



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

August 6, 2020

Mr. Fadi Diya  
Senior Vice President and  
Chief Nuclear Officer  
Ameren Missouri  
Callaway Energy Center  
8315 County Road 459  
Stedman, MO 65077

SUBJECT: CALLAWAY PLANT, UNIT NO. 1 – OPERATING QUALITY ASSURANCE  
MANUAL CHANGE REVISION 34b (EPID L-2020-LLQ-0004 [COVID-19])

Dear Mr. Diya:

By letter dated July 8, 2020 (Agencywide Documents Access and Management System Accession No. ML20190A195), Union Electric Company, dba Ameren Missouri (the licensee) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) for approval of a revision to the Operating Quality Assurance Program as described in the Operating Quality Assurance Manual for Callaway Plant, Unit No. 1 (Callaway).

Due to actions taken in response to the Coronavirus Disease 2019 (COVID-19) public health emergency, the existing 90-day grace period for completing triennial vendor audits/surveys for some of Ameren Missouri's suppliers will expire on August 31, 2020. As the length of the public health emergency is unknown, Ameren Missouri proposes to adopt a 25 percent grace period (9 months) for audits/surveys to address the current situation (as well as any similar situation in the future) provided that procedurally specified administrative controls are met. The proposed revision results in a reduction of commitment to the previously accepted quality assurance program that was submitted for NRC review and approval in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a)(4).

The NRC staff has reviewed the licensee's request and concludes that the proposed changes to Operating Quality Assurance Manual, Revision 34b, for Callaway, complies with the applicable quality assurance requirements in Appendix B to 10 CFR Part 50 and Subpart G to 10 CFR Part 72 while implementing the 25 percent extension of audit or survey frequency during extenuating circumstances. Therefore, the NRC staff finds the licensee's proposed changes to the Operating Quality Assurance Manual, Revision 34b, for Callaway are acceptable.

F. Diya

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If you have any questions, please contact me at 301-415-8371 or via e-mail at [Mahesh.Chawla@nrc.gov](mailto:Mahesh.Chawla@nrc.gov).

Sincerely,

*/RA/*

Mahesh Chawla, Project Manager  
Plant Licensing Branch IV  
Division of Operating Reactor Licensing  
Office of Nuclear Reactor Regulation

Docket Nos. 50-483 and 72-1045

Enclosure:  
Safety Evaluation

cc: Listserv



UNITED STATES  
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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION  
CHANGE TO THE OPERATING QUALITY ASSURANCE MANUAL, REVISION 34b

UNION ELECTRIC COMPANY

CALLAWAY PLANT, UNIT NO. 1

DOCKET NOS. 50-483 and 72-1045

1.0 INTRODUCTION

By letter dated July 8, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20190A195), Union Electric Company, dba Ameren Missouri (the licensee), submitted a request to the U.S. Nuclear Regulatory Commission (NRC) for approval of a revision to the Operating Quality Assurance (QA) Program as described in the Operating Quality Assurance Manual (OQAM) for the Callaway Plant, Unit No. 1 (Callaway). The proposed revision results in a reduction of commitment to the previously accepted QA program that was submitted for NRC review and approval 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, the licensee's submittal requested the wording within the Callaway OQAM, Section 18, "Audits," to be expanded to permanently include provisions for an extended grace period for the completion of triennial vendor audits and surveys during extenuating circumstances. Due to the actions taken in response to the Coronavirus 2019 (COVID-19) public health emergency, the existing 90-day grace period for completing triennial vendor audits and surveys for some of the licensee's suppliers will expire on August 31, 2020. As the length of the public health emergency is unknown, the licensee proposed to adopt a 25 percent grace period (i.e., 9 months) for audits and surveys to address the current public health emergency situation, as well as any similar situation in the future, provided that procedurally specified administrative controls are met.

2.0 REGULATORY BASIS

The regulation in 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. This includes changes made to the QA program description as presented in the safety analysis report or in a topical report that must be submitted as specified in 10 CFR 50.54(a)(4).

The submittal of a change to the QA program description 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 to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 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 of Appendix B to 10 CFR Part 50, 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."

The Callaway OQAM also supports the QA program for the Dry Cask Storage System and Independent Spent Fuel Storage Facility at the Callaway site; therefore, the proposed change also affects the requirement set forth in Subpart G, "Quality Assurance," to 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

The regulation in 10 CFR Part 72.154(a) requires, in part, the establishing of measures to ensure that "purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must 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 current version of the Callaway OQAM, Revision 34a, Section 18.11 states the following:

Applicable elements of suppliers' quality assurance programs shall be audited (post-award) on a triennial basis. A 90-day grace period may be applied to this activity. Audits generally should be initiated when sufficient work is in progress to determine whether the organization is complying with the established quality assurance provisions. Subsequent contracts or contract modifications which significantly enlarge the scope of activities by the same suppliers shall be considered in establishing audit requirements. In addition, the need for a triennial audit may be precluded upon evaluation and documentation by the NOS [Nuclear Oversight] Department that the results of mini audits performed during source verification and source surveillance activities confirm the adequacy and implementation of the supplier's QA program.

The licensee submitted the OQAM, Revision 34b for Callaway, and requested the addition of new Subsection 18.11.1 which states:

An overall 25% extension (9 months) for triennial audits or surveys may be exercised during periods where performance of such activities is not feasible as a result of extenuating circumstances. Examples of extenuating circumstances would include, but are not limited to: 1) declaration of a national emergency;

2) severe localized or national weather conditions or damage to licensee or supplier infrastructure; or 3) localized outbreak of a severe health concern to the public and licensee.

Continued use of suppliers that have exceeded the maximum allowed audit or survey time due to extenuating circumstances is allowed if the following conditions are met:

- a. A documented evaluation must be performed to summarize why the audit or survey could not be performed prior to the end of the 90-day grace period and to provide the basis for maintaining the supplier as an approved supplier during the 25% (9-month) grace period. While implementing procedures must describe elements to be included in the documented evaluation, the following items should be considered as applicable:
  - For 10 CFR 50, Appendix B suppliers, verification that the supplier's quality assurance program is still committed to meeting the requirements of 10 CFR 50, Appendix B.
  - For commercial suppliers who are approved based on commercial grade survey, verification the supplier has maintained adequate documented programmatic controls in place for the activities affecting the critical characteristics of the item/services being procured.
  - Evaluation of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and any open findings since the previous triennial audits describing impact on the items/services being procured from that supplier.
  - Review of procurement history since last triennial audit/survey including receipt inspection results to identify any potential issues. The results of the performance history must be included in the evaluation.
  - The degree of standardization of the items being procured. For instance, suppliers of catalog items which are used across multiple industry with widely accepted good performance histories would be considered good candidates for a 25% (9-month) grace period.
- b. If concerns are identified based on the above evaluation, the following mitigating actions may be considered:
  - Enhanced receiving inspections beyond visual inspections and quality checks.
  - Identification of any additional requirements/restrictions to be placed on the supplier.
- c. For audits/surveys performed during the 25% grace period, the audit/survey shall include a review of activities performed by the supplier since the 36-month audit/survey expiration date.

- d. The allowance would only apply to existing suppliers on the Qualified Supplier's List.
- e. The 25% grace period discussed above is applicable to domestic and international suppliers.
- f. For audits/surveys performed during the 25% grace period, the audit/survey "clock" does not have to reset backwards to the original expiration date for which the audit/survey should have been performed. The end of the audit or survey would determine the date of the next triennial audit/survey.

In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water] Edition," Section 17.5, Revision 1, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," dated August 2015 (ADAMS Accession No. ML15037A441), and Regulatory Guide (RG) 1.28, Revision 5, "Quality Assurance Program Criteria (Design and Construction)," dated October 2017 (ADAMS Accession No. ML17207A293).

The extension of the audit frequency during extenuating circumstances as proposed by the licensee will provide greater flexibility in its consideration of other similar events, such as the ongoing COVID-19 pandemic. The current national emergency puts a restriction on domestic and international travel and limits access to vendor facilities by non-employees. As a result, the licensee's existing 90-day grace period for completing triennial vendor audits and surveys will expire for some of its suppliers on August 31, 2020, and beyond. Without further extension, the affected suppliers would have to be removed from Callaway's Qualified Suppliers List within 90 days of the triennial audit or survey expiration date, which would adversely impact the licensee's ability to procure safety-related items and services for Callaway. As the duration of the current national emergency is unknown, the NRC staff agrees that an overall extension of 25 percent to the triennial audit frequency for supplier audits and surveys may be implemented for extenuating circumstances. This extension would not be limited to three consecutive audit and survey cycles as previously approved by an NRC safety evaluation (ADAMS Accession No. ML051570349) and would be applicable to all audit and survey cycles.

During the extenuating circumstances, the licensee may continue to use suppliers that have exceeded the maximum allowed audit or survey time based on the conditions set forth in new Subsection 18.11.1 within the Callaway OQAM, Revision 34b. The NRC staff finds that the descriptions provided in Subsection 18.11.1 and the existing language within the Callaway OQAM are consistent with the following NRC staff's considerations for allowing extension to the periodicity of audits and surveys for suppliers during extenuating circumstances:

- a. There is verification that the supplier is still implementing a QA program that meets Appendix B to 10 CFR Part 50.
  - i. For suppliers with delinquent surveys, the entity shall ensure that the suppliers have maintained adequate documented programmatic controls in place for the activity affecting quality.
- b. The alternative method of the 25 percent extension is applicable to domestic and international suppliers.

- c. Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions.
- d. If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include, as appropriate, the following:
  - i. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
  - ii. Results of previous source verifications, audits, survey and receiving inspection activities.
  - iii. Operating experience of identical or similar products furnished by the same supplier.
  - iv. Results of audits and inspection from other sources (e.g. customer, ASME, or NRC inspection).
- e. If the contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the supplier will provide documented justification the change(s) are adequately addressed by its QA program controls.

The overall 25 percent extension for supplier audits and surveys would only be applicable to extenuating circumstances such as 1) declaration of a national emergency; 2) severe localized or national weather conditions; or 3) localized outbreak of a severe health concern to the public and licensee, as described in the proposed revision to the Callaway OQAM.

The 25 percent extension for supplier audits and surveys during extenuating circumstances is a different alternative to the current 90-day grace period allowed in Subsection 18.11 of the current OQAM, Revision 34a. The current 90-day grace period will remain unchanged for conditions not meeting the extenuating circumstances threshold. Examples of conditions not meeting extenuating circumstances threshold include, but not limited to, 1) staffing limitations impacting the timeliness of an audit or survey; and 2) scheduling conflicts by either Ameren Missouri, its suppliers or sub-tier suppliers. The expectations for the use of the 25 percent extension would be limited to implementation for extenuating circumstances and that the licensee will attempt to maintain the current triennial audit or survey period before exercising the 25 percent extension.

Unlike the existing alternative on the use of a 90-day grace period, under the 25 percent extension, the licensee would not have to reset the "audit clock" backwards when the audit or survey is finally performed to the original date the audit or survey should have been performed. The date that the audit or survey is finally performed would be the start of the new triennial audit or survey frequency. The NRC staff considered that should multiple events of a severe nature occur closely together, the requirement for not allowing the audit clock to be reset forward would result in an additional potential scheduling constraint on the licensee, its suppliers or sub-tier suppliers, in completing audits or surveys in a timely manner.

The NRC staff considered the maturity of the licensee's QA program and its supply chain oversight in determining this allowance of a 25 percent extension for audits or surveys to be completed from the date of the expiration of the triennial audit or survey frequency. The NRC staff also considered the potential risk significance of extending the audit or survey frequency by 25 percent, as well as the potential impact on the operation of Callaway and its reliance on its suppliers and sub-tier suppliers on the licensee's ability to secure safety-related items during extenuating circumstances. Based on the maturity of the licensee's QA program, the expected duration that the licensee will be under extenuating circumstances, and the licensee's continuous monitoring of ongoing and previous supplier performance, the NRC staff determined that there is minimal risk associated with implementing the extended audit or survey frequency during extenuating circumstances. Therefore, the NRC concluded that the conditions stated above ensure that reasonable assurance of the quality of items and services will continue to be maintained during this extension period.

#### 4.0 CONCLUSION

The NRC staff reviewed the licensee's OQAM, Revision 34b submittal for Callaway. As stated above, the NRC staff concludes that there is reasonable assurance that the licensee's Operating QA Program for Callaway will continue to meet the requirements of Appendix B to 10 CFR Part 50 and Subpart G to 10 CFR Part 72 while implementing the 25 percent extension of audit or survey frequency during extenuating circumstances. Therefore, the NRC staff finds that the licensee's proposed changes in the Callaway OQAM, Revision 34b, are acceptable.

Principal Contributor: Yiu Law

Date: August 6, 2020



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 MANUAL CHANGE REVISION 34b (EPID L-2020-LLQ-0004 [COVID-19])  
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