Ameren MISSOURI

Callaway Plant

July 8, 2020

ULNRC-06588

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

10 CFR 50.54(a)(4)

Ladies and Gentlemen:

DOCKET NUMBERS 50-483 and 72-1045
CALLAWAY PLANT UNIT 1
UNION ELECTRIC CO.
RENEWED FACILITY OPERATING LICENSE NPF-30
PROPOSED REVISION TO OPERATING QUALITY ASSURANCE MANUAL (REV. 34b)

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 Callaway Plant. The proposed change is deemed to constitute a reduction in commitment. Specifically, per Callaway Plant OQAM Change Notice (OQAMCN) 20-001, the wording within OQAM section 18.11 is 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 actions taken in response to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE), 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% 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. If approved, the change would promote consistency among licensees and suppliers, including the major NSSS suppliers whose requests for similar changes to their quality assurance programs have been approved by the NRC.

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 Callaway OQAM also supports the quality assurance program for the Dry Cask Storage System (DCSS) and Independent Spent Fuel Storage Facility (ISFSI) at the Callaway

Plant site, the justification for the proposed change 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 18 Markup," provides the affected OQAM pages and identifies the changes through the use of text inserts.
3) Attachment 3, "OQAM Appendix A," provides the affected OQAM Appendix A pages and identifies changes through the use of text inserts.

NRC review and approval of the proposed change to the OQAP is requested pursuant to the provisions of 10 CFR 50.54(a)(4)(iv). The regulation specifies that such a proposed change shall be regarded as accepted by the Commission upon receipt of a letter to that effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first. In this case, approval of the requested change is respectfully requested to be approved on or by August 31, 2020. An approval letter is therefore requested ahead of the 60-day allowance.

The requested approval date is due to the extended duration of the COVID-19 PHE and the actions taken to mitigate its consequences. Restrictions on travel and access to some facilities has precluded the completion of audit/survey activities at those facilities. Without the requested 25% grace period, and beginning on September 1, 2020, several suppliers of safety related items and services would have to be removed from the qualified suppliers list (QSL) for Callaway Plant, which would adversely impact Ameren Missouri's ability to procure such items and services for the facility (due to expiration of the audit period). The impact of the PHE mitigating actions continues to grow while the actions remain in effect and will intensify as preparations continue for the upcoming Callaway Plant refueling outage (fall 2020). The requested, longer grace period will allow an opportunity to recover from the audit delays following the refueling outage.

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

If there are any questions, please contact Mr. Earl Mayhorn at 314-605-9701.

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

Sincerely,

Fadi Diya
Sr. Vice President &
Chief Nuclear Officer

Executed on: 07/08/2020

Attachment 1 -- Description and Justification for Changes
Attachment 2 -- OQAM Section 18 Markup
Attachment 3 -- OQAM Appendix A Markup

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Missouri Public Service Commission

Description and Justification for Changes

References:

1. Ameren Missouri Letter ULNRC-06539, "Operating Quality Assurance Manual (OQAM) Revision 34," dated October 24, 2019. [ADAMS Accession Number ML19302G424]
2. Ameren Missouri Letter ULNRC-06562, "Operating Quality Assurance Manual (OQAM) Interim Revision 34a," dated January 23, 2020. [ADAMS Accession Number ML20028E064]
3. NRC Letter with the subject Callaway Plant Unit No. 1 – Operating Quality Assurance Manual Change Revision 34A (EPID L-2020-LLQ-0000) dated June 8, 2020. [ADAMS Accession Number ML20141L745]
4. Final Safety Evaluation by the Office of Nuclear Reactor Regulation for Westinghouse Electric Company Topical Report, "Quality Management System (QMS)," Revision 8.0. (EPID L-2020-TOP-0022) [ADAMS Accession Number ML20132A321]
5. Office of Nuclear Reactor Regulation Minimal Revisions Review Topical Report Final Safety Evaluation for GE Hitachi Nuclear Energy Topical Report NEDO-11209A, "Quality Assurance Program Description (QAPD)." (EPID L-2020-TOP-0023) [ADAMS Accession Number ML20140A322]

Summary of proposed change:

Ameren Missouri is requesting a change to Callaway Plant's Operating Quality Assurance Manual (OQAM) to allow an extended grace period for vendor audit and survey expiration dates during extenuating circumstances such as national emergencies, pandemics, and other similar situations. Due to actions taken in response to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE), Ameren Missouri's existing 90-day grace period for completing triennial vendor audits/surveys will expire for some of its suppliers on August 31, 2020. The public health emergency has resulted in restrictions on domestic and international travel, limitations on access to vendor facilities by non-employees, and additional state and regional restrictions.

As the duration of the public health emergency is unknown, Ameren Missouri proposes to extend the present 90-day grace period to a 25% grace period for audits/surveys of vendors and suppliers. This would result in an overall extension of up to 9 months for the triennial audit/survey frequency during extenuating circumstances. This proposed change represents a similar approach to the 25% grace period endorsed by the NRC for non-licensees (References 4 and 5).

An evaluation of the proposed change against the criteria in 10 CFR 50.54(a)(3) concluded that the expanded grace period constitutes a reduction in commitment in accordance with 10 CFR 50.54(a)(4). Consequently, NRC approval is required.

Attachment 2 to this letter provides a markup of the affected pages of OQAM section 18 from OQAM Interim Revision 34a. It should be noted that Ameren Missouri's last periodic update submitted to the NRC was OQAM Revision 34, which was submitted in October 2019 (Reference 1). However, by Ameren Missouri letter ULNRC-06562, dated January 23, 2020 (Reference 2), a change affecting OQAM section 16 was submitted which involved a reduction in commitment. The change was approved by the NRC by letter dated June 8, 2020 (Reference 3), and therefore, OQAM Interim Revision 34a was issued internally to reflect that approved change.

Reason for the Change:

Ameren Missouri is proposing a change to the OQAM to allow a longer grace period for the performance of triennial vendor audits and surveys during defined extenuating circumstances. Actions put in place in response to the current COVID-19 PHE jeopardize the ability of Ameren Missouri to meet its Quality Assurance Program requirements along with the ability of Ameren Missouri's suppliers to meet their regulatory commitments associated with external audit/survey frequencies. As the duration of the current national emergency is unknown, Ameren Missouri proposes a further extension beyond the currently allowed 90-day grace period such that a 25% grace period would be allowed for audits/surveys. This would permit an overall extension of up to 9 months for audits/surveys with a triennial frequency.

Ameren Missouri considered the maturity of the industry and its supply chain oversight in requesting the allowance of a 25% extension for audits and surveys with a triennial frequency. Ameren Missouri also considered the potential risk significance of extending the audit/survey frequency by 25% and its potential effect on supplier performance against the continuing need to procure safety related parts and services. Ameren Missouri is applying the conditions stated below to provide reasonable assurance that the quality of items and services will continue to be maintained during the 25% grace period.

1) Ameren Missouri is requesting the triennial audit/survey interval extension of up to 25% only for extenuating circumstances that continue beyond 90 days past the original audit or survey expiration date.

2) This grace period is applicable for each audit/survey cycle.

3) During the 25% grace period, evaluations of supplier performance would be performed and documented.

4) When determining the next audit/survey period following use of the 25% grace period, the audit/survey "clock" would not need to be reset back to the original expiration date for the audit/survey just completed.

Consistent with current practice during periods of non-extenuating circumstances, Ameren Missouri will continue to meet the NRC expectation that audits/surveys be performed within the triennial timeframe. The current 90-day grace period will remain unchanged for conditions not meeting the extenuating circumstances threshold. Examples of conditions not meeting the extenuating circumstances threshold include but are not limited to: 1) staffing limitations impacting the timeliness of an audit/survey, and 2) scheduling conflicts by either Ameren Missouri, the supplier or the sub-tier supplier. When the 90-day extension expires, the remainder of the 25% grace period may be applied during extenuating circumstances only. The 90-day grace period cannot be applied after the 25% grace period ends.

Justification:

This OQAM change is necessary due to travel and facility access restrictions imposed in response to the COVID-19 public health emergency. Without approval of this OQAM change, suppliers would have to be removed from Callaway Plant's Qualified Suppliers List (QSL) within 90 days of the triennial audit/survey expiration date, which would adversely impact Ameren Missouri's ability to procure safety related items and services for Callaway Plant. The availability of these safety related parts supports the continued safe operation of the plant. In addition, this change provides the following benefits:

- This change will allow successive uses of a 25% grace period (such that the end date of an extended audit/survey - and not the triennial end date that otherwise would have applied without the extension - determines the start date of the next audit/survey period). This simplifies the tracking and management of the next audit/survey date.
- This change is applicable to Ameren Missouri's suppliers of basic components and suppliers approved via commercial grade surveys.
- This change will include boundaries for use of a 25% grace period and include a documented basis for the extension.

OQAM section 18 addresses the programmatic requirements associated with audits. Section 18.11 specifically addresses the triennial audit requirements for suppliers. This section currently specifies that a 90-day grace period may be applied to the triennial audit activity. The proposed change per OQAM CN 20-001 does not involve any changes to the current requirements or text in Section 18.11; however, Ameren Missouri proposes to insert a new section 18.11.1 to add provisions for an extended grace period for supplier audits and surveys.

The inserted section would contain an explicit allowance to extend the audit frequency by up to 25% (9 months) for triennial audits and surveys during extenuating circumstances. This paragraph would also provide examples of extenuating circumstances in order to guide the appropriate use of the allowance. This new section contains an explicit statement that the continued use of a supplier is allowed provided certain conditions are met. Those conditions include documenting an evaluation of the necessity of using the 25% allowance prior to exceeding the 90-day grace period specified in section 18.11. The elements of the documented evaluation would be proceduralized in implementing procedure GDP-ZZ-00003, "NOS Regulatory Required External Assessments."

The evaluation includes verification that 10 CFR 50 Appendix B suppliers remain committed to their 10 CFR 50 Appendix B quality assurance program, that commercial suppliers have maintained adequately documented program controls for activities affecting the critical characteristics of the items/services being procured, the status of any significant open issues with the NRC, 10 CFR Part 21 Notifications, and open findings since the previous triennial audit, review of the procurement history for issues pertaining to the items(s) procured, and the degree of standardization of the items procured. These considerations provide confidence in the suitability of the supplier and the supplied items during the additional audit frequency extension being applied.

The inserted section also specifies mitigating actions that may be taken should the evaluation identify concerns with the supplier or supplied items/services. The additional actions could include a range of activities, but the recommended minimum actions include enhanced receipt inspections and the imposition of additional requirements or restrictions on the supplier.

The inserted section stipulates that the next audit/survey performed must address the totality of the supplier's performance for the triennial period and any applied extension.

The inserted section makes clear that this allowance is only applicable to those suppliers that have been already evaluated and added to the Qualified Supplier List (QSL). Further, the inserted section makes clear that this allowance is applicable to both domestic and international suppliers. Lastly, the inserted section addresses the logistics for determining the start date and due date for subsequent audits of the supplier. These three provisions address implementation and logistical questions postulated for the extension provision.

Basis for continued compliance with the requirements of 10 CFR 50 Appendix B and 10 CFR 72 Subpart G:

Evaluation against 10 CFR 50 Appendix B

10 CFR 50 Appendix B, Criterion VII, *Control of Purchased Material, Equipment, and Services*, requires that measures shall be established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the

procurement documents. This criterion also requires that the effectiveness of the control of quality by contractor and subcontractors shall be assessed by the applicant or designee at internals consistent with the importance, complexity, and quantity of the product or services. Ameren Missouri complies with this quality standard through the performance of audits/surveys of suppliers as stipulated in OQAM Section 18.11. The provisions adopted through this OQAM change will provide needed flexibility during extenuating circumstances while compensating for the extended assessment frequency through performance of evaluations that preserve confidence in the continued ability of the supplier to provide parts/services in conformance with the quality requirements stipulated in the procurement documents.

10 CFR 50 Appendix B Criterion XVIII, *Audits*, requires a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated. Following this OQAM change, Ameren Missouri will remain in compliance with each of these requirements since the proposed change does not alter the current program or process for conducting audits. Consistent with this Appendix B criterion, the process and factors to be considered prior to applying the 25% extension will be specified in implementing procedure GDP-ZZ-00003, "NOS Regulatory Required External Assessments." Documented evaluations will be retained as a record consistent with current practices.

Evaluation against 10 CFR 72 Subpart G (Due to Callaway Plant OQAM Applicability to DCSS/ISFSI)

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 Plant OQAM. 10 CFR 72.154, *Control of purchased material, equipment, and services*, requires that measures shall be established to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. This criterion also requires that the effectiveness of the control of quality by contractor and subcontractors shall be assessed by the applicant or designee at internals consistent with the importance, complexity, and quantity of the product or services. Ameren Missouri complies with this quality standard through the performance of audits/surveys of suppliers as stipulated in OQAM Section 18.11. The provisions adopted through this OQAM change will provide needed flexibility during extenuating circumstances while compensating for the extended surveillance frequency through performance of evaluations that preserve confidence in the continued ability of the supplier to provide parts/services in conformance with the quality requirements stipulated in the purchase orders.

10 CFR 72.176, *Audits*, requires a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated. Following this OQAM change, Ameren Missouri will remain in compliance with each of these requirements since the proposed change does not alter the current program or process for conducting audits. Consistent with 10 CFR 72 Subpart G, the process and factors to be considered prior to applying the 25% extension will be specified in procedures. Documented evaluations will be retained as a record consistent with current practices.

Evaluation against Industry Precedent

This proposed change is similar to recent NRC approvals of changes to Quality Assurance topical reports for non-licensees. For example, the Final Safety Evaluation by the Office of Nuclear Reactor Regulation for Westinghouse Electric Company Topical Report, "Quality Management System (QMS)," Revision 8.0 (EPID L-2020-TOP-0022) [ADAMS Accession Number ML20132A321] (Reference 4) documents the acceptability of a Topical Report change that similarly adopted a 25% extension in the audit/survey interval that may be applied during exigent circumstances. The changes documented in the SER closely match those proposed by Ameren Missouri.

A second example involves Office of Nuclear Reactor Regulation Minimal Revisions Review Topical Report Final Safety Evaluation for GE Hitachi (GEH) Nuclear Energy Topical Report NEDO-11209A, "Quality Assurance Program Description (QAPD)," (EPID L-2020-TOP-0023) [ADAMS Accession Number ML20140A322] (Reference 5) which documents the adoption of a new section [18.5.2] to incorporate exigent condition requirements. While slight wording differences exist between the GEH QAPD and Ameren Missouri's proposal, the overall considerations required for the continued use of a supplier during the 25% extension are comparable.

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. Interim Revision 34a of the OQAM currently reflects the commitments in the program description as accepted by the NRC. The proposed change involves extending the grace period for the completion of supplier audits and surveys by 25% during extenuating circumstances. While the requirements to perform audits and surveys of

suppliers will still be satisfied, a 25% extension represents a duration longer than the currently allowed 90-day extension provided in OQAM section 18.11.

10 CFR 50.54(a)(i) through (vi) identify examples of changes that are not considered to be reductions in commitment. This change does not satisfy those criteria. This change does not involve the use of a quality assurance alternative or exception approved by an NRC safety evaluation issued to a licensee.

The proposed change does not 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 Plant'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.

Conclusion:

Based on the foregoing, this change is a reduction in commitment and prior NRC review and approval is required prior to implementation of the change. This change is compliant with 10 CFR 50 Appendix B and is acceptable with respect to the requirements of 10 CFR 72 Subpart G.

OQAM Section 18 Markup

The following presents the content of OQAM section 18, *Audits*. This text is reflected in OQAM Revision 34 which was previously provided via Reference 1 of Attachment 1. Interim Revision 34a (Reference 2) did not affect this OQAM section. The proposed changes are denoted using blue color and underlined text for new, inserted material. There is no deleted content or change to the existing text.

18 AUDITS

18.1 A comprehensive audit program shall be established and implemented by Ameren Missouri to verify internal and external quality activities' compliance with the OQAP. The audit program shall assure that all applicable elements of the Program have been developed, documented, and are being effectively implemented and shall provide for the reporting and review of audit results by management. The audit system is described in manuals and procedures. Nonconformances and program deficiencies shall be identified and corrective action shall be initiated and verified. See Section 3.14 for a specific audit topic.

18.2 The Ameren Missouri audit system shall include the performance of audits and surveillances by the Nuclear Oversight (NOS) Department. Audits determine, through investigation, the adequacy of and adherence to established procedures, instructions, specifications, codes, and other applicable contractual and licensing requirements and the effectiveness of implementation. Surveillances involve the periodic or continuous monitoring of the operation or performance of a supplier, item, component, or system. Surveillance in this audit sense should not be confused with inspections for the purpose of process control or product acceptance or with requirements relating to test, calibration or inspection to assure that the necessary quality of systems and components is maintained, that facility operations are within the safety limits, and that limiting conditions of operations are being met (surveillance tests). NOS personnel performing surveillances should be familiar with the area to be surveilled and the applicable implementing procedure(s) governing surveillances. Surveillances may also be performed by personnel from other organizations, but these require no unique personnel qualifications or certifications (except when performed for product acceptance). See Sections 10.6, 10.7, 10.8, 11.10, 11.11, 11.12, and 18.4.

18.3 The Director, Nuclear Oversight shall establish a program which provides for the qualification and training of NOS Department audit and surveillance personnel. Audits shall be directed by an Audit Team Leader (ATL) who is a certified Lead Auditor. A Lead Auditor is an individual certified as qualified to direct an audit, perform an audit, report audit findings, and to evaluate corrective action. Other personnel may assist Lead Auditors in the conduct of audits; namely, technical specialists, management representatives, auditors and other Lead Auditors. The persons having direct responsibility for performance of the activities being audited shall not be involved in the selection of the audit team. Personnel selected for NOS auditing or surveillance assignments shall have training or experience commensurate with the scope, complexity, or special nature of the activities to be reviewed or investigated and shall have no direct responsibility for the area being evaluated. The NOS personnel training program shall provide general orientation and specific training which develop competence for performing audits or surveillances. Training records shall provide a history of NOS personnel training, evaluations, qualification, certifications, and retraining.

18.4 NOS Department personnel who perform audit and surveillance activities shall be qualified in accordance with the requirements prescribed in NOS Department procedures. Lead Auditor qualification requirements shall include education or professional status, previous work experience or training, training received through Ameren Missouri, on-the-job performance and participation in surveillances or audits as an auditor, a qualification examination, and other factors applicable to auditing not defined by procedure. The qualification certification of Lead Auditors shall be based on an evaluation of these factors by the Director, Nuclear Oversight. The maintenance of proficiency by Lead Auditors shall be accomplished by active participation in the audit process; a review of program, codes, standards, procedures and other document revisions related to the OQAP; or participation in training programs. The Director, Nuclear Oversight shall provide for annual assessments of each Lead Auditor to determine proficiency. As long as a Lead Auditor is performing satisfactorily and is maintaining proficiency, there is no limit on the period of certification. However if at any time the Lead Auditor's performance is evaluated as being unacceptable, Lead Auditor certification shall be rescinded. In addition the failure to maintain proficiency for a period of two years or more shall be basis for Lead Auditor certification revocation. If certification is rescinded or revoked, requalification shall be required prior to recertification.

18.5 The Director, Nuclear Oversight shall be responsible for assuring the implementation of a comprehensive system of planned audits to verify compliance with the OQAP. The Director, Nuclear Oversight has sufficient authority and organizational freedom to schedule and perform both internal and external audits. This individual has the organizational responsibility to measure and assure the overall effectiveness of the OQAP and is independent of the economic pressures of production when opposed to safety or quality. The Director, Nuclear Oversight has direct access to the Senior Vice President and Chief Nuclear Officer.

18.6 The audit system shall include internal and external audits. The system shall be planned, documented, and conducted to assure coverage of the applicable elements of the OQAP, and overall coordination and scheduling of audit activities. Audit results shall be periodically reviewed by the NOS Department for quality trends and results reported to the appropriate management. The Director, Nuclear Oversight shall monitor the OQAP audit program to assure audits are being accomplished in accordance with the requirements described herein and for overall Program effectiveness. The Director, Nuclear Oversight shall ensure an independent review of the onsite audit program is conducted periodically, to assure that audits are being performed in accordance with the OQAP. Appropriate levels of management shall be provided copies of internal and external audit reports.

18.7 Internal audits shall be conducted by the NOS Department and shall be performed with a frequency commensurate with their safety significance. An audit of safety-related functions shall be completed in accordance with formal audit schedules within a period of two (2) years. A grace period of 90 days may be applied to performance of internal audits provided the two (2) year frequency for the following audit performance is not set forward. Each element of the OQAP, such as design control and document control, and each area of Plant operations shall be audited.

18.8 Supplementary to the biennial requirements to audit safety-related functions:

- Audits of Unit activities (listed below) SHALL be conducted on a performance based frequency by the NOS Department, not to exceed 24 months *
  a) The conformance of Unit operation to provisions contained within the Technical Specifications and applicable license conditions;
  b) The performance, training and qualifications of the entire Unit staff;
  c) The results of actions taken to correct deficiencies occurring in Unit equipment, structures, systems or method of operation that affect nuclear safety;
  d) The performance of activities required by the Operational Quality Assurance Program to meet the criteria of Appendix B, 10 CFR Part 50,
  e) The Radiological Environmental Monitoring Program and the results thereof;
  f) The OFFSITE DOSE CALCULATION MANUAL and implementing procedures;
  g) The PROCESS CONTROL PROGRAM and implementing procedures for processing and packaging of radioactive wastes;
  h) The performance of activities required by the Quality Assurance Program for effluent and environmental monitoring; and
  i) Any other area of Unit operation considered appropriate by the Senior Vice President and Chief Nuclear Officer.

* A grace period of 90 days may be applied to the 24 month frequency for internal audits, provided the 24 month frequency for the following audit performance is not set forward.

18.8.1 The following areas shall be reviewed or audited per the frequency specified in applicable regulations:

⇒ Radiological Protection program
⇒ Security program
⇒ Access Authorization
⇒ Fitness-For-Duty program
⇒ Radiological Emergency Response Plan

18.8.2 In addition to the audits conducted under 18.8.a) – i) and 18.8.1, a triennial Fire Protection Program audit shall be conducted with an audit scope that includes the following:

a) FP Program as defined in FSAR SP, Section 9.5.1;
b) Fire Protection Quality Assurance Program (FSAR-SP, Section 9.5.1.6.2);
c) NFPA 805 Fire Protection Monitoring Program (FSAR-SP, Section 9.5.1.4.2);
d) This triennial audit utilizes a qualified outside independent Fire Protection Consultant (non-Ameren).

18.9 During Plant modifications or other major unique activities, audits shall be scheduled as required to assure that Quality Assurance Program requirements are properly implemented.

18.10 External audits shall be conducted by or for the NOS Department as a method for the evaluation of procurement sources and as a post-award source verification of conformance to procurement documents. Audits conducted by other organizations (with similar orders with the same supplier), including other utilities or A/E's, may be employed as a means of post-award source verification in lieu of Ameren Missouri performed audits and may not necessarily audit specific items furnished to Ameren Missouri. These audits and surveillances shall utilize personnel qualified in accordance with this OQAM and shall be conducted in accordance with this OQAM and NOS Department procedures. Commercial grade items do not require pre-or post-award audits. Similarly, items which are relatively simple and standard in design and manufacture may not require supplier qualification or post-award audits to assure their quality.

18.10.1 When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys need not be performed provided all of the following conditions are met:

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
   a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005 or ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
   b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
   c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
2. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
   a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 or ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
   b. The purchase order's requirements are met.

18.11 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 supplier 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 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.

18.11.1 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 audit 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 quantity checks.
- Identification of any additional requirements/restrictions to be placed on the supplier.

c. For audits/surveys performed during the25% 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.

18.12 Supplementary to audits, annual evaluations of suppliers shall be performed which take into account, as applicable: 1) the review of supplier furnished documents such as certificates of conformance, nonconformance notices, and corrective actions; 2) results of previous source verifications, audits, and receiving inspections; 3) operating experience of identical or similar products furnished by the same supplier; 4) results of audits from other sources, and 5) for providers of commercial-grade calibration and testing services, continued maintenance of laboratory accreditation for the specific services supplied to CEC. A 90 day grace period may be applied to this activity.

18.13 Audits shall also be conducted when: 1) significant changes are made in functional areas of the Quality Assurance Program such as significant reorganization or procedure revisions; or 2) when it is suspected that the quality of the item is in jeopardy due to deficiencies in the Quality Assurance Program; or 3) when a systematic, independent assessment of Program effectiveness is considered necessary; or 4) when it is necessary to verify implementation of required corrective action.

18.14 Audits shall be conducted using written plans in accordance with NOS Department procedures. The procedures require evaluation of work areas, activities, processes, goods, services, and the review of documents and records for quality-related practices, procedures, and instructions to determine the effectiveness of the implementation of the OQAP and compliance with 10 CFR 50, Appendix B. The audit plan shall identify the audit scope, the requirements, the activities to be audited, organizations to be notified, the applicable documents, the schedule, and the written procedures or checklists as appropriate. The audit plan and any necessary reference documents shall be available to the audit team members.

18.15 An audit team consists of one or more auditors. A Lead Auditor shall be appointed Audit Team Leader. The Audit Team Leader shall be responsible for the written plans, checklists, team orientation, audit notification, pre-audit conference, audit performance, post-audit conference, reporting, records, and follow-up activity to assure corrective action.

The audited organization should be informed of adverse findings. Agreement or disagreement with a finding may be expressed in the response from the audited organization. (refer to Appendix A, Subsection 4.3.2.5 of ANSI N45.2.12)

Any adverse findings shall be reported in a post-audit conference with team members and the audited organization, unless the post-audit conference is waived by the management of the audited organization. (refer to Appendix A, Section 4.3.3 of ANSI N45.2.12)

18.15.1 Formal audit reports shall be prepared and submitted within 30 days after the post-audit conference (or last day of the audit, whichever is later) to:

- the audited organization for internal audits conducted in accordance with the Sections described herein, and
- specifically, the Senior Vice President and Chief Nuclear Officer for audits conducted in accordance with Section 18.8.

OQAM Appendix A Markup

The following presents the content of OQAM Appendix A. This text is reflected in OQAM Revision 34 which was previously provided via Reference 1 of Attachment 1. Interim Revision 34a (Reference 2) did not affect this OQAM section. The proposed changes are denoted using blue color and underlined text for new, inserted material. No content was deleted, and no existing text was revised.

Appendix A provides a compilation of how the CEC Operating Quality Assurance Program (OQAP) conforms to the NRC Regulatory Guides to which the program is committed. This Appendix provides clarifications, captures exceptions, and lists ANSI standards to which the program is committed. This change to Appendix A is a conforming change that affects a portion of the description regarding compliance with Regulatory Guide 1.144, *Auditing of Quality Assurance Programs for Nuclear Power Plants*, Revision 1 dated September 1980.

The proposed OQAM provision to allow a 25% extension for triennial audits or surveys during extenuating circumstances is an exception to the provisions of Regulatory Guide 1.144, Section C.3.b.(2) and, as such, would be identified in Appendix A.

REGULATORY GUIDE 1.144 **REVISION 1** **DATED 9/80**

Auditing of Quality Assurance Programs for Nuclear Power Plants (Endorses ANSI N45.2.12-1977)

DISCUSSION:

Ameren Missouri complies with the recommendations of this Regulatory Guide with the following clarifications:

With regard to Section C.3.b(2) of Regulatory Guide 1.144, the requirements of the section are accepted with the following interpretation:

Supplier Audits – SectionC.3.b.(2) of Reg. Guide 1.144, Revision 1 states that audits be performed on a "triennial basis". The 90-day grace period may be applied to this activity. 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 audit 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 quantity 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.

Supplier Evaluation – Section C.3.b.(2) of Reg. Guide 1.144, Revision 1 states that documented evaluations be performed "annually". The 90 day grace period may be applied to this activity.

"When procuring commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), the accreditation process and accrediting body may be credited with carrying out a portion of the Purchaser's duties of verifying acceptability and effective implementation of the calibration or testing service laboratory's quality assurance program.

In lieu of performing commercial grade survey or accepting a commercial grade survey performed by another licensee, a documented review of the laboratory's accreditation is performed which includes a verification of the following:

1. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005 or ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
2. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
3. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

Also, annual evaluations of commercial-grade calibration service suppliers shall verify continued maintenance of laboratory accreditation."

With regard to Section 1.4 of ANSI N45.2.12 - 1977 titled Definitions: With one exception (Program Deficiencies) the definitions in this Standard which are not included in Regulatory Guide 1.74 (ANSI N45.2.10) shall be used; definitions which are included in ANSI N45.2.10 shall be used as clarified in Ameren Missouri's commitment to Regulatory Guide 1.74. The one excepted definition and a clarified definition (of audit) relevant to this Standard are defined in this Appendix under Regulatory Guide 1.74.

With regard to Section 2.1 of ANSI N45.2.12-1977 titled General: Identical or equivalent controls are provided in this OQAM, Section 18.3 regarding the second paragraph discussing audit team selection.

With regard to Section 2.2 of ANSI N45.2.12 - 1977 titled Personnel Qualification: The qualification of Ameren Missouri audit personnel shall be accomplished as described to meet the requirements of Regulatory Guide 1.146 (ANSI N45.2.23 - 1978) as endorsed in this Appendix and OQAM Section 18.

With regard to Section 2.3 (and subsections 2.3.1 through 2.3.3) of ANSI N45.2.12 - 1977 titled Training: The training of Ameren Missouri audit personnel shall be accomplished as described to meet the requirements of Regulatory Guide 1.146 (ANSI N45.2.23 - 1978) as endorsed in this Appendix and OQAM Section 18.

With regard to Section 2.4 of ANSI N45.2.12 - 1977 titled Maintenance of Proficiency: The maintenance of proficiency of Ameren Missouri audit personnel shall be accomplished as described to meet the requirements of Regulatory Guide 1.146 (ANSI N45.2.23 - 1978) as endorsed in this Appendix and OQAM Section 18.

With regard to Section 3.3 of ANSI N45.2.12 - 1977 titled Essential Elements of the Audit System: Ameren Missouri shall comply with subsection 3.3.5 as it was originally written (subsection 3.2.5) in ANSI N45.2.12, Draft 3, Revision 4: "Provisions for reporting on the effectiveness of the Quality Assurance Program to the responsible management." For the auditing organization (Ameren Missouri), effectiveness shall be reported as required by OQAM Section 18. Other than audit reports, Ameren Missouri may not directly report on the effectiveness of the quality assurance programs to the audited organization when such organizations are outside of Ameren Missouri.

Subsection 3.3.6 requirements are considered to be fulfilled by compliance with the organization and reporting measures outlined in this OQAM. In every case either identical or equivalent controls are provided in the sections of the referenced documents.

Subsection 3.3.7 requires verification of effective corrective action on a timely basis.

Verification of the implementation of corrective action is performed as indicated in Section 16 of this OQAM. Corrective action program effectiveness is determined through audit or surveillance as described in Section 18 of this OQAM, using previously issued corrective action documents as input to the scope of audits and surveillances. Additionally, trending of corrective action documents will be used to reveal potentially ineffective corrective actions and the effectiveness of the corrective action program.

With regard to Section 3.4 of ANSI N45.2.12-1977 titled Audit Planning: Identical or equivalent controls are provided in this OQAM, Section 18.

With regard to Section 3.5 of ANSI N45.2.12 - 1977 titled Scheduling: Identical or equivalent controls are provided in this OQAM, Section 18 for the requirements of Subsections 3.5.1 and 3.5.2. Subsection 3.5.3.1 is interpreted to mean that Ameren Missouri may procedurally control qualification of a contractor's or supplier's quality assurance

program prior to awarding a contract or purchase order by means other than audit. The measures outlined in Sections 4 and 7 of this OQAM address the requirements of Subsection 3.5.3.1.

With regard to Section 4.3.1 of ANSI N45.2.12 - 1977 titled Pre-Audit Conference: Ameren Missouri shall comply with requirements of this Section by inserting the word "Normally" at the beginning of the first sentence. This clarification is required because, in the case of certain unannounced audits or audits of a particular operation or work activity, a pre-audit conference might interfere with the spontaneity of the operation or activity being audited. In other cases, persons who should be present at a pre-audit conference may not always be available: such lack of availability should not be an impediment to beginning an audit. Even in the above examples, which are not intended to be all inclusive, the material set forth in Section 4.3.1 shall normally be covered during the course of the audit.

With regard to Section 4.3.2 of ANSI N45.2.12 - 1977 titled Audit Process:

(a) Subsection 4.3.2.2 could be interpreted to limit auditors to the review of only objective evidence; sometimes and for some Program elements, no objective evidence may be available. Ameren Missouri shall comply with an alternate sentence which reads: "When available, objective evidence shall be examined for compliance with Quality Assurance Program requirements. If subjective evidence is used (e.g. personal interviews, direct observations by the auditor), then the audit report must indicate how the evidence was obtained."

(b) Subsection 4.3.2.4 is modified as follows to take into account the fact that some nonconformances are virtually "obvious" with respect to the needed corrective action: "When a nonconformance or Quality Assurance Program deficiency is identified as a result of an audit, unless the apparent cause, extent, and corrective action are readily evident, further investigation shall be conducted by the audited organization in an effort to identify the cause and effect and to determine the extent of the corrective action required."

(c) Subsection 4.3.2.5 contains a recommendation which is clarified with the definition of "acknowledged by a member of the audited organization" to mean that "a member of the audited organization has been informed of the findings." Agreement or disagreement with a finding may be expressed in the response from the audited organization.

(d) Subsection 4.3.2.6 is modified as follows to account for the fact that immediate notification is not always possible: "Conditions requiring immediate corrective action (i.e. those which are so severe that any delay would be undesirable) shall be reported immediately to the audited organization and as soon as practical to the management thereof."

With regard to Section 4.3.3 of ANSI N45.2.12 - 1977 titled Post-Audit Conference: Ameren Missouri shall substitute and comply with the following paragraph:

> "For external audits, a post-audit conference shall be held with management of the audited organization to present audit findings and clarify misunderstandings; where no adverse findings exist, this conference may be waived by management of the audited organization: such waiver shall be documented in the audit report. Unless unusual operating or maintenance conditions preclude attendance by appropriate managers/supervisors, a post-audit conference shall be held with managers/supervisors for internal audits for the same reasons as above. Again, if there are no adverse findings, management of the internal audited organization may waive the post-audit conference: such waiver shall be documented in the audit report."

With regard to Section 4.4 of ANSI N45.2.12 - 1977 titled Reporting:

(a) This Section requires that the audit report shall be signed by the Audit Team Leader (ATL); this is not always the most expeditious route to take to assure that the audit report is issued as soon as practical. Ameren Missouri shall comply with Section 4.4 as clarified in the following opening:

> "An audit report, which shall be signed by the Audit Team Leader (ATL), or the ATL's supervisor in the ATL's absence, shall provide: . . ."

In cases where the audit report is not signed by the ATL due to absence, one record copy of the report must be signed by the ATL upon return. The report shall not require the ATL's review/concurrence/signature if the ATL is no longer employed by Ameren Missouri at the time the audit report is issued.

(b) Ameren Missouri shall comply with subsection 4.4.3 clarified to read: "Supervisory level personnel with whom significant discussions were held during the course of pre-audit (where conducted) audit, and post-audit (where conducted) activities."

(c) Audit reports may not necessarily contain an evaluation statement regarding the effectiveness of the Quality Assurance Program elements which were audited, as required by subsection 4.4.4, but they shall provide a summary of the audited areas and the results which identify the importance of any adverse findings.

With regard to Section 4.5.1 of ANSI N45.2.12 - 1977 titled By Audited Organization: Ameren Missouri shall comply with the following clarification of the Section: Management of the audited organization or activity shall review and investigate adverse audit findings, as necessary, (e.g., where the cause is not already known, another organization has not already investigated and found the cause, etc.) to determine and schedule appropriate remedial action. The audited organization shall assure documentation of remedial action taken is provided. Adverse audit findings shall be evaluated to determine the need for action to prevent recurrence. If such action is deemed necessary, the results of the investigation (root cause analysis), the corrective action taken or planned to prevent recurrence, and a schedule for implementation shall be provided by the audited organization. Such evaluations and implementation of actions shall be scheduled and performed consistent with the safety significance of the item. The audited organization shall take appropriate action to assure corrective action is accomplished as scheduled. In the event the action or schedule of implementation must be changed, the audited organization shall provide a revised response on or before the originally scheduled completion date which statuses the corrective action and states its completion date. Evaluation progress and corrective action implementation will be performed and tracked in accordance with provisions of Section 16 of the Ameren Missouri Operating Quality Assurance Manual.

With regard to Section 4.5.2 of ANSI N45.2.12-1977 titled By Auditing Organization: Ameren Missouri shall comply with the following clarification of the section: For internal audits, performed by or for the Nuclear Oversight Department, follow-up actions will be taken by the audited organization as described in Section 16 of this OQAM. The internal audit program implemented in Section 18 of this OQAM provides assurance that the corrective action program requirements are properly implemented. By sampling responses to conditions adverse to quality, the adequacy of root cause analysis, implementation of remedial action, and action to prevent recurrence are verified to assure effective corrective action program implementation. Therefore, the auditing organization will not necessarily evaluate the adequacy and assure action is identified and accomplished for each adverse finding. External audits shall comply with section 4.5.2 of ANSI N45.2.12-1977.