor assessments will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by the declaration.

EPRI TR 3002020796 includes guidance for conducting vendor assessments utilizing "hybrid" techniques. A hybrid approach, as defined by EPRI TR 3002020796, is an assessment conducted with one or more team members participating in-person at the facility being assessed while other team members are participating remotely. The NRC staff has no regulatory

restrictions or defined conditions for when a hybrid assessment of vendors may be utilized. The proposed change to the SNC QATR would use the guidance in EPRI TR 3002020796 to demonstrate that an effective assessment was conducted by team members participating remotely.

2.0 REGULATORY EVALUATION

The regulation 10 CFR 50.54(a)(4) sets forth the NRC's regulatory requirements regarding changes to a QA program description. Changes to a QA program description that reduce the licensee's commitments must be submitted and receive NRC approval prior to implementation. Changes made to the QA program description as presented in the safety analysis report (SAR) or in a topical report that must be submitted as specified in 10 CFR 50.4. The submittal of a change to previously accepted QA program description included or referenced in the SAR must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, and the QA program description commitments previously accepted by the NRC.

The regulatory requirement for QA program audits of suppliers is set forth in Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Criterion VII requires, in part, the establishing of measures for assuring that "purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, **inspection at the contractor or subcontractor source**, and examination of products upon delivery."

3.0 TECHNICAL EVALUATION

The requirement to perform vendor audits was first described in the 1973 Quality Control Bulletin (QCB) titled, "AEC [Atomic Energy Commission] Interpretation of the 18 Criteria of Quality Assurance of 10 CFR Part 50, Appendix B," (ADAMS Accession No. ML033630060). The 1973 QCB stated that Criterion VII of Appendix B to 10 CFR Part 50 requires (emphasis added in bold text):

"...These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery..."

The AEC position, regarding the requirements from Criterion VII of Appendix B to 10 CFR Part 50, as described in the 1973 QCB is that:

"...Implementing procedures shall be explicit in the method or means to be used in source evaluation and selection, and shall include, as a minimum, assignment of responsibility, a quantitative or qualitative list of issues to be evaluated and a mean of documenting and verifying conformance with the procedure. Inspection at the source by the licensee or his designated agent, shall be performed in accordance with procedures and shall be provide quantitative or qualitative acceptance for the area evaluated..."

American National Standards Institute (ANSI) N45.2.10-1973, "Quality Assurance Requirements Terms and Definitions," provides terms and definitions that were determined to be generally acceptable for use in Regulatory Guide (RG) 1.74, "Quality Assurance Terms and Definition," (ADAMS Accession No. ML12216A008), February 1974. ANSI N45.2.10-1973 defines Audit as:

"An activity to determine through investigation, the adequacy of, and adherence to, established procedures, instructions, specifications, codes, and standards or other applicable contractual and licensing requirements, and the effectiveness of implementation."

American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance Program Requirements for Nuclear Facility Applications," as found acceptable by NRC RG 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 5, (ADAMS Accession No. ML17207A293) with certain clarifications and regulatory positions. ASME NQA-1-2015 defines Audit and External Audit as:

Audit:

"A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance."

External Audit:

"An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization."

Furthermore, Basic Requirement 7, "Control of Purchased Items and Services," Paragraph 200," Supplier Evaluation and Selection," includes language that states in part:

"Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:....(c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality assurance program."

Commercial-grade surveys (CGSs) are typically performed to verify one or more critical characteristics based on the documented programmatic controls that the supplier applies for dedication of the item or service. Regulatory requirements and guidance related to the use of CGSs to accept a basic component for use, are provided in Criterion VII of Appendix B to 10 CFR Part 50; NRC Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs" (ADAMS Accession No. ML16344A092); NQA-1; and EPRI TR 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," September 2014, as found acceptable by NRC Regulatory Guide 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, June 2017 (ADAMS Accession No. ML17041A206), and defines CGS survey of supplier.

In all cases, both the regulatory requirements and guidance refer to audits (i.e. external audits) and CGSs as being performed “at the contractor or subcontractor source,” “by direct observation,” or “at the location of material procurement or manufacture,” respectively.

Given technological advances since the requirements of Appendix B were first promulgated, SNC requested to modify their QATR to utilize the guidance in EPRI TR 3002020796 in lieu of the regulatory requirements of Criterion VII for performing audits and CGSs. The change will provide guidance for the application of video and other real-time communication technologies for the successful performance of remote audits and CGSs. The use of this method of verification will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by the declaration.

The proposed change will provide alternate methods of conducting audits and CGSs at the contractor or subcontractor source under certain conditions. The use of these methods of verification will only be applicable when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from those locations affected by State and national declarations. Furthermore, these methods (i.e. provisional and fully remote assessments) are to be used for those previously qualified suppliers to renew their qualifications. These methods are not to be used to qualify new suppliers.

To incorporate the use of remote audits and CGSs, SNC established the following changes to their QATR: (1) Section 7.2, “NQA-1-1994 Commitment,” and Part III, “Regulatory Commitments,” were revised to reflect that remote audits and CGSs will be conducted in accordance with the guidance in EPRI TR 3002020796; (2) the EPRI technical report was incorporated by reference in the SNC QATR; (3) guidance will be used to perform fully remote and provisional remote assessments only during periods of exigent conditions; and (4) the application of the guidance will be limited by the application of the EPRI TR’s screening questions.

As noted previously, the EPRI TR 3002020796 was prepared to provide licensees and vendors with guidance for using communication and video capabilities to perform remote audits and CGSs in extreme circumstances where it is not possible to perform traditional in-person audits and CGSs due to conditions that threaten the health and safety of individuals performing these assessments. The NRC staff reviewed EPRI TR 3002020796 and SNC’s quality controls to utilize the EPRI technical report guidance. The NRC staff determined that implementing adequate quality controls prior to performing a remote assessment [audits and CGSs] should address the limitations identified in EPRI TR 3002020796.

The EPRI TR 3002020796 provides a screening process to determine if remote assessment is appropriate for the activities being verified prior to conducting the assessment. The screening questions included in Section 6, “Process for Evaluating Use of Remote Assessment Techniques,” of EPRI TR 3002020796 provide licensees and vendors with a process that can be used to evaluate the technical and quality requirements of interest to determine the extent to which remote assessment techniques can be applied effectively.

Based on the quality controls in place, the NRC staff concludes that the performance of fully remote assessments and provisional remote assessments will be an effective alternative for performance of audits and CGSs activities during exigent conditions. Although remote performance assessments cannot fully replace the ability to evaluate, observe, and verify activities at the source, the use of modern communication technologies permits a remote assessment plan to be developed and implemented that will continue to satisfy the relevant

criteria of Appendix B to 10 CFR Part 50, providing an equivalent, and therefore, an acceptable level of quality control. If the audit team determines that the vendor's QA program has been adequately implemented, then the next audit would meet the threshold for conducting on a normal triennial audit frequency. The proposed change would only be applicable to activities that can be justified by applying the controls described in the EPRI TR 3002020796.

4.0 CONCLUSION

The NRC staff has reviewed SNC's submittal for implementation of EPRI TR 3002020796 in its QATR provided in the letter dated May 7, 2021, as supplemented with clarifications by letter dated May 26, 2021. The NRC staff's position of allowing alternatives, due to temporary suspension of performance assessments at the source based on restrictions such as travel, access to supplier's facility, etc., associated with exigent conditions (e.g. COVID-19), are not intended to replace the ability to evaluate, observe, and verify activities at the source. Permanent suspension of in-person assessments at the source cannot be granted without a change to the regulation. The NRC staff has reviewed SNC's submittals and the guidance in EPRI TR 3002020796 and determined that the implementation of EPRI TR 3002020796 will continue to meet the requirements of Criterion VII of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

Principal Contributor: Jonathan Ortega-Luciano

Date: June 22, 2021