January 23, 2020

ULNRC-06562

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

10 CFR 50.54(a)(4)

Ladies and Gentlemen:

DOCKET NUMBER 50-483 and 72-1045
CALLAWAY PLANT UNIT 1
UNION ELECTRIC CO.
RENEWED FACILITY OPERATING LICENSE NPF-30
Operating Quality Assurance Manual (OQAM) Interim Revision 34a

Pursuant to 10 CFR 50.54(a)(4), Ameren Missouri (Union Electric Company) herewith transmits a request to approve a change to the Operating Quality Assurance Program (OQAP) as described in the Operating Quality Assurance Manual (OQAM) for the Callaway Plant. The proposed change is deemed to constitute a reduction in commitment. Specifically, per Callaway OQAM Change Notice (OQAMCN) 18-001, the wording within OQAM section 16.3 is to be revised to remove the list of specific conditions that are examples of Significant Conditions Adverse to Quality (SCAQs). In addition, a definition of a SCAQ will be adopted from the American Society of Mechanical Engineers (ASME) NQA-01-2008, "Quality Assurance Requirements for Nuclear Facility Applications."

The following documents are enclosed pursuant to 10 CFR 50.54(a)(4):

1. Attachment 1, "Description and Justification for Changes," explains the proposed changes to the OQAM, provides the reason for the changes, and provides the basis for concluding the OQAM, as revised, will continue to meet the requirements of 10 CFR 50 Appendix B. Because the same text is used to support the quality assurance program for the Dry Cask Storage System (DCSS) and Independent Spent Fuel Storage Facility (ISFSI) at the Callaway site, this justification also supports the conclusion that the requirements of Subpart G of 10 CFR Part 72 will continue to be met.

2. Attachment 2, "OQAM Section 16 Markup," provides the affected OQAM pages and identifies the changes through the use of strikeovers and inserts.

In accordance with the provisions of 10 CFR 50.54(a)(4)(iv), NRC review and approval of the proposed change to the OQAP is requested. Barring communication to the contrary, Ameren Missouri will regard the change as approved 60 days following submittal to the Commission.

It should be noted that this submittal does not contain any new commitments (subject to control under the Commitment Management Program for Callaway).

If there are any questions, please contact Hrach Minassian at 402-672-1064.

I declare under penalty of perjury that the foregoing is true and correct.

Sincerely,

Fadi M. Diya
Sr. Vice President and
Chief Nuclear Officer

Executed on: 1/23/2020

Attachments:

Attachment 1 – Description and Justification for Changes
Attachment 2 - OQAM Section 16 Markup

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Index and send hardcopy to QA File A160.0761

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Mr. Jay Silberg (Pillsbury Winthrop Shaw Pittman LLP)
Mr. Dan Beck (Missouri Public Service Commission)

Description and Justification for Changes

References:

1. Ameren Missouri Letter ULNRC-06539, "Operating Quality Assurance Manuals (OQAM) Revision 34," dated October 24, 2019

Summary of proposed change:

This change revises the wording of Operating Quality Assurance Manual (OQAM) section 16.3 to adopt a definition of a Significant Condition Adverse to Quality (SCAQ) based on the definition provided in American Society of Mechanical Engineers (ASME) NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I, *Introduction*, Section 400, *Terms and Definitions.* The change includes removing the list of examples of SCAQs currently contained in OQAM section 16.3. As revised, section 16.3 would continue to contain Callaway Energy Center's definition of a SCAQ.

An evaluation of the proposed revision against the criteria in 10 CFR 50.54(a)(3) concluded that elimination of the examples constitutes a reduction in commitment since the deletion could result in fewer conditions meeting the definition of a SCAQ.

Attachment 2 to this letter provides the affected OQAM pages, including a markup of the current OQAM section 16 as provided in OQAM Revision 34. The complete OQAM Revision 34 was previously provided to the NRC via Reference 1. The changes to OQAM section 16.3 are depicted below. Bold text reflects added content and the strikethrough font denotes deleted material.

16.3 **A significant condition adverse to quality is a condition adverse to quality that, if uncorrected, could have a serious effect on safety or operability.** Conditions adverse to quality which impede the implementation or reduce the effectiveness of the Operating QA Program shall be considered significant conditions adverse to quality. ~~Significant conditions adverse to quality may include, but are not limited to, noncompliance with procedural requirements which impact nuclear or personnel safety; reportable events, including reportable violations of the Technical Specifications; adverse nonconformance trends; deficiencies identified in the OQAP; recurring conditions for which past corrective action has been ineffective; managerial controls which could result in the failure of a plant system to perform its intended function: National Pollutant Discharge Elimination System (NPDES) violations; accidental, unplanned or uncontrolled radioactive releases; operating abnormalities, deviations from expected performance of plant equipment and of unanticipated deficiencies in the design or operation of structures, systems, or components which affect nuclear safety; and other conditions found to present potential hazards to nuclear safety.~~

Reason for the Change:

The adoption of the NQA-1-2008 definition results in language in the OQAM that is comparable to that used by other nuclear power plants and associated with NRC and industry documents. In the past, there has been difficulty in benchmarking other utility practices due mainly to the overly descriptive detail contained in Callaway's definition of a SCAQ. This has also resulted in questions regarding Callaway's practices when evaluated by external entities who are accustomed to a SCAQ definition based on, or comparable to, the NQA-1-2008 definition. The NQA-1-2008 definition was also chosen based on its endorsement in 10 CFR 50.55a(a)(1)(v).

In NQA-1-2008 Part I, *Introduction,* section 400, *Terms and Definitions*, the definition of a *condition adverse to quality* is provided. Within that definition is the definition for a SCAQ which reads, "A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability." For inserting this definition into OQAM section 16.3, the definition is modified in that the words "a condition adverse to quality" are substituted for the word "one," which allows the definition to function as a stand-alone sentence.

The deletion of the examples contained in OQAM section 16.3 removes detail that is better suited for inclusion in the station administrative procedures. Following this change, Callaway's Correction Action Program procedure, APA-ZZ-00500, *Corrective Action Program*, along with its Appendices, will continue to provide the programmatic requirements, definitions, and screening criteria that satisfy OQAM section 16.1 and 10 CFR 50 Appendix B requirements. Currently, the OQAM SCAQ examples prompt considerable interpretation regarding the bounds of the examples provided. This results in the expenditure of resources to determine the compliance of corrective action program screening activities. In addition, the current examples provide a mix of quality related criteria, non-quality related criteria and significant adverse conditions from other regulatory requirements. This mix of requirements contributes to confusion in the interpretation and application of the Corrective Action Program.

Retaining the current first sentence of OQAM section 16.3 preserves the current definition of a SCAQ, which reduces the required change management activities resulting from this OQAM change. In addition, it preserves a clear statement that conditions which impede the effectiveness of the Operating QA Program are to be considered SCAQs.

Justification:

The basis for continued compliance with the requirements of 10 CFR 50 Appendix B and 10 CFR 72 Subpart G is as follow:

Evaluation against 10 CFR 50 Appendix B – 10 CFR 50 Appendix B, Criterion XVI, Corrective Action, reads:

> 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. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

Following approval of the proposed change, OQAM section 16.1 will continue to require the established measures for ensuring that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In addition, OQAM section 16.1 will continue to require the administrative controls to ensure that for significant conditions adverse to quality, the cause of the condition is determined and corrective action taken to preclude repetition. Lastly, OQAM section 16.1 will continue to require the identification of a significant condition adverse to quality, the cause of the condition, and the documentation of the corrective action taken, as well as the reporting of that to appropriate levels of management. Therefore, the requirements of 10 CFR 50 Appendix B will continue to be reflected in the OQAM.

These OQAM-required administrative controls are implemented in station administrative procedure APA-ZZ-00500, *Correction Action Program.* The administrative controls pertaining to SCAQs are implemented via appendices to APA-ZZ-00500. Recognition and classification of identified conditions is accomplished in accordance with APA-ZZ-00500, Appendix 17, *Screening Process Guidelines.* The determination of cause, formulation of corrective actions to preclude repetition, and verification of corrective action effectiveness are accomplished in accordance with APA-ZZ-00500 Appendix 12, *Significant Adverse Condition – ADCN-1.*

Evaluation against 10 CFR 72 Subpart G Requirements (considered because of the Callaway OQAM applicability to DCSS/ISFSI based on OQAM Appendix B.)

Subpart G of 10 CFR 72 establishes the requirements for the Quality Assurance Program applicable to the Dry Cask Storage System (DCSS) including the Independent Spent Fuel Storage Facility (ISFSI). These requirements have been incorporated into Appendix B of the Callaway OQAM. The expectations for implementation of the Corrective Action Program as it pertains to DCSS/ISFSI activities are established in 10 CFR 72.172 which reads as follows:

> The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition,

and the corrective action taken must be documented and reported to appropriate levels of management.

OQAM Appendix B Section 16.0, *Corrective Action*, states, "Corrective action for DCSS structures, systems, components, and activities shall be as described in OQAM, Section 16.0." This statement will remain true and is unchanged by this activity. Neither the Callaway OQAM Appendix B nor 10 CFR Part 72 provides a definition of a significant condition adverse to quality specific to DCSS/ISFSI components/activities.

The proposed change to adopt a definition consistent with the ANSI/ASME NQA-1-2008 definition will continue to provide a definition that satisfies the description provided in OQAM Appendix B and 10 CFR 72.172. This ensures that OQAM Appendix B Section 2.0, *Quality Assurance Program*, requirements will continue to be met.

Rationale for Classification as a Reduction in Commitment:

10 CFR 50.54(a)(3) permits changes to be made to the quality assurance program description without prior NRC approval providing the change does not reduce the commitments in the program description as accepted by the NRC. Revision 34 of the OQAM currently reflects the commitments in the program description as accepted by the NRC. The proposed change involves two elements which are evaluated separately.

The first change adopts the definition of a SCAQ from ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I, *Introduction*, Section 400, *Terms and Definitions*. The definition in NQA-1-2008 is modified in that the words "a condition adverse to quality" are substituted for the word "one," as previously noted. This substitution allows the definition to function as a stand-alone sentence. While the full NQA-1-2008 quality standard is not being adopted, the proposed change does conform to the definition provided in ASME NQA-1-2008. Based on the combination of the endorsed language and the fact that this adopted definition increases the level of the QA program description, this change, by itself, is not considered a reduction in commitment.

The second change removes examples used to characterize a SCAQ (as currently included in OQAM section 16.3 and shown on page 1 of this attachment) without comparable language being present in any other part of the OQAM. The deletion of this classification criteria could result in fewer adverse conditions being identified as significant conditions adverse to quality and is, therefore, a reduction in commitment.

10 CFR 50.54(a)(3)(i) through (vi) identifies examples of changes that are not considered to be reductions in commitment. The proposed Callaway OQAM change does not meet any of those criteria. The change does not involve the use of a quality assurance alternative or exception approved by an NRC safety evaluation. (A query of ADAMS was unable to locate a safety evaluation for a comparable quality assurance program change.) The proposed change does not involve the use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text. The proposed change does not involve the use of

generic organizational charts to indicate functional relationships, authorities, and responsibilities. The proposed change does not involve organizational revisions that involve persons or the performance of quality assurance functions.

The proposed change does involve the elimination of quality assurance program information that is not duplicated in quality assurance regulatory guides and quality assurance standards to which Callaway is committed. Callaway's QA Program is based on commitment to the guidance provided in Regulatory Guide (RG) 1.33, *Quality Assurance Program Requirements (Operation)*, (Revision 2, 1978) and follows the guidance of the Regulatory Position stated in that RG as modified by the exceptions described in Appendix A of the OQAM. Further, the OQAM does specify the programmatic requirements of the corrective action program consistent with the RG and its endorsed ANSI standards. However, these referenced standards do not contain a comparable definition of a SCAQ, nor do they provide a list of examples for classifying a condition adverse to quality as a SCAQ comparable to that being removed from the OQAM. For this reason, this change is considered a reduction in commitment.

Conclusion:

Based on the foregoing, the proposed change may be considered a reduction in commitment such that prior NRC review and approval is required prior to implementation of the change. The Callaway OQAM, however, as revised per the proposed change, will remain compliant with 10 CFR 50 Appendix B. The proposed change is also acceptable in regard to the requirements of 10 CFR 72 Subpart G.

OQAM Section 16 Markup

The following presents the content of the affected pages from OQAM section 16, *Corrective Action.* OQAM Revision 34 was previously provided via Reference 1 of Attachment 1. The proposed changes are denoted using bold text for inserted material and the strikethrough font for deleted material.

16. CORRECTIVE ACTION

16.1 Measures shall be established to assure that conditions adverse to quality are promptly identified, reported, and corrected. Such measures shall be established in a program or programs which are proceduralized. These procedures, as a minimum, shall:

1) Define responsibilities for identifying and correcting conditions adverse to quality. Such corrections may be defined as remedial action.

2) Define responsibility for verifying that remedial action was taken for conditions adverse to quality.

3) Define responsibilities for determination of conditions adverse to quality which are significant. Significant conditions adverse to quality will require both remedial action and action to prevent recurrence.

4) Define responsibility for performing root cause evaluation, determining necessary actions to prevent recurrence, implementing those actions and verifying completion of those actions for significant conditions adverse to quality.

5) Provide a method for documenting the identification of conditions adverse to quality. This documentation shall also include the root cause or causes and the action implemented to prevent recurrence for significant conditions adverse to quality.

6) Provide methods for reporting significant conditions adverse to quality to appropriate levels of management. Acceptable methods include direct address, distribution of copies, electronic access or review of summaries of the conditions. These methods shall include reporting of significant conditions adverse to quality to review committees.

7) Provide methods for submitting reports required by external agencies concerning conditions adverse to quality.

8) Provide for developing and analyzing trends on at least a semiannual basis. Trending of conditions adverse to quality identified at suppliers' facilities is performed as part of the annual supplier evaluation per OQAM, Section 18.12.

16.2 Conditions adverse to quality which are classified as nonconformances shall be controlled in accordance with the additional requirements described in OQAM, Section 15.

16.3 **A significant condition adverse to quality is a condition adverse to quality that, if uncorrected, could have a serious effect on safety or operability.** Conditions adverse to quality which impede the implementation or reduce the effectiveness of the Operating QA Program shall be considered significant conditions adverse to quality. ~~Significant conditions adverse to quality may include, but are not limited to, noncompliance with procedural requirements which impact nuclear or personnel safety; reportable events, including reportable violations of the Technical Specifications; adverse nonconformance trends; deficiencies identified in the OQAP; recurring conditions for which past corrective action has been ineffective; managerial controls which could result in the failure of a plant system to perform its intended function: National Pollutant Discharge Elimination System (NPDES) violations; accidental, unplanned or uncontrolled radioactive releases; operating abnormalities, deviations from expected performance of plant equipment and of unanticipated deficiencies in the design or operation of structures, systems, or components which affect nuclear safety; and other conditions found to present potential hazards to nuclear safety.~~

16.4 Conditions adverse to quality which involve defects in basic components shall be reviewed for reporting applicability under 10 CFR 21 and other Federal reporting requirements.

16.5 The nature of the condition adverse to quality may be such that remedial actions must be taken immediately, whereas development and implementation of corrective action to preclude recurrence may take substantially longer.

16.6 Engineering Design or Projects personnel shall review conditions adverse to quality which involve design deficiencies or which involve recommending design/configuration changes as corrective action. Fuel Cycle Management should review conditions adverse to quality for fuel related issues. The ORC shall review significant conditions adverse to quality.

16.7 Corrective action documents shall be closed by verifying the implementation and adequacy of corrective action. The closure of corrective action documents shall be accomplished as promptly as practicable after the corrective action taken has been verified. Verification may be accomplished through direct observations, written communications, re-audit, surveillances, or other appropriate means.

16.8 Copies of completed corrective action documents shall be available for management review (hard copy or electronic media). The Nuclear Oversight Department shall periodically review corrective action documents and identify significant conditions. Summaries of significant conditions adverse to quality shall be submitted to appropriate levels of management.

16.9 Corrective action documents shall be reviewed for the effectiveness of the corrective actions taken and analyzed for potential adverse quality trends. Nuclear Oversight shall evaluate the analyses, the identification of adverse trends, and the acceptability of actions taken on these trends through routine audit and surveillance activities. The results of these assessments shall be reported to management.