Attachment 2 to
ULNRC-06777

**OQAM INTERIM REVISION 35a MARK-UP,
IDENTIFYING CHANGES THROUGH THE USE OF STRIKEOVERS AND INSERTS**

This attachment provides the Callaway Energy Center (CEC) Operating Quality Assurance Manual (OQAM) Interim Revision 35a which reflects the incorporated OQAM Change Notices through the use of strikeovers and inserts.

This Attachment includes 53 pages.

Ameren
MISSOURI

CALLAWAY ENERGY CENTER

OPERATING QUALITY ASSURANCE MANUAL

(OQAM)

Rev. 035a

File Code A210.0012

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1. ORGANIZATION

1.1 Ameren Missouri has established an organization for Quality Assurance activities. This Section identifies the organizational structure; management positions and responsibilities; and delegation of authority for the development, implementation and maintenance of the Operating Quality Assurance Program (OQAP). Ameren Missouri shall retain responsibility for the establishment and execution of the OQAP, although certain Program activities may be delegated to others. The organization responsible for implementing appropriate portions of the OQAP is shown in Chapter 13 of the FSAR. The Callaway Energy Center (CEC)[3] operating organization is also shown in Chapter 13 of the FSAR.

1.2 The Senior Vice President and Chief Nuclear Officer is responsible for initiating the Quality Assurance Program, formulating the policy, and authorizing and assuring Program implementation. This individual is responsible for directing activities within Nuclear Generation[4] which support the engineering, construction, testing, and operation of the CEC and coordinating support activities performed by others who are not under their direct administrative control. This individual has corporate responsibility for the operation and physical control of the CEC. This individual reports to the President and Chief Executive Officer – Ameren Missouri, who in turn reports to the Chairman and Chief Executive Officer. The Chairman and Chief Executive Officer has ultimate responsibility for the CEC.

1.2.1 The Senior Vice President and Chief Nuclear Officer is responsible for the activities of all Nuclear Generation departments. This responsibility includes:

- assuring a high level of quality is achieved in Plant operations and support activities,
- the execution of the administrative controls and quality assurance program,
- the safe, legal and efficient operation and maintenance of the Plant,
- protecting the health and safety of the public and Plant personnel

1.2.2 The Senior Vice President and Chief Nuclear Officer is responsible for ensuring an independent review of matters involving safe operation of the plant is conducted at least once ~~per twelve months~~ each calendar year. The review addresses matters that management determines warrant special attention, such as plant programs, performance trends, employee concerns, or other matters related to safe plant operations. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent (from cost and schedule considerations) from the organizations responsible for those activities. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence. Results are documented and reported to the Senior Vice President and Chief Nuclear Officer.

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[2] Not used.

[3] Ameren Missouri now refers to Callaway Plant Unit 1 [e.g. the name on the licensing Docket] as the Callaway Energy Center (CEC). Callaway Plant is used where the Operating License, Technical Specifications, or other license basis document is specifically referenced.

[4] Organization titles "Nuclear Division," "Nuclear Function," "Nuclear Business Line" and "Nuclear Segment" used in written instructions are equivalent to the generic title "Nuclear Generation" used in the FSAR and this OQAM.

1.3 The ~~Director~~ Manager, Nuclear Oversight (NOS)[5] reports to the Senior Vice President and Chief Nuclear Officer (CNO) on Quality Assurance Program and administrative matters. The ~~Director~~ Manager, Nuclear Oversight has direct access to the Senior Vice President and CNO on significant Nuclear Oversight matters. The ~~Director~~ Manager, Nuclear Oversight is responsible to the Senior Vice President and Chief Nuclear Officer for assuring the OQAP is being effectively implemented for operating activities; directing the overall Quality Assurance Program for Ameren Missouri including Program development, maintenance, and verification of implementation; and providing a constant independent overview of nuclear plant safety. The ~~Director~~ Manager, Nuclear Oversight has sufficient authority, organizational freedom, and independence to effectively assure compliance with OQAP requirements as they control CEC and offsite quality activities; and shall bear no cost, schedule, or production responsibilities which unduly influence attention to quality matters. A communication path shall exist between the ~~Director~~ Manager, Nuclear Oversight, Supervisors, NOS, and the Senior Vice President and Chief Nuclear Officer, as well as the other Nuclear Generation management, thus providing a direct path to inform management regarding conditions affecting quality and nuclear plant safety. The qualifications of the ~~Director~~ Manager, Nuclear Oversight are at least equivalent to those specified in ANSI/ANS-3.1-1978, "Selection, Qualification, and Training of Nuclear Power Plant Personnel," Sections 4.2.4 and 4.4.5. The ~~Director~~ Manager, Nuclear Oversight is located at CEC and provides technical direction and administrative guidance, to the Nuclear Oversight staff.

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1.3.1 The ~~Director~~ Manager, NOS directs Supervisors NOS, and Supervisor QC, who have primary duties for assuring implementation of the OQAP and who devote full attention to this effort. They provide for maintenance of the Operating Quality Assurance Manual (OQAM); for audit, surveillance, and evaluation of nuclear supplier quality activities; and for performing those procurement document reviews assigned to their personnel. The activities of the NOS staff assure implementation of the OQAP. The ~~Director~~ Manager, Nuclear Oversight is responsible to evaluate CEC operations from a safety perspective.

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1.3.2 The Quality Control Group reports to the ~~Director~~ Manager, NOS. They are responsible for work activities such as the preparation of inspection procedures and/or checklists to support maintenance and modification activities as described in Section 6, work activity inspections as described in Section 10, receipt inspections as described in Section 7~~.0~~, and non-destructive examinations as directed by Engineering.

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1.3.3 The ~~Director~~ Manager, Supervisor QC and Supervisors in the Nuclear Oversight Department are authorized by the Senior Vice President and Chief Nuclear Officer to stop work on ongoing quality activities in accordance with approved procedures. During the operating phase they have the authority to stop unsatisfactory work during repair, maintenance, and refueling activities and the authority to recommend to the Senior Director, Nuclear Operations stop work affecting the continuation of Plant operation. Other stop work authority shall be delineated in procedures. The continuance of an activity which would cover up a deficiency and preclude identification and correction, or increase the extent of the deficiency is subject to stop work action by the Nuclear Oversight Department. The ~~Director~~ Manager, Nuclear Oversight has no duties or responsibilities unrelated to NOS that would prevent full attention to NOS matters.

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[5] Organizational title "Quality Assurance" used in written instruction is equivalent to the title "Nuclear Oversight" as used in the FSAR and this OQAM.

1.4 The authorities and duties of persons and organizations performing quality assurance functions shall be clearly established. Such persons have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to evaluate corrective action. Assurance of quality by checking, auditing, inspecting, or otherwise verifying Program activities shall be by personnel other than the individual or group performing the specific activity.

1.5 Other Ameren Services or Ameren Missouri divisions may provide safety-related services which augment and support selected Program activities. These organizations shall be required to implement controls consistent with the OQAP requirements applicable to their scope of activities. The coordination of these activities is the responsibility of the Senior Vice President and Chief Nuclear Officer.

1.6 The Onsite Review Committee (ORC) and NOS shall provide independent review of those items required below.

1.7 The ORC shall function to advise the Senior Director, Nuclear Operations on all matters related to nuclear safety. The Senior Director, Nuclear Operations shall be Chairman of the ORC.

1.7.1 ORC membership shall include a minimum of six additional members appointed by the Chairman. Selected members shall include, at a minimum, management responsible for the following areas of expertise and who collectively possess competence in Quality Assurance Practices:

a) Operations
b) Maintenance
c) Chemistry
d) Radwaste
e) ~~Health Physics~~ Radiation Protection
e) Nuclear Engineering

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1.7.2 All alternate members shall be appointed in writing by the ORC Chairman to serve on a temporary basis.

1.7.3 The ORC shall meet at least once per calendar month and as convened by the ORC Chairman or designated alternate.

1.7.4 The quorum of the ORC necessary for the performance of the ORC responsibility and authority provisions shall consist of the Chairman or designated alternate and four members of which no more than two shall be alternates.

1.7.5 The ORC shall maintain written minutes of each ORC meeting that, at a minimum, document the results of all ORC activities. Copies shall be provided to the Senior Vice President and Chief Nuclear Officer.

1.7.6 The ORC shall be responsible for:

a) Deleted.

b) Review of 10 CFR 50.59 and 10 CFR 72.48 evaluations[6] regarding:

- procedures,
- changes to procedures, equipment, systems or facilities, and
- tests or experiments completed under the provision of 10 CFR 50.59 and 10 CFR 72.48 to verify that such actions did not require prior NRC approval.

c) Review of proposed procedures and changes to procedures, equipment, systems or facilities which may involve prior NRC approval as defined in 10 CFR 50.59 and 10 CFR 72.48[6];

d) Review of proposed test or experiments which may involve prior NRC approval as defined in 10 CFR 50.59 and 10 CFR 72.48[6];

e) Review of proposed changes to Technical Specifications or Operating License;

f) Investigation of all violations of the Technical Specifications including the forwarding of reports covering evaluation and recommendations to prevent recurrence to the Senior Vice President and Chief Nuclear Officer.

g) Review of report of operating abnormalities, deviations from expected performance of plant equipment and of unanticipated deficiencies in the design or operation of structures, systems or components that affect nuclear safety;

h) Review of all REPORTABLE EVENTS;

i) Review of the plant Security Plan;

j) Review of the Radiological Emergency Response Plan;

k) Review of changes to the PROCESS CONTROL PROGRAM, the OFFSITE DOSE CALCULATION MANUAL, and Radwaste Treatment Systems;

l) Review of any accidental, unplanned or uncontrolled radioactive release including the preparation of reports covering evaluation, recommendations, and disposition of the corrective action to prevent recurrence and the forwarding of these reports to the Senior Director, Nuclear Operations.

m) Review of Unit operations to detect potential hazards to nuclear safety;

n) Investigations or analysis of special subjects as requested by the Senior Vice President and Chief Nuclear Officer.

o) Review of Unit Turbine Overspeed Protection Reliability Program and revisions thereto;

p) Review of the Fire Protection Program.

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[6] Consistent with 10 CFR 72.210 and the requirements of 10 CFR 72.212(b)(5) through (b)(8), 10 CFR 72.48 evaluations performed by the CoC holder under their quality program do not require ORC review.

1.7.7 The ORC shall:

a) Deleted.

b) Recommend in writing to the Senior Director, Nuclear Operations approval or disapproval of documents, and changes thereto, considered under Section 1.7.6.e), 1 .7.6.i), 1.7.6.j), 1.7.6.k), 1.7.6.l), 1.7.6.o), and 1.7.6.p) above.

c) Render determinations in writing with regard to whether or not each item considered under Sections 1.7.6.b) through 1.7.6.e), and 1.7.6.m), above, require a license amendment per 10 CFR 50.59 or an NRC Certificate of Compliance (CoC) Amendment per 10 CFR 72.48; and

d) Provide written notification within 24 hours to the Senior Vice President and Chief Nuclear Officer of disagreement between ORC and the Senior Director, Nuclear Operations; however, the Senior Director, Nuclear Operations shall have responsibility for resolution of such disagreements.

e) Each REPORTABLE EVENT shall be reviewed by the ORC and submitted to the Senior Vice President and Chief Nuclear Officer.

2. QUALITY ASSURANCE PROGRAM

2.1 Ameren Missouri has established an OQAP which controls activities affecting quality. The Program encompasses those quality activities necessary to support the operating phase of the CEC and shall comply with 10 CFR 50, Appendix B - "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" as described herein and with the Regulatory Position of Regulatory Guide 1.33. This Manual also complies with requirements of 10 CFR 72, Subpart G "Quality Assurance", as applicable to the scope of work being performed and described in Appendix B of this OQAM. Commitments, clarifications, alternatives, and exceptions to the Regulatory Position of Regulatory Guide 1.33 are stated in Appendix A of this OQAM. In addition, the OQAP has incorporated the commitments made in responding to applicable NRC questions. The text of the NRC questions applicable to the OQAP, along with the responses, are maintained as a QA Record separate from the OQAM. The Senior Vice President and Chief Nuclear Officer has reviewed the Program and formulated the policy in addition to authorizing Program implementation. This responsibility has been established by the Chairman and Chief Executive Officer of Ameren Missouri for establishing and implementing the Quality Assurance Program requirements.

2.2 Lines of authority and responsibility have been established from the Chairman and Chief Executive Officer to the Senior Vice President and Chief Nuclear Officer and the onsite operating organization. These relationships shall be documented and updated, as appropriate, in the form of organization charts, functional descriptions of departmental responsibilities, and job descriptions for key personnel having direct operating, support or audit responsibility. Where specific responsibilities are assigned within the OQAP, the prescribed individual shall retain the overall responsibility; however, subject to applicable regulatory constraints, authority may be delegated to subordinates. Considering these same regulatory constraints, the authority of a subordinate may always be assumed by a superior.

2.3 Updating and revision of the OQAP as described in this OQAM shall be in accordance with the applicable requirements of 10 CFR 50.54 (a), 10 CFR 50.71 and 10 CFR 72.

2.4 The pertinent requirements of the OQAP apply to all activities affecting the safety-related functions of those structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The safety-related structures, systems and components identified in Table 3.2-1 of the Callaway-SP Final Safety Analysis Report (FSAR). This list includes structures, systems, and components identified during the design and construction phase and may be modified as required during operations consistent with their importance to safety. Modifications to this list require the approval of the ~~Director~~ Manager, Nuclear Oversight and the Director, Engineering Design & Projects and shall be issued and controlled in accordance with Section 6. The development, control, and use of computer programs to be used in safety-related activities are within the scope of the OQAP. The degree of controls applicable to each computer program shall be consistent with the program's importance to safety-related activities. Consumables which could affect the form, fit or function of safety-related structures, systems, and components, although not listed in Table 3.2-1 of the Callaway-SP FSAR, are also under the control of the OQAP.

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2.5 The OQAP shall be implemented throughout the operating life of the CEC. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

2.6 Consistent with the schedule for accomplishing quality activities, the OQAP shall be established and documented by written policy, program manual, and procedure manuals. Persons conducting safety- related activities shall be responsible to implement approved procedures. The OQAP shall utilize the following document types to describe Program objectives:

1) Operating Quality Assurance Program Policy/ Introduction Statement

The Operating Quality Assurance Program Policy statement establishes governing principles in accordance with the requirements of 10 CFR 50, Appendix B and 10 CFR 72, Subpart G.

The Operating Quality Assurance Program Policy statement and any revisions thereto shall be approved by the Senior Vice President and Chief Nuclear Officer.

2) Operating Quality Assurance Manual (OQAM)

The OQAM contains a delineation of the Policy statement, quality assurance requirements, assignment of responsibilities, and a definition of organizational interfaces. The OQAM is the written description of the OQAP. Approval of the OQAM is by the Senior Vice President and Chief Nuclear Officer and the ~~Director~~ Manager, Nuclear Oversight.

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3) CEC Operating Procedures

The CEC Operating Procedures consist of a multi-volume set of Plant operating procedures prepared or reviewed by the staff with the aid of other SNUPPS utilities, Nuclear Engineering, the Lead A/E, the NSSS Supplier, and Fuel Fabricator. These procedures are controlled, reviewed, approved, and issued in accordance with Administrative Procedures which implement the requirements of the Technical Specifications and this OQAM. These Operating Procedures include administrative controls consistent with those required by Regulatory Guide 1.33.

The final approval of the PROCESS CONTROL PROGRAM and the OFFSITE DOSE CALCULATION MANUAL, and revisions thereto shall be by the Senior Director, Nuclear Operations. The final approval of other Administrative Procedures and revisions thereto shall be by the Senior Director Nuclear Operations.

4) Other Instructions

The review and approval of policies, manuals, work authorizing documents and revisions thereto shall be in accordance with approved Administrative Procedures.

2.7 Ameren Missouri may employ the safety-related services of architect engineers, NSSS suppliers, fuel fabricators, constructors, and others, which provide or augment Ameren Missouri efforts during the operating phase. These organizations shall be required to work under a quality assurance program whose controls are consistent with the scope of their effort. This does not preclude any organization from working under the Ameren Missouri OQAP. The quality assurance program of outside organizations shall be subject to review, evaluation and acceptance by the Nuclear Oversight Department prior to the initiation of safety-related work. Vendor programs and procedures shall also meet Ameren Missouri's commitment to USNRC Generic Letter 83-28.

2.8 Disputes which may arise between NOS or QC personnel and personnel in other Ameren organizations which cannot be resolved shall be referred to the next higher level of management for resolution. Disputes which cannot be resolved through these levels shall be resolved ultimately by the Chief Executive Officer.

2.9 Preservice (PSI) and Inservice (ISI) inspection, testing, and examination activities may be performed by outside organizations. These inspections and other operating phase "code" activities shall comply with the requirements of the applicable Code Edition and Addenda of the ASME Boiler and Pressure Vessel Code. This compliance includes the independent third-party inspection coverage of "code" items by an Authorized Nuclear Inspector.

2.10 General indoctrination and training programs shall be developed for personnel performing safety-related activities to assure that responsible functions, departments, and individuals are knowledgeable regarding quality policy and requirements of applicable manuals and procedures. The requirements for training of CEC personnel are described in Section 13.2 of the Callaway-SA FSAR. The training of permanent Plant personnel is the responsibility of the Director, Training. Personnel performing complex, unusual, or hazardous work shall be instructed in special indoctrination or briefing sessions. Emphasis shall be on special requirements for safety of personnel, radiation control and protection, unique features of equipment and systems, operating constraints, and control requirements in effect during performance of work. Training shall be conducted as required to, as a minimum, meet the requirements of Ameren Missouri's commitment to Regulatory Guide 1.8 (ANSI/ANS 3.1), Regulatory Guide 1.33 (ANSI N18.7), other Regulatory Guides as endorsed in OQAM Appendix A, and other regulatory requirements. Records of training shall be maintained as described in Section 17. Where required by code or standard, personnel are trained or qualified according to written procedures in the principles and techniques of performing specific activities. Special equipment, environmental conditions, skills, or processes shall be provided as necessary for the effective implementation of the OQAP.

2.10.1 A retraining and replacement training program for the unit staff shall be maintained under the direction of the Director, Training.

2.10.2 The training programs for Shift Managers, Operating Supervisors, Reactor Operators, and Shift Technical Advisors shall meet or exceed the requirements and recommendations of Section 5 of ANSI/ANS 3.1-1981 as endorsed by Regulatory Guide 1.8, Rev. 2, with the same exceptions as contained in the current revision to the Operator Licensing Examiner Standards, NUREG-1021, ES-202, and 10 CFR Part 55.

2.10.3 All other training programs with the exception of the Radiation Protection program shall meet or exceed the requirements and recommendations of Section 5 of ANSI/ANS 3.1-1978. Radiation Protection program shall meet the requirements of ANSI/ANS 3.1-2014 as endorsed by Regulatory Guide 1.8, Rev. 4 with the exception of the Radiation Protection Manager which shall continue to meet the requirements of Regulatory Guide 1.8, Rev. 1, September, 1975 as clarified by USNRC HPPOS-020.

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2.10.4 Training shall include familiarization with relevant industry operational experience identified by the Performance Improvement Department.

2.11 An audit system shall be established to assure management is advised of Program effectiveness. The implementation and effectiveness of the OQAP shall be assessed through an audit program of quality activities which includes design, procurement, modification, and operation. The ~~Director~~ Manager, Nuclear Oversight is responsible for a system of planned audits to assure OQAP compliance, with a frequency commensurate with the Program aspect's safety significance and in accordance with the requirements of Section 18. This individual is responsible for conducting audits of offsite and onsite activities. Deficiencies identified during the audit process are reported to responsible management of the organization involved in the resolution and follow-up to assure corrective action.

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2.12 The Senior Vice President and Chief Nuclear Officer provides for an independent assessment of the scope, implementation, and effectiveness of the OQAP to assure compliance with policy, commitments, and the requirements of 10 CFR 50, Appendix B and 10 CFR 72, Subpart G as set forth in this OQAM. This assessment shall be conducted biennially with a scheduling allowance of plus three months for each assessment and a combined time interval for any three consecutive assessment intervals not to exceed 6.25 years. This assessment may be by representatives of other utilities, outside consultants, or Ameren Missouri management representatives. In addition, various reports are issued to the Senior Vice President and Chief Nuclear Officer on a periodic basis to assist this individual's independent assessment of the OQAP (e.g., semiannual trend analysis, and periodic NOS audit reports).

2.13 Implementation of OQAP controls over activities affecting quality assures achieving the objective of the Ameren Missouri OQAP to provide management with adequate confidence that activities affecting quality regarding the design, installation, modification, and operation of the CEC are performed consistent with policy. Documentation of the accomplishment of OQAP objectives is maintained in the form of records of data and other information as necessary to support operation, maintenance, repair, modification, refueling, and inservice inspection.

2.14 Ameren Missouri Management has established standards of performance, which exceed those set forth by the Regulatory Agencies. As a management initiative in this area, Ameren Missouri has defined the word "must" to impose management directed performance standards in excess of and in addition to established Regulatory directed performance. From the viewpoint of Ameren Missouri employees and contractors, there is no difference in the degree of compliance mandated by use of the words "shall" or "must." Compliance with actions initiated by use of either "shall" or "must" is audited and surveilled by the NOS Department. Failure to implement a "must" mandated activity requires corrective action in the same way as failure to implement a "shall" mandated activity. However, from an external viewpoint, internally imposed "must" requirements (i.e., those in excess of Regulatory requirements) are not intended to be subject to enforcement action. "Must" is defined in Appendix A of this OQAM under Regulatory Guide 1.74.

4. PROCUREMENT DOCUMENT CONTROL

4.1 Safety-related procurements shall be documented. Procurement document control applies to documents employed to obtain safety-related materials, parts, components, and services required to support Plant activities. Written procedures establish requirements and assign responsibility for measures to assure applicable regulatory requirements, design bases, and other requirements necessary to assure quality are included in procurement documents

4.2 Written procedures shall include controls, as applicable, for preparation, content, review, approval, and processing of the following related procurement documents:

1) Purchase Requisitions
2) Purchase Orders
3) Letters of Intent
4) Engineering Service Agreements (agreements for engineering, construction, or consultant services) (ESAs)
5) Contracts
6) Specifications
7) Drawings

Collectively, these procedures shall assure that technical and quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA Program requirements.

4.3 Consideration of the verification activities to be employed for item or service acceptance should begin during the purchase requisition, ESA, or contract preparation and review stage. Planning of verification activities shall include a review of the established acceptance criteria and identified documentation. Verification methods which may be employed include certifications (certificates of conformance and material certificates or test reports), source verification, receiving inspection, and post-installation tests established by Ameren Missouri. Selected verification methods may be indicated as inspections, examinations, tests, or documentation reviews. The extent of the acceptance methods and associated verification activities is a function of the purchased item's or service's complexity and relative safety significance, as well as the supplier's past performance.

4.4 Acceptance by source verification should be considered when the item or service is vital to Plant safety; or the quality characteristics are difficult to verify after receipt; or the item or service is complex in design, manufacture, inspection or test. Verification in this sense involves a physical presence to monitor, by observation, designated activities for the purpose of evaluating supplier performance and product acceptability

4.5 Purchase requisitions must be employed to initiate the procurement of safety-related materials, parts, components, and services while ESAs must be used to contract for safety-related engineering, construction, or consultant services. Contracts, purchase orders generated from purchase requisitions, and ESAs must be employed to procure certain goods and services associated with the nuclear fuel cycle. Purchase requisitions for safety-related materials, parts, components, and services and ESAs for professional services may be initiated by personnel in the Nuclear Oversight Department; Nuclear Engineering; Fuel Cycle Management Department; or the unit staff.

4.6 The procurement of spare or replacement parts for safety-related structures, systems, and components shall be subject to the QA Program controls in effect at the time the order is issued; and to codes, standards, and technical requirements which are equal to or better than the original requirements or as may be required to reduce the probability for repetition of defects. Procurement document control preparation measures shall further assure that safety-related components, piece parts, materials, and services are purchased to specifications and codes equivalent to those specified originally or those specified by a properly reviewed and approved revision; packaged and transported in a manner to assure the non-degradation of quality during transit; and properly documented to show compliance with applicable specifications, codes, and standards.

4.7 Each item or service to be procured is evaluated by the procurement document originator to determine whether it performs a safety-related function or involves activities which affect the function of safety-related materials, parts, or components and to appraise the importance of this function to Plant or public safety. For those cases where it is unclear if an individual piece (part of a safety-related structure, system, component or service) is governed by the OQAP, an engineering evaluation shall be conducted. The evaluation shall be conducted by Nuclear Engineering and shall classify the safety relationship of the service or questionable component, parts or items of safety-related structures, systems, and components. Evaluations shall be documented for future reference.

4.8 Provisions for the following shall be included in procurement documents as applicable. These provisions may be addressed by invoking a supplier's approved quality program in the procurement document.

1) The scope of work and basic administrative and technical requirements including drawings, specifications, regulations, special instructions, and applicable codes and industrial standards and procedural requirements identified by titles and revision levels. Procurement documents shall also include special process instructions; identification of inspection, test and acceptance requirements; and any special requirements for activities such as designing, identifying, fabricating, cleaning, erecting, packaging, handling, shipping, and storing.

2) Requirement that the supplier have an acceptable Quality Assurance Program which implements the appropriate sections and elements of ANSI N45.2-1977 or the ASME code as applicable as established for the item or service to be supplied. This requirement is not applicable to commercial grade items which utilize a supplier's standard or proven design to meet published product descriptions.

3) Requirements for supplier surveillance, audit, and inspection including provisions for Ameren Missouri or agent access to facilities and records and for identification of witness and hold points.

4) Requirements for extending applicable requirements of Ameren Missouri procurement documents to lower-tier suppliers and subcontractors. These requirements shall include right-of-access to subsupplier facilities and records by Ameren Missouri.

5) Requirements for suppliers to obtain Ameren Missouri approval of nonconformances to procurement document requirements dispositioned "use-as-is" and "repair" and conditions of their disposition including identification of those subject to Ameren Missouri approval prior to further processing.

6) Applicability of 10 CFR 21 reporting requirements.

7) Documentation requirements including records to be prepared, maintained, submitted for approval, or made available for review, such as, drawings, specifications, procedures, procurement documents, inspection and test records, personnel and procedural qualifications, chemical and physical test results, and instructions for the retention, transfer, and disposition of records.

8) Requirements that the supplier furnish documentation which identifies the purchased item and provides traceability to the procurement requirements met by the item and documentation identifying any procurement requirements which have not been met.

4.9 Commercial grade calibration and/or testing services may be procured from commercial laboratories based on the laboratory's accreditation to ISO/IEC-17025 by an Accreditation Body (AB) which is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) provided all of the following are met:

1) A documented review of the supplier's accreditation is performed and includes a verification of the following:

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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.

d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

2) The purchase documents require that:

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a. The service must be provided in accordance with their accredited ~~ISO/IEC 17025:2005 or~~ ISO/IEC-17025:2017 program and scope of accreditation.

b. As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. *(for calibration services only)*

c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration. *(for calibration services only)*

d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

e. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

f. Subcontracting of these accredited services is prohibited.

g. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.

3) It is validated, at receipt inspection, that the laboratory's documentation certifies that

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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.

4.10 The originating organization shall perform a documented independent review of procurement documents to assure requirements are correctly stated, inspectable, and controllable and that there are adequate acceptance and rejection criteria. This review shall be performed by personnel who have access to pertinent information, and who have an adequate understanding of the requirements and intent of the procurement documents.

4.11 Bids or proposals shall be evaluated by individuals or groups to evaluate the following subjects, as applicable to the type of procurement as described in 4.11.1, 4.11.2, 4.11.3, and 4.11.4:

1) Technical considerations
2) Quality Assurance requirements
3) Research and development effort
4) Suppliers' personnel qualifications
5) Suppliers' production capability
6) Suppliers' past performance
7) Alternates
8) Exceptions

4.11.1 Supply Chain Operations shall initiate and coordinate bid evaluation activities for those proposals received in response to requisitions. Supply Chain Operations shall review bids or proposals, except those associated with ESAs or nuclear fuel cycle related goods or services, for alternates or exceptions to procurement document requirements (areas 7 and 8 above) taken by the Supplier. These reviews shall be documented.

4.11.2 The originating organization shall review bids or proposals in all eight areas for ESAs; and for parts, equipment, or services that are not a direct replacement, or from the original approved supplier. They shall also review areas 1 through 3 above for replacement parts or equipment ordered from the original supplier as part of procurement document preparation.

4.11.3 The Nuclear Oversight Department and the originating organization review areas 4 through 6 above as part of maintaining a supplier on the Qualified Supplier List as described in the OQAM, Sections 7.0 and 18.0.

4.11.4 The Fuel Cycle Management Department shall evaluate bids or proposals for fuel cycle goods or services in the above areas.

4.12 Bids or proposals with alternates or exceptions identified in Section 4.11 by Supply Chain Operations shall also be evaluated by the originating organization to provide additional assurance that no unacceptable conditions result from such changes. Unacceptable conditions identified in bid or proposal evaluations shall be resolved prior to purchase award.

4.13 Letters of intent may be utilized with suppliers of materials, parts, components, and services for the purpose of reserving schedule space prior to the resolution of the commercial requirements to be included in a purchase order, contract, or ESA. If employed, letters of intent must normally specify that no safety-related activities may begin until an approved purchase order, contract, or ESA is executed. Letters of intent shall be prepared, approved and issued by Supply Chain Operations for those suppliers to be covered by purchase order, by the originating organization for ESA's, or by the Fuel Cycle Management Department for contracts for nuclear fuel cycle-related goods and/or services. However in the event a letter of intent is issued for the purpose of securing an agreement and thereby allow safety-related work to begin prior to the issuance of such documents, it shall include the applicable quality and technical requirements, as specified by the originating organization.

4.14 Supply Chain Operations is responsible for reviewing purchase orders to verify that the technical and quality requirements have been accurately transferred from the requisition to the purchase order. Approval of the purchase requisition, letter of intent, ESA, or contract shall be by an individual who has approval authority and signifies that the technical and quality review of the document has been completed. Contracts initiated for nuclear fuel cycle-related goods and/or services shall be the responsibility of the Senior Vice President and Chief Nuclear Officer with preparation and negotiation by the Fuel Cycle Management Department. Nuclear fuel cycle-related contracts and ESAs for professional services shall be executed by the Senior Vice President and Chief Nuclear Officer or another company officer in accordance with Nuclear Generation and corporate procedures related to agreements or contracts for services.

4.15 Additions, modifications, exceptions, and other changes to procurement document quality and technical requirements shall require a review equivalent to that of the original document and approval by the originator or the originating department approval authority. Commercial consideration changes shall not require review and concurrence by the originator. Conditions specified on the Qualified Suppliers List (QSL) that apply to a vendor may be revised without concurrence from the originating organization since they are imposed without the knowledge of the originator.

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 The activities affecting quality associated with the operating phase shall be accomplished and controlled by:

1) Preparing procedures, instructions, specifications, drawings or checklists of a type appropriate to the activity and its importance to safety which specify the methods for complying with 10 CFR 50, Appendix B, 10 CFR 72, Subpart G, and the Technical Specifications;

2) Including in these documents quantitative or qualitative acceptance criteria for verifying that an activity has been satisfactorily accomplished;

3) Having responsible personnel approve these documents prior to accomplishing an activity; and

4) Using approved drawings, procedures, instructions or checklists to accomplish an activity;

The degree of control imposed shall be consistent with the relative importance of the activity to safety.

5.2 Nuclear Generation and other responsible functions and departments shall provide written procedures and drawings as required to support the CEC operating phase. These procedures shall prescribe those activities affecting safety-related structures, systems, and components. It is recognized that skills normally possessed by qualified personnel may not require detailed step-by-step delineations in written procedures.

5.2.1 Each procedure and administrative policy of Technical Specification 5.4.1 and changes thereto, including temporary changes shall be reviewed prior to implementation as set forth in OQAM Sections 5.3.1 and 5.6.1 through 5.6.6.

5.2.2 The plant Administrative Procedures and changes thereto shall be reviewed in accordance with the Operational Quality Assurance Manual and approved in accordance with Sections 5.3.1 and 5.6.1 through 5.6.5. The associated implementing procedures and changes thereto shall be reviewed and approved in accordance with Sections 5.3.1 and 5.6.1 through 5.6.5.

5.3 The Senior Director, Nuclear Operations shall be responsible for providing specific guidance via Administrative Procedures for the development, review and approval of other Plant operating procedures to govern activities which affect safety or quality consistent with the Technical Specifications. Similar guidance shall be provided for revisions and temporary changes to Plant operating procedures. A revision of a procedure may constitute a procedure review.

5.3.1 Procedures required by OQAM Sections 5.2.1 and 5.2.2, Technical Specification 5.4.1 and 5.5, and other procedures which affect plant nuclear safety, and changes thereto, shall be prepared, reviewed and approved. Each such procedure or procedure change shall be reviewed by a qualified individual/group other than the individual/group which prepared the procedure or procedure change, but who may be from the same organization as the individual/group which prepared the procedure or procedure change. With the exception of Nuclear Oversight procedures, procedures shall be approved by the appropriate Department Head as designated in writing by the Senior Director, Nuclear Operations. The ~~Director~~ Manager, Nuclear Oversight shall approve Nuclear Oversight procedures. The Senior Director, Nuclear Operations shall approve the PROCESS CONTROL PROGRAM and the OFFSITE DOSE CALCULATION MANUAL. The Senior Director, Nuclear Operations shall approve other Administrative Procedures and Radiological Emergency Response Plan implementing procedures. The Security Manager or designee shall approve the Security Plan implementing procedures. Temporary changes to procedures which do not change the intent of the approved procedures shall be approved for implementation by two members of the plant staff, at least one of whom

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holds a Senior Operator license, and documented. The temporary changes shall be approved by the original approval authority within 14 days of implementation. For changes to procedures which may involve a change in intent of the approved procedures, the person authorized above to approve the procedure shall approve the change prior to implementation;

5.4 The approval, issue and control of implementing procedures, manuals, policies, work authorizing documents, and as-built drawings shall be prescribed in Administrative Procedures consistent with the requirements of Sections 2, 5 and 6.

5.5 Deleted.

5.6 Maintenance and modification procedures shall be reviewed in accordance with Section 6.2.

5.6.1 Proposed changes or modifications to plant nuclear safety-related structures, systems and components shall be reviewed as designated by the Senior Director, Nuclear Operations. Each such modification shall be reviewed by a qualified individual/group other than the individual/group which designed the modification, but who may be from the same organization as the individual/group which designed the modifications. Proposed modifications to plant nuclear safety-related structures, systems and components shall be approved prior to implementation by the Senior Director, Nuclear Operations.

5.6.2 Proposed tests and experiments, which affect plant nuclear safety and are not addressed in the Final Safety Analysis Report or Technical Specifications, shall be prepared, reviewed, and approved pursuant to 10 CFR 50.59 or 10 CFR 72.48. Each such test or experiment shall be reviewed by a qualified individual/group other than the individual/group which prepared the proposed test or experiment. Proposed tests and experiments shall be approved before implementation by the Senior Director, Nuclear Operations.

5.6.3 Individuals responsible for reviews performed in accordance with Sections 5.3.1, 5.6.1, and 5.6.2 shall be designated by the appropriate Department Head. Each such review shall include a determination of whether or not additional, cross-disciplinary, review is necessary. If deemed necessary, such review shall be performed by qualified personnel of the appropriate discipline.

5.6.4 Each review shall include a determination of whether or not a license amendment or NRC CoC Amendment is involved. Pursuant to 10 CFR 50.59 or 10 CFR 72.48, NRC approval of items involving license or NRC CoC amendments shall be obtained prior to implementation.

5.6.5 The Plant Security Plan and Radiological Emergency Response Plan, and implementing procedures, shall be reviewed at least once per 12 months. Recommended changes to the implementing procedures shall be approved in accordance with Section 5.3.1. Recommended changes to the Plans shall be reviewed pursuant to the Operational Quality Assurance Manual and approved by the Senior Director, Nuclear Operations. NRC approval shall be obtained as appropriate.

5.6.6 Records of the activities described in Sections 5.3.1 and 5.6.1 through 5.6.5 shall be provided to the Senior Director, Nuclear Operations, and ORC as necessary for required reviews.

5.7 Special process procedures supplied by outside organizations shall be reviewed in accordance with Section 9.6.

5.8 In addition to the procedures identified in Table 13.5-1 of the Callaway-SA FSAR (CALLAWAY PLANT ADMINISTRATIVE PROCEDURES), the OQAP includes procedural coverage in the following areas: design control; Engineering change control; preparation, review, approval, and revision of specifications, drawings, requisitions, Engineering Service Agreements, contracts and procedures (instructions); QA indoctrination and training; auditor training; supplier evaluations; receipt and transfer of records; document control; quality program audits; corrective action; inspection; inspection, test and operating status; and special processes.

5.9 Applicable procedures shall be reviewed and revised as necessary as described in Appendix A, Regulatory Guide 1.33 (ANSI N18.7-1976, Section 5.2.15).

5.10 Administrative corrections are simple changes that are handled different than the normal revision process.

Administrative Correction revisions are used to revise procedures when the following criteria are met:

1) Correction is editorial.
2) Changes to procedures including correcting grammatical errors, spelling errors, and other errors.
3) Corrections do not alter the purpose, scope, or intent of the step or the procedure.
4) No change to the acceptance criteria.
5) Procedure change incorporates issued Temporary Changes against the procedure which have received final approval.

Administrative Correction revisions are reviewed and approved by the Approval Authority (Department Head) in accordance with Section 5.3.1.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 Materials, equipment, and services shall conform to procurement documents as prescribed in Section 4. Provisions shall be established to control activities affecting quality associated with the procurement of material, equipment and services including:

1) The preparation, review, and change control of procurement documents as described in Section 4
2) Bid evaluation and award as described in Section 4
3) Procurement source selections
4) Verification activities (surveillance, inspection, and audit) required by the purchaser
5) Control of nonconformances as described in Section 15
6) Corrective action as described in Section 16
7) Material, equipment, and service acceptance
8) Control of quality assurance records
9) Audits of the procurement program as described in Section 18

7.2 Ameren Missouri shall assure that suppliers providing safety-related materials, equipment, or services are acceptable procurement sources. Provisions shall be made for supplier evaluations which assess their capabilities prior to award by: l) source evaluation; or 2) review for objective evidence of quality; or 3) a review of supplier history. When evaluations are performed, the assessment of a supplier's capability shall be specific to the procured item, commodity, or service and the supplier's ability to provide the items or services in accordance with procurement document requirements. Suppliers of hardware and services which are manufactured prior to award, considered a commercial grade item, or implemented under the Ameren Missouri OQAP, do not require pre-award source evaluation or post-award audits which attest to their capability as a procurement source.

7.3 During Callaway's operating life, procurements may be made from: 1) suppliers judged capable (prior to award) of providing items or services in accordance with procurement document requirements and a quality assurance program appropriate for the item or service procured; 2) suppliers and others in possession of hardware manufactured prior to award and whose acceptability can be determined by receiving inspection, an examination of quality verification documentation, or other suitable means; 3) suppliers of commercial grade items able to be ordered solely on the basis of published product descriptions (catalog information); and 4) outside organizations working under the Ameren Missouri OQAP. Regardless of the basis for the acceptability of the procurement source, prior to the issuance of a purchase order or execution of a contract or ESA, a verification of the supplier/outside organization's acceptability shall be documented. Except in unusual circumstances (e.g. replacement parts are needed to preclude the development of some unsafe or undesirable condition), an evaluation of a Supplier's acceptability as a procurement source shall be accomplished prior to award. In the case of purchase orders, the supplier shall be verified as an acceptable procurement source for the item or service being procured. Purchase orders may be issued prior to an assessment of suppliers' capability provided a prohibition on safety-related work is imposed. Such suppliers may be released to begin safety-related work when evaluated to be an acceptable procurement source.

7.4 Code certified material may be obtained from an ASME accredited Material Manufacturer or Material Supplier for repair or replacement applications. However Ameren Missouri may also obtain Code certified materials from non-ASME accredited Material Manufacturers or Material Suppliers if such Manufacturers or Suppliers are otherwise qualified as stipulated in Sections 4 and 7 of the OQAM. These provisions are consistent with ASME Code Interpretation XI-1-83-50R dated May 14, 1985.

7.5 Procurement source evaluation and selection involves the Nuclear Oversight Department and the originating organization. The evaluation and selection process shall be specified in department procedures and may vary depending on the complexity and relative importance to safety of the item or service. Nuclear Engineering, Fuel Cycle Management, the unit staff or other organizations may be requested to provide input to the qualification evaluations of suppliers.

7.6 Procurement source selection and evaluations shall consider one or more of the following:

1) Experience of users of identical or similar products of the prospective supplier. NRC Vendor Inspection reports, ASME Certificates of Authorization (C of A), audit reports, Ameren Missouri records accumulated in previous procurement actions, and Ameren Missouri product-operating experience may be used in this evaluation. Supplier history shall reflect recent capability. Previous favorable quality experience with suppliers may be an adequate basis for judgments attesting to their capability. When an NRC Vendor Inspection report, an audit report, or an ASME C of A is used to establish a supplier's acceptability as a procurement source, the document shall be identified.

2) An evaluation of the supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated. This may include review and evaluation of the supplier's QA Program, Manual, and Procedures, as appropriate; and responses to questionnaires.

3) A source evaluation of the supplier's technical and quality capability as determined by a direct evaluation (audit or surveillance) of facilities, personnel and Quality Assurance Program implementation.

4) For commercial grade items, the procurement source selection should consider one or more of the following:

   a) Survey of documented supplier controls over critical characteristics and that supplier activities adequately control the items supplied, and verify the implementation of manufacturer's measures for control of design, process, and material changes.

   b) Acceptable supplier/item performance record utilizing monitored performance of the item, industry product tests, national codes, and standards (not specific to the nuclear industry), or other industry databases (UL, INPO NPRDS, EPRI EQDB, ANSI, NEMA, MIL-STDS, NRC Bulletins/Notices, and Licensee Event Reports, etc.) that is directly related to the item's critical characteristics and intended application.

7.7 Procurement source evaluations involve a review of technical and quality assurance considerations. Technical considerations include the design or manufacturing capability and technical ability of suppliers to produce or provide the design, service, item, or component. Quality assurance considerations include one of the previously defined methods of supplier evaluation and a consideration of changes in a supplier's Quality Assurance Program or capabilities. The measures employed to evaluate a supplier's continued acceptability as a procurement source (after the initial source evaluation) are described in Section 18.

7.8 Organizations participating in the procurement process shall prepare procedures to monitor and evaluate suppliers' performance to procurement document requirements. These procedures shall include provisions for: 1) controlling documents generated or processed during activities fulfilling procurement requirements; 2) identifying and processing change information; 3) establishing a method of control and documentation of information exchange with the supplier; and 4) audit or surveillance of supplier activities.

7.9 Depending on the complexity or scope of the item or service, Supply Chain Operations and/or the originating organization shall initiate award activities. Meetings or other forms of communication may be held to establish the intent of Ameren Missouri in monitoring and evaluating the supplier's performance, establish an understanding of procurement requirements, and identify supplier activities to be utilized in fulfilling requirements. The depth and necessity of these activities shall be a function of the relative importance, quantity, uniqueness, complexity, frequency of transactions with the same supplier, and the supplier's past performance. Ameren Missouri hold and witness points shall be documented as early as practicable in the procurement process.

7.10 The originating organization shall establish measures for monitoring supplier-generated document submittals against procurement document requirements. Similarly, measures shall be established for reviewing and approving supplier generated documents for use. Changes to procurement documents shall be in accordance with the controls described in Section 4.

7.11 Supplier monitoring activities may be performed by personnel from Nuclear Oversight, Nuclear Engineering, Protective Services, Fuel Cycle Management, the unit staff, or outside organizations in accordance with plans to perform inspections, examinations or tests. Supplier monitoring activities may include:

1) Audits of supplier quality assurance program implementation
2) Monitoring, witnessing, or observing inspections, examinations, and performance tests
3) Surveillance of manufacturing processes
4) Audits of supplier records to verify certification validity and the resolution of nonconformances

7.12 To support the control of purchased material, copies of purchase orders and other appropriate procurement documents shall be forwarded to the applicable receiving or acceptance point. Departments receiving or utilizing procured items or services shall establish measures to maintain and control procurement documents until the items or services are received and accepted. These documents shall include purchase orders, drawings and specifications, approved changes, and other related documents.

7.13 Receiving inspection instructions shall be documented. These instructions include specifying inspections or tests of commercial grade items procured from suppliers on the basis of product performance. Should it become necessary to upgrade stocked non-safety related items to specific requirements, inspections, tests, or documentation reviews may be employed to establish the items' acceptability. Documentation shall be generated as a result of Ameren Missouri receiving inspection activities.

7.14 Acceptance of items and services shall include one or more of the following:

1) Written certifications
2) Source verification
3) Receiving inspection
4) Post-installation test (in addition to one of the above).

7.15 Commercial grade items shall rely on proven design and utilize verification methods by the purchaser, to the extent appropriate to item application. Procedures provide for the acceptance of commercial grade items based on one or more of the following:

1) Special Tests and Inspections
2) Survey of Supplier (Commercial Grade)
3) Source Verification
4) Acceptable Supplier/Item Performance Record

Method 4 should not be used alone unless:

a. The established historical record is based on industry wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application; and

b. The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable).

7.16 Where required by Code, regulation or contract requirement, documentary evidence that items conform to procurement documents shall be available during receiving inspection or prior to use of such items. Where not precluded by other requirements, documentary evidence may take the form of written certificates of conformance. When certificates of conformance are employed as a means of item acceptance, verification of the validity of supplier certificates and the effectiveness of the certification systems shall be conducted at intervals commensurate with the supplier's past quality performance. Certificates of conformance and compliance shall be required to be signed or accompanied by a signed letter of transmittal. Where acceptance is based upon source verification, documented evidence of these surveillances shall be furnished to the Plant Quality Control organization by the responsible Ameren Missouri organization or their designated agent prior to acceptance.

7.16.1 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.
   d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

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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.

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7.17 Acceptance by receiving inspection shall be utilized as a prime method of verification and may be utilized as the sole means of item acceptance when items are relatively simple and standard in design and manufacture, such as certain spare parts; when items are adaptable to standard or automated inspections; and when inspections do not require operations which could adversely affect the integrity, function, or cleanliness of the item. When other methods are utilized, receiving inspection shall be employed to verify that items have not sustained damage.

7.18 Quality Control personnel performing receiving inspection shall be certified to ANSI N45.2.6-1978, (as clarified in OQAM Appendix A Regulatory Guide 1.58). Other unit staff personnel qualified to ANS 3.1-1978 may be utilized to perform receipt inspections requiring specialized skills, such as receipt inspection of radioactive material, bulk chemicals and diesel fuel. During outages, extensive modifications, or other special circumstances, receiving inspection may be assigned to an outside organization(s).

7.19 Final acceptance of items shall be by Quality Control personnel or designated inspection personnel. The final acceptance of services shall be the responsibility of the originating organization. Acceptance shall be documented.

7.20 Receiving inspection activities shall include:

1) Verifying that materials, parts, and components, have been identified by tagging or other means; or that they are segregated and controlled in areas separate from the storage facilities for accepted items.

2) Verifying that items for acceptance have been examined for physical damage, correctness of identification and quality documentation, and completeness of specified quality documentation.

3) Verifying that received items conform to procurement documents by inspecting or, where appropriate, testing using approved procedures and calibrated tools, gages and measuring equipment to verify the acceptability of items, including those from commercial grade suppliers.

4) Providing final acceptance after determining that required verifications are complete and acceptable. Items determined to be acceptable for use shall be tagged with an accept tag or other means of identification or segregation, and released for storage or use. Conditional acceptance of items by receiving inspection shall be procedurally controlled.

5) Verifying that received items which do not conform to procurement documents are segregated (if practicable) and processed in accordance with Section 15.

7.21 Acceptance by post-installation test may be utilized following one of the preceding acceptance methods. Post-installation testing shall be used as the prime means of acceptance verification when it is difficult to verify item quality characteristics; the item requires an integrated system checkout or test; or the item cannot demonstrate its ability to perform when not in use. Post-installation test requirements and acceptance documentation shall be established by Ameren Missouri.

10. INSPECTION

10.1 A program for the inspection of safety-related activities shall be established and executed to verify conformance with applicable documented instructions, procedures, drawings, and specifications. Inspections and monitoring of processes which serve an inspection function shall be performed by personnel qualified to perform assigned tasks and who are independent of individuals who perform the activity

10.2 Required inservice inspection of structures, systems or components shall be planned and executed. Inspection methods shall be established and executed to verify that the characteristics of an item remain within specified limits.

10.3 Inspection of activities at the CEC shall be at intervals based on the status and importance of the activities. Guidelines shall be established to indicate the minimum frequency for inspecting maintenance, modification, and special processes activities to provide a basis for subsequent monitoring planning.

10.4 Engineering Programs shall be responsible for assuring the development of preservice and inservice (PSI/ISI) inspection programs; the reference PSI/ISI examination plans for ASME Code Class 1, 2, and 3 systems and components including steam generator eddy current examination; the NDE procedures required by the reference plans; and the initial updating of the reference plans and procedures to reflect "as-built" conditions and the technical requirements of the applicable Code Edition and Addenda prior to the issuance of the inservice inspection plans and procedures.

10.5 Engineering Programs shall be responsible for assuring the development of the inservice testing program plan for pumps and valves, the test procedures required by this plan, and the securing of consulting services in this area. In addition, Engineering Programs shall be responsible for administering and performing the PSI/ISI program and implementing the examination and testing plans developed within Nuclear Generation. They are also responsible for updating the reference plans and NDE procedures subsequent to the issuance of the inservice inspection plans and procedures. The services of an outside organization may be secured to conduct the PSI/ISI examinations.

10.6 An inspection personnel qualification program shall be established to assure inspection activities are being performed by personnel trained and qualified to a capability necessary for performance of the activity. Plant procedures shall prescribe the qualification requirements of inspection personnel. The Director, Training shall be responsible for providing related technical and quality training appropriate to the certification/qualification of Ameren Missouri personnel.

10.7 Quality Control inspection personnel or other personnel who perform "inspection" activities shall be qualified within their respective areas of responsibility. The qualification of QC inspection personnel shall be defined in three levels of capability as described in ANSI N45.2.6-1978. Other personnel performing "inspection" activities shall have appropriate experience, training, and retraining to assure competence in accordance with ANSI/ANS-3.1-1978 and applicable codes and standards. Inspection assignments shall be consistent with the qualification of an individual. In instances where the education and experience recommendations are not met by QC inspection personnel who are to be certified to ANSI N45.2.6-1978, Ameren Missouri shall demonstrate by documented results of written examinations and evaluations of actual work proficiency that individuals possess comparable or equivalent competence.

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10.8 Personnel from outside organizations performing QC inspection activities associated with safety-related items at the CEC shall be certified as required by ANSI N45.2.6-1978.

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10.8.1 Personnel from outside organizations or Ameren personnel who are not Nuclear Generation personnel selected to perform other activities associated with safety-related items at the CEC shall meet one or more of the following for the activities which they are performing:

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- be certified as required by ANSI N45.2.6-1978,
- meet the education and experience requirements applicable to the position,
- be qualified through Ameren Missouri's "systematic approach to training",
- be qualified through a vendor's training and qualification program, which has been approved by Ameren Missouri.

10.9 When contractors or vendors are retained to perform work activities or to provide services associated with safety-related items at the CEC, the qualification of inspection personnel and the conduct of inspections associated with that contracted work activity or service shall meet the requirements stipulated in the applicable procurement documents. As an example, if a vendor was contracted to conduct eddy current examinations of the CEC steam generators, then the persons performing the examination would be qualified as required by the vendor's quality assurance program unless otherwise specified in the applicable procurement documents.

10.10 Procedures which specify inspection activities shall provide for the following, as required: 1) the inclusion of independent inspection or monitoring of processes when required; 2) the identification of inspection personnel; 3) the documentation of inspection results; 4) a description of the method of inspection including any mandatory hold points; 5) the identification of the characteristics and activities to be inspected; 6) the acceptance and rejection criteria; and 7) specifying the necessary measuring and test equipment. Inspection requirements may be obtained from drawings, instructions, specifications, codes, standards, or regulatory requirements.

10.11 The inspection function shall be conducted in accordance with written approved procedures which specify inspection scope; personnel qualification requirements; and data collection requirements. Inspection or testing, as appropriate, shall be employed as a means of verifying suitable performance subsequent to a component replacement or repair.

10.12 Instructions, procedures, and supporting documentation shall be provided to inspection personnel for use prior to performing inspection activities. Inspection results shall be documented. Procedures shall prescribe the review and approval authority for inspection results.

10.13 Indirect control by monitoring processing methods, equipment, and personnel shall be utilized as a control if inspection of processed items is impossible or disadvantageous. Both inspection and monitoring of processes shall be provided when control is inadequate without both.

10.14 Inspection data shall be analyzed and evaluated to verify completeness of results, achievement of inspection objectives, and operational proficiency of equipment and systems; to identify additional inspection requirements; and to identify necessary changes to the installation inspection procedures. The acceptance of an item shall be documented by authorized personnel. Modification, repair or replacement of items performed subsequent to final inspection shall require reinspection or retest to verify acceptability.

11. TEST CONTROL

11.1 Testing programs shall be established to demonstrate that safety-related structures, systems, and components will perform satisfactorily in service. Testing programs include such tests as initial startup testing, surveillance tests, Inservice Testing (IST) pump and valve tests, computer code verification and/or validation (V&V) tests, and other tests, including those associated with failure analysis and the acceptance of purchased material. A test is performance of those steps necessary to determine that systems or components function in accordance with predetermined specifications.

11.2 Provisions shall be established for the performance of surveillance testing to assure that the necessary quality of systems and components is maintained, that facility operations are within the safety limits, and that limiting conditions for operation can be met. The testing frequency shall be as prescribed in the Callaway Plant Technical Specifications. The provisions for surveillance testing shall include the preparation of a surveillance testing schedule(s) which reflects the status of in-plant surveillance tests. Qualified personnel shall perform surveillance tests.

11.3 Appropriate tests shall also be performed subsequent to Plant modifications, maintenance or significant operating procedure changes to confirm expected results. Tests provide a level of confidence in structure, system or component operation or functional acceptability.

11.4 When required by procurement documents, testing shall be employed as a means of purchased material and equipment acceptance. Acceptance testing of this nature shall be performed during receiving inspection or subsequent to installation in accordance with Section 7.

11.5 Equipment failure or malfunction analysis testing may also be performed. The causes of malfunctions shall be investigated, evaluated, and recorded. Experience with malfunctioning equipment and similar components shall be reviewed and evaluated to determine whether a like kind replacement component can be expected to perform its function reliably.

11.6 Testing shall be performed in accordance with written procedures which incorporate or reference the requirements and acceptance limits contained in applicable Callaway Plant Technical Specifications, drawings, instructions, procurement documents, specifications, codes, standards, and regulatory requirements.

11.7 Administrative procedures, test procedures, or checklists shall include: provisions for assuring all prerequisite conditions are met; test equipment calibration requirements; testing method instructions including hold or witness points; limiting conditions and acceptance/rejection criteria; and data collection and test result approval requirements.

11.8 Test data shall be analyzed and evaluated by qualified individuals or groups to verify completeness of results, achievement of test objectives, and operational proficiency of equipment and systems; to identify additional test requirements; and to identify necessary changes to the installation test procedures. Equipment found to be deficient shall be identified in accordance with Section 14. Surveillance test procedure results which fail to meet the requirements and acceptance criteria of Callaway Plant Technical Specifications shall be documented and reviewed in accordance with Section 15. Deficiencies identified as nonconforming shall be processed in accordance with Section 15.

11.9 Review and approval of tests and experiments not described in the FSAR shall be conducted as specified in the OQAM Section 5, 10 CFR 50.59, and 10 CFR 72.48.

11.10 A program shall be established to assure testing activities are performed by personnel trained and qualified to a capability necessary for performance of the activity. Plant procedures and procurement documents shall prescribe the qualification requirements for testing personnel. Provisions may be made for on-the-job training of individuals not qualified to the program provided they are supervised or overseen by qualified individuals for the activities being performed. The Director, Training shall be responsible for providing related technical and quality training for Ameren Missouri personnel who perform testing.

11.11 Personnel within the various Ameren organizations may perform testing activities including implementing test procedures and the evaluation and reporting of test results. The assignment of Plant testing personnel shall be under the direction and control of the Senior Vice President and Chief Nuclear Officer. The qualification of QC testing personnel shall be defined in three levels of capability as described in ANSI N45.2.6-1978. Other personnel performing "testing" activities shall have appropriate experience, training, and retraining to assure competence in accordance with ANSI/ANS-3.1-1978 and applicable codes and standards. Testing assignments shall be consistent with the qualification of an individual. In instances where the education and experience recommendations are not met by QC testing personnel who are to be certified to ANSI N45.2.6-1978, Ameren Missouri shall demonstrate by documented results of written examinations and evaluations of actual work proficiency that individuals possess comparable or equivalent competence.

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11.12 Personnel from outside organizations or Ameren personnel who are not Nuclear Generation personnel selected to perform other testing activities associated with safety-related items at the CEC shall meet one or more of the following for the activities which they are performing:

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- be certified as required by ANSI N45.2.6-1978,
- meet the education and experience requirements applicable to the position,
- be qualified through Ameren Missouri's "systematic approach to training,"
- be qualified through a vendor's training and qualification program, which has been approved by Ameren Missouri.

11.13 When contractors or vendors are retained to perform work activities or to provide services associated with safety-related items at the CEC, the qualification of testing personnel and the conduct of tests associated with that contracted work activity or service shall meet the requirements stipulated in the applicable procurement documents. As an example, if a vendor were contracted to conduct testing of the main steam line safety valves at the CEC, then the persons performing the testing/valve settings would be qualified as required by the vendor's quality assurance program unless otherwise specified in the applicable procurement documents.

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~~ Manager, 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.

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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~~ Manager, 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~~ Manager, 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.

OQAMCN 21-002

18.5 The ~~Director~~ Manager, Nuclear Oversight shall be responsible for assuring the implementation of a comprehensive system of planned audits to verify compliance with the OQAP. The ~~Director~~ Manager, 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~~ Manager r, Nuclear Oversight has direct access to the Senior Vice President and Chief Nuclear Officer.

OQAMCN 21-002

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~~ Manager, 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~~ Manager, 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.

OQAMCN 21-002

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.
   d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

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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.

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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 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.

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 CONFORMANCE TO APPLICABLE NRC REGULATORY GUIDES

This Appendix briefly discusses the extent to which Ameren Missouri's Operating Quality Assurance Program (OQAP) conforms to NRC published Regulatory Guides for the Callaway Energy Center (CEC). All statements within the Regulatory Position Section (C) of the Regulatory Guides are considered requirements unless a specific exception or clarification has been proposed by Ameren Missouri and accepted by the NRC. This is true regardless of the qualifier (i.e., "shall" or "should") which prefaces the statement. Unless further qualified by a statement within the corresponding Regulatory Guide, ANSI/ANS Standards "shall" statements denote requirements while "should" statements denote recommendations. Clarifications, alternatives, and exceptions to these Regulatory Guides are identified herein. Ameren Missouri's position on other Regulatory Guides is given in Appendix 3A of the Callaway-SA and Callaway-SP Final Safety Analysis Reports (FSARs).

In each of the ANSI standards referenced by one of the listed Regulatory Guides, other documents (i.e. other standards, codes, regulations or appendices) required to be included as a part of the standard are either identified at the point of reference or are described in a special section of the standard. The specific applicability or acceptability of these listed standards, codes regulations or appendices is either covered in other specific areas in the FSAR or this Operating QA Manual (OQAM), including tables, or such documents are not considered as requirements, although they may be used as guidance. When sections are referenced within a standard, it is understood that Ameren Missouri shall comply with the referenced section as clarified.

REGULATORY GUIDE 1.8 **REVISION 2** **DATED 4/87**

Qualification and Training of personnel for Nuclear Power Plants (Endorses ANSI/ANS 3.1-1981 for Shift Supervisor (Section 4.3.1.1), Senior Operator (Section 4.3.1.2), Licensed Operators (Section 4.5.1.2), Shift Technical Advisor (Section 4.4.8), and Radiation Protection (Section 4.4.4) only, and ANSI/ANS N18.1-1971 for all other positions).

DISCUSSION:

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

Revision 1, dated 9/75, applies to the position of Radiation Protection Manager only. For the position of Radiation Protection Manager only, Regulatory Guide 1.8, Revision 1, September, 1975 is clarified by USNRC HPPOS-020, Clarification of Regulatory Guide 1.8 on Qualification of Radiation Protection Manager. Regulatory Guide 1.8, Rev 4 issued June 2019 which endorses ANSI/ANS 3.1 2014, applies to equivalent positions within the Radiation Protection organization except for the Radiation Protection Manager.

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The experience, training, and education requirements for the positions of Shift Manager, Operating Supervisor, and Reactor Operator, and personnel fulfilling the duties of Shift Technical Advisor shall meet or exceed the requirements and recommendations of ANSI/ANS 3.1-1981 as endorsed by the Regulatory Guide 1.8, Revision 2, with the same exceptions as contained in the current revision to the Operating Licensing Examiner Standards, NUREG-1021, ES-202.

For all other positions, qualification and training shall comply with ANSI/ANS 3.1-1978 as clarified below:

Refer to Callaway-SA FSAR Section 13.1 for a discussion of the qualifications of personnel responsible for plant operation and support.

Personnel responsible for directing or supervising the conduct of safety-related preoperational and startup tests and for review and approval of safety-related preoperational and startup test procedures or results met the qualifications of the Regulatory Guide, but were not required to be certified.

Ameren Missouri may use additional Ameren employees or contract personnel to augment the unit staff. These groups include, but are not limited to, Ameren personnel from outside Nuclear Generation as well as supplemental Radiation Protection and I&C technicians and QC inspectors. Except for Radiation Protection, when used to perform safety-related activities, these personnel shall meet the education and experience requirements of ANSI/ANS 3.1-1978 for equivalent positions or specified education and experience requirements for non-equivalent positions. When supplemental contract Radiation Protection personnel are used to perform safety-related activities, these personnel shall meet the education and experience requirements of ANSI/ANS 3.1-2014 for equivalent positions or specified education and experience requirements for non-equivalent positions. As an alternative, these personnel can be qualified for assigned tasks either by Ameren Missouri through its systematic approach to training or by Vendors with Ameren Missouri approved training and qualification programs. Inspection, examination and testing personnel shall meet the requirements for certification as inspection, examination or testing personnel as set forth in Ameren Missouri s commitment to ANSI N45.2.6-1978 given elsewhere in this Appendix.

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With regard to Section 5.6 of ANSI/ANS 3.1 - 1978 titled Documentation: Ameren Missouri shall maintain records in accordance with and to meet the requirements of OQAM Section 17 and ANSI N45.2.9 as specified herein.

REGULATORY GUIDE 1.28 **REVISION 2** **DATED 2/79**

Quality Assurance Program Requirements (Design and Construction) (Endorses ANSI N45.2-1977)

DISCUSSION:

This Regulatory Guide is not applicable to the operating phase. However, ANSI N45.2-1977 will be applied to suppliers of safety-related items, components or services, as appropriate, as described under Regulatory Guide 1.123 (ANSI N45.2.13-1976).

REGULATORY GUIDE 1.30 **INITIAL ISSUE** **DATED 8/72**

Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electronic Equipment (Safety Guide 30) (Endorses ANSI N45.2.4-1972/IEEE 336-1971)

DISCUSSION:

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

For maintenance and modification activities Ameren Missouri shall comply with the Regulatory Position established in this Regulatory Guide in that QA programmatic/administrative requirements included therein (subject to the clarifications

REGULATORY GUIDE 1.38 **REVISION 2** **DATED 5/77**

Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants (Endorses ANSI N45.2.2-1972)

DISCUSSION:

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

With regard to Section 1.4 of ANSI N45.2.2 - 1972 titled Definitions: Definitions in this Standard which are not included in 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.

With regard to Section 2.1 of ANSI N45.2.2 - 1972 titled Planning: (First sentence) The specific items to be governed by the Standard shall be identified in Callaway-SP FSAR Table 3.2-1, which lists those structures, systems and components to which the Ameren Missouri QA Program is applied.

With regard to Section 2.3 of ANSI N45.2.2 - 1972 titled Results: The specific methods for performing and documenting tests and inspections are given in OQAM Sections 10 and 11. The requirements in these Sections shall be implemented in lieu of the general requirements here. In every case either identical or equivalent controls are provided in the sections of the referenced Standards or documents.

With regard to Section 2.4 of ANSI N45.2.2 - 1972 titled Personnel Qualifications: Specific requirements for personnel qualifications are set forth in the OQAM description and in the commitments in this Appendix. These requirements shall be implemented in lieu of the general requirements stated in this Section. In every case either identical or equivalent controls are provided in the sections of the referenced Standards or document.

With regard to Section 2.7 of ANSI N45.2.2 - 1972 titled Classification of Items: Ameren Missouri may choose not to explicitly use the four level classification system. However, the specific requirements of the Standard that are appropriate to each class are generally applied to the items suggested in each classification and to similar items, as determined by engineering. Engineering actions performed in accordance with this section of the Standard are conducted with NOS/QC involvement and are subject to NOS audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee. For other activities, NOS audits and surveillances, and QC inspection activities assure NOS/QC involvement.

With regard to Section 3.2.1 of ANSI N45.2.2 - 1972 titled Level A Items: As an alternate to the requirements for packaging and containerizing items in storage to control contaminants (Items (4) and (5)), Ameren Missouri may choose a storage atmosphere which is free of harmful contaminants in concentrations that could produce damage to stored items, as determined by engineering. Similarly (for Item (7)) Ameren Missouri may obviate the need for caps and plugs, as determined by engineering, with an appropriate storage atmosphere, and may choose to protect weld-end preparations and threads by controlling the manner in which the items are stored. These clarifications apply whenever items (4), (5) or (7) are subsequently referenced and to Section 3.5.1 titled Caps and Plugs and Section 3.4 titled Methods of Prevention. Engineering actions performed in accordance with this section of the Standard are conducted with NOS/QC involvement and are subject to NOS audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee. For other activities, NOS audits and surveillances, and QC inspection activities assure NOS/QC involvement.

With regard to Section 3.3 of ANSI N45.2.2 - 1972 titled Cleaning: (Third sentence) Ameren Missouri interprets "documented cleaning methods" to allow generic cleaning procedures to be written which shall be implemented, as necessary, by trained personnel. Each particular cleaning operation shall be either governed by an individual cleaning procedure or by a generic procedure either of which shall specify method(s) of cleaning or type(s) of solvent(s) that may be used in a particular application.

With regard to Section 3.4 of ANSI N45.2.2 - 1972 titled Methods of Preservation: (First sentence) Ameren Missouri shall comply with these requirements subject to the clarifications of Section 3.2.1 (4) and (5) above, and the definition of the phrase "deleterious corrosion" to mean that corrosion which cannot be subsequently removed and which adversely affects form, fit, or function.

With regard to Section 3.6 of ANSI N45.2.2 - 1972 titled Barrier and Wrap Material and Desiccants: This Section requires the use of nonhalogenated materials in contact with austenitic stainless steel. Refer to Regulatory Guide 1.37 for the Ameren Missouri position.

With regard to Section 3.7.1 of ANSI N45.2.2 - 1972 titled Containers: Cleated, sheathed boxes may be used up to 1000 lbs. rather than 500 lbs. as specified in 3.7.1(1). This type of box is safe for, and has been tested for, loads up to 1000 lbs. Other national standards allow this (see Federal Specification PPP-B-601). Special qualification testing shall be required for loads above 1000 lbs.

With regard to Section 3.7.2 of ANSI 45.2.2 - 1972 titled Crates and Skids: Crates shall be used for equipment in excess of 1000 lb. in weight. Skids or runners shall be used on boxes with a gross weight of approximately 100 lb. or more, allowing sufficient floor clearance for forklift tines (as nominally provided by 4 inch lumber).

With regard to Section 4.2.2 of ANSI N45.2.2 - 1972 titled Closed Carriers: The use of fully enclosed furniture vans, as recommended in (2) of this Section, is not considered a requirement. Stated for information only, Ameren Missouri shall assure adequate protection from weather or other environmental conditions by a combination of vehicle enclosure and item packaging.

With regard to Section 5.2.1 of ANSI N45.2.2 - 1972 titled Shipping Damage Inspection: Stores personnel shall normally visually scrutinize incoming shipments for damage of the types listed in this Section; this activity is not necessarily performed prior to unloading. Since required items receive the Item Inspection of Section 5.2.2, separate documentation of the Shipping Damage Inspection is not necessary. Release of the transport agent after unloading and the signing for receipt of the shipment may be all of the only action taken to document completion of the Shipping Damage Inspection. Any nonconformance noted shall be documented and dispositioned as required by OQAM Section 15. The person performing the visual scrutiny during unloading is not considered to be performing an inspection function as defined under Regulatory Guide 1.74; therefore, while this person shall be trained to perform this function, this person may not necessarily be certified to Regulatory Guide 1.58 (ANSI N45.2.6-1978) as an Inspector.

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With regard to Section 5.2.2 of ANSI N45.2.2 - 1972 titled Item Inspection: The second division of this subsection requires six additional inspection activities if an item was not inspected or examined at the source. Engineering shall determine and document the extent of receipt inspection based on consideration of items in Section 5.2.2. Engineering actions performed in accordance with this section of the Standard are conducted with NOS/QC involvement and are subject to NOS audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee. For other activities, NOS audits and surveillances, and QC inspection activities assure NOS/QC involvement.

With regard to Section 6.1.2 of ANSI N45.2.2 - 1972 titled Levels of Storage: Subpart (2) is replaced with the following:

(2) Level B items shall be stored within a fire resistant, weathertight, and well ventilated building or equivalent enclosure in which measures have been taken against vandalism. This building shall be situated and constructed so that it is not normally be subject to flooding; the floor shall be paved or equal, and well drained. If any outside waters should come in contact with stored equipment, such equipment shall be labeled or tagged nonconforming, and then the nonconformance document shall be processed and evaluated in accordance with OQAM Section 15. Items shall be placed on pallets or shoring or shelves to permit air circulation. The building shall be provided with heating and temperature control or its equivalent to reduce condensation and corrosion. Minimum temperature shall be 40° F and maximum temperature shall be 140° F or less if so stipulated by a manufacturer.

With regard to Section 6.2.1 of ANSI N45.2.2 - 1972 titled Access to Storage Areas: Items which fall within the Level D classification of the standard shall be stored in an area which may be posted to limit access, but other positive controls such as fencing or guards shall not normally be provided, with engineering's concurrence. Engineering actions performed in accordance with this section of the Standard are conducted with NOS/QC involvement and are subject to NOS audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee. For other activities, NOS audits and surveillances, and QC inspection activities assure NOS/QC involvement.

With regard to Section 6.2.4 of ANSI N45.2.2 - 1972 titled Storage of Food and Associated Items: The sentence is replaced with the following:

"The use or storage of food, drinks, and salt tablet dispensers in any storage area shall be controlled and shall be limited to designated areas where such use or storage is not deleterious to stored items, with engineering's concurrence."

Engineering actions performed in accordance with this section of the Standard are conducted with NOS/QC involvement and are subject to NOS audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee. For other activities, NOS audits and surveillances, and QC inspection activities assure NOS/QC involvement.

With regard to Section 6.2.5 of ANSI N45.2.2 - 1972 titled Measures to Prevent Entrance of Animals: The sentence is replaced with the following:

"Exterminators or other appropriate measures shall be used to control animals to minimize possible contamination and mechanical damage to stored material."

With regard to Section 6.3.3 of ANSI N45.2.2 - 1972 titled Storage of Hazardous Materials: The sentence is replaced with the following:

"Hazardous chemicals, paints, solvents, and other materials of a like nature shall be stored in approved cabinets or containers which are not in close proximity to installed safety-related systems."

The placement of hazardous material storage lockers in the Plant is based upon installed safety-related systems, not particular components.

With regard to Section 6.4.2 of ANSI N45.2.2 - 1972 titled Care of Items: The following alternates are provided for the indicated subparts:

(5) "Space heaters in electrical equipment shall be energized unless a documented engineering evaluation determines that such space heaters are not required."

(6) "Large (greater than or equal to 50 HP) rotating electrical equipment shall be given insulation resistance tests on a scheduled basis unless a documented engineering evaluation determines that such tests are not required."

(7) "Prior to being placed in storage, large (greater than or equal to 50 HP or when designed to be used with a prime mover of greater than or equal to 50 HP) horizontal rotating equipment shall be evaluated by engineering to determine if shaft rotation in storage is required: the results of the evaluation shall be documented. If rotation is required, it shall be performed at specified intervals, be documented, and be conducted so that parts receive a coating of lubrication where applicable and so that the shaft does not come to rest in the same position occupied prior to rotation. For long shafts or heavy equipment subject to undesirable bowing, shaft orientation after rotation shall be specified and obtained."

(8) Maintenance requirements specified by the manufacturer's instructions are addressed in this OQAM, Section 13.3.

With regard to Section 6.5 of ANSI N45.2.2 - 1972 titled Removal of Items from Storage: Ameren Missouri does not consider the last sentence of this Section to be applicable to the Operating Phase due to the relatively short period of time between installation and use. The first sentence of the Section is replaced with:

> "Ameren Missouri shall develop, issue, and implement a procedure(s) which cover(s) the removal of items from storage. The procedure(s) shall assure that the status of material issued is known, controlled, and appropriately dispositioned."

With regard to Section 7.4.2, a subsection to Section 7.4 of ANSI N45.2.2-1972 titled Inspection of Equipment and Rigging: Stated for information only, it is Ameren Missouri's position that this relates to the operability of the hoisting equipment and does not preclude re-rating as allowed by Section 7.3.

REGULATORY GUIDE 1.39 **REVISION 2** **DATED 9/77**

Housekeeping Requirements for Water-Cooled Nuclear Power Plants (Endorses ANSI N45.2.3-1973)

DISCUSSION:

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

For maintenance and modification activities Ameren Missouri shall comply with the Regulatory Position established in this Regulatory Guide in that QA programmatic/administrative requirements included therein (subject to the clarifications below) shall apply to these maintenance and modification activities even though such requirements may not have been in effect originally. Technical requirements associated with the maintenance or modification shall be equal to or better than the original requirements (e.g., code requirements, material properties, design margins, manufacturing processes, and inspection requirements), or as required to preclude repetition of defects.

(c) nuclear oversight audits cover frequency and effectiveness of use of the Supervisors as design verifiers to guard against abuse.

With regard to Section 1.4 of ANSI N45.2.11 - 1974 titled Definitions: 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 this Appendix.

With regard to the 4th paragraph of subsection 2.1 and subsection 2.2.12, under Program Requirements, and Section 11 (including subsections 11.1 through 11.7) of ANSI N45.2.11 - 1974, titled Audits: Ameren Missouri's audit program shall be implemented in accordance with and to meet the requirements of Regulatory Guide 1.144 (ANSI N45.2.12) as endorsed in this Appendix, and OQAM Sections 16 and 18. In every case either identical or equivalent controls are provided in the sections of the referenced Standards or documents.

With regard to Section 6 of ANSI N45.2.11-1974 titled Design Verification, the formal design verification process applies to design changes.

REGULATORY GUIDE 1.74 **INITIAL ISSUE** **DATED 2/74**

Quality Assurance Terms and Definitions (Endorses ANSI N45.2.10-1973)

DISCUSSION:

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

Ameren Missouri reserves the right to define additional words or phrases which are not included in this Standard. Such additional definitions shall be documented in appropriate procedures or in Sections of the Operating QA Manual.

In addition to the Standard's definition of "Inspection," Ameren Missouri shall use the following: "Inspection (when used to refer to activities that are NOT performed by NOS or QC personnel) - Examining, viewing closely, scrutinizing, looking over or otherwise checking activities. Personnel performing these functions are not necessarily certified to Regulatory Guide 1.58 (ANSI N45.2.6-1978)." These activities are controlled by the CEC Operating Procedures.

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When Ameren Missouri intends for Inspection to be performed in accordance with the Operating QA Program by personnel certified as required by that Program and for activities defined by "Inspection" in ANSI N45.2.10, appropriate references to QC group or the procedures to be used for performing the activity shall be made. If such references are NOT made, inspections are to be considered under the additional definition given above.

In addition to the Standard's definition of "procurement documents," Ameren Missouri shall utilize the definition given in ANSI N45.2.13. The compound definition is given as follows: Procurement documents - Contractually binding documents that identify and define the requirements which items or services must meet in order to be considered acceptable by the purchaser. They may include documents which authorize the seller to perform services or supply equipment, material or facilities on behalf of the purchaser (e.g. Engineering Service Agreement agreements for engineering, construction, or consulting services), contracts, letters of intent, purchase requisitions, purchase orders, or proposals and their acceptance, drawings, specifications, or instruction which define requirements for purchase.

"Bids" - Supplier quotation submitted in response to specified technical and quality requirements for which price and delivery are primary considerations.

"Proposals" - Supplier offerings that define the scope of supply as well as specific technical and quality requirements for a product or service. Such offerings usually require negotiation prior to acceptance as either a purchase order, contract, or Engineering Service Agreement.

"Program Deficiencies" (Not defined in ANSI N45.2.10, but used and defined differently in Regulatory Guide 1.144 (ANSI N45.2.12)) - Failure to develop, document or implement effectively any applicable element of the Operating QA Program.

"Quality Assurance Program Requirements" (Not defined in ANSI N45.2.10 but used and defined differently in ANSI N45.2.13) - Those individual requirements of the Operating QA Program which, when invoked in total or in part, establish the requirements of the quality assurance program for the activity being controlled. Although not specifically used in the Operating QA Program, ANSI N45.2 may be imposed upon Ameren Missouri's suppliers.

"Independent Verification" - Verification by an individual other than the person who performed the operation or activity being verified that required actions have been completed. Such verification need not require confirmation of the identical action when other indications provide assurance or indication that the prescribed activity is in fact complete. Examples include, but are not limited to: verification of a breaker opening by observed remote breaker indication lights; verification of a set point (made with a voltmeter or ammeter for example) by observing the actuation of status or indicating lights at the required Panel-meter indicated value; verification that a valve has been positioned by observing the starting or stopping of flow on meter indications or by remote value positions indicating lights.

"Audit" (This is a modification of the word's definition - to allow the use of subjective evidence if no evidence is available - as defined in Section 1.4 of ANSI N45.2.12 - 1977 (Regulatory Guide 1.144) and Section 1.4.3 of ANSI N45.2.23 - 1978 (Regulatory Guide 1.146) as opposed to the definition given in ANSI N45.2.10 - 1973) - A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence where available, (subjective evidence may be used when objective evidence is not available), that applicable elements of the Quality Assurance Program have been developed, documented and effectively implemented in accordance with specified requirements. An audit should not be confused with surveillance or inspection for the sole purpose of process control or product acceptance.

"Must" - (Not defined in any ANSI Standard) - An internally auditable requirement imposed by Ameren Missouri management upon its employees, contractors, and agents - above and in excess of the legally binding requirements of the appropriate regulatory body. Such items are internally required but not externally enforceable. (See additional discussion under Section 2.14 of the OQAM.)

"Unit staff" - (Not defined in any ANSI standard) - Means those personnel who report to the Senior Director, Nuclear Operations. This term shall also be synonymous with the "onsite operating organization" described (but not defined) in ANSI N18.7-1976, Section 3.4.2; the "unit staff" as used in the OQAM and in Callaway Plant Technical Specifications Section 5.2 and its subparts; including "operating staff" and "unit organization" as described in the Callaway Plant Technical Specifications Section 5.2.1 and 5.2.2, respectively; and personnel having "line responsibility for operation of the unit" as used in the OQAM.

"Like kind replacements" - (Not defined in any ANSI standard) - Like kind replacements include both exact item replacements and other item replacements which are not "exact" but meet the original design requirements.

REGULATORY GUIDE 1.88 **REVISION 2** **DATED 10/76**

Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records (Endorses ANSI N45.2.9-1974)

DISCUSSION:

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

With regard to Section 3.2.1 of ANSI N45.2.9 - 1974 titled Generation of Quality Assurance Records: The phrase "completely filled out" is clarified to mean that sufficient information is recorded to fulfill the intended purpose of the record. It is the information, not the form, that is the record. Thus the information, not the form, needs to be complete to furnish documented "evidence of activities affecting quality".

With regard to Section 3.2.2 of ANSI N45.2.9 - 1974 titled Index: The phrase "an index" is clarified to mean a collection of documents or indices which, when taken together, supply the information attributed to "an index" in the Standard.

The specific location of a record "within a storage area" may not be delineated. (e.g. The specific location within a computer record file may not be constant. Further, Ameren Missouri may utilize a computer assisted random access filing system where such location could not be readily "documented," or would such a location be "relevant.") The storage location shall be delineated, but where file locations change with time, the specific location of a record within that file may not always be documented.

With regard to Section 4.2 of ANSI N45.2.9 - 1974 titled Timeliness: Ameren Missouri's contractual agreement with its contractors and suppliers shall constitute fulfillment of the requirements of this Section.

With regard to Section 5.3.3 of ANSI N45.2.9-1974: The phrase "A method for verifying that the records received are in agreement with the transmittal document . . .", is clarified to mean that internal CEC generated records received are in agreement with procedural guidelines contained in CEC Administrative procedures. If a transmittal does exist (e.g. on supplier-generated documents, etc.), the records received will be verified against the transmittal document.

The following clarification is substituted for the current subsection 5.4.3: "Provisions shall be made for special processed records (such as radiographs, photographs, negatives, microfilm and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity as appropriate to the records type." Consideration shall be given to manufacturer's recommendation.

With regard to Section 5.5 of ANSI N45.2.9 - 1974 titled Safekeeping: Routine General Offices and Plant site security systems and access controls shall be provided: no special security systems are required to be established for record storage areas.

With regard to Section 5.6 of ANSI N45.2.9 - 1974 titled Facility: This Section provides no distinction between temporary and permanent facilities. To cover temporary storage, the following clarification is added: "Active records (those completed but not yet duplicated or placed on microfilm) may be temporarily stored in one-hour fire rated file cabinets. In general, records shall not be maintained in such temporary storage for more than three months after completion without

REGULATORY GUIDE 1.123 **REVISION 1** **DATED 7/77**

Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants (Endorses ANSI N45.2.13-1976)

DISCUSSION:

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

With regard to Section 1.3 of ANSI N45.2.13 - 1976 titled Definitions: With two exceptions (Procurement Document and Quality Assurance Program Requirements) 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 two exceptions are defined in this Appendix under Regulatory Guide 1.74.

With regard to Section 1.2.2 of ANSI N45.2.13 - 1976 titled Purchaser's Responsibilities: Item C is one of the options which may be used by Ameren Missouri to assure quality; however, any of the options given in 10 CFR 50, Appendix B, Criterion VII as implemented by OQAM Sections 4 and 7 may also be used.

With regard to Section 3.1 of ANSI N45.2.13 - 1976 titled Procurement Document Preparation, Review and Change Control: The phrase "the same degree of control" is stipulated to mean "equivalent level of review and approval." The changed document may not always be re-reviewed by the originator; however, at least an equivalent level of supervision shall review and approve any changes.

With regard to Section 3.2.3 of ANSI N45.2.13 – 1976 titled Quality Assurance Program Requirements, the requirements of the Section are accepted with the following exceptions:

"As defined in 10CFR21.3, basic components include: safety related structures, systems, components or parts thereof; and also include safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Procurement documents for basic components are not required to impose a quality assurance program consistent with ANSI N45.2, provided that all the following are met:

1. The basic components meet the definition of commercial grade item in 10CFR21.3.
2. The basic components are dedicated by the Purchaser in accordance with the Purchaser's 10CFR50 Appendix B quality assurance program as described in 10CFR21.3 and 10CFR21.21(c).
3. The Purchaser adopts appropriate procedures for notifications to satisfy 10CFR21.21.

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 each of the following conditions are met:

1) A documented review of the supplier's accreditation is performed and includes a verification of the following:

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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.
d) The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

2) The purchase documents require that:

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a) The service must be provided in accordance with their accredited ~~ISO/IEC 17025:2005 or~~ ISO/IEC-17025:2017 program and scope of accreditation.
b) As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out of tolerance. (for calibration services only)
c) The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)
d) The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
e) Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
f) Subcontracting of these accredited services is prohibited.
g) Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.

3) It is validated, at receipt inspection, that the laboratory's documentation certifies that:

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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.

With regard to Section 3.4 of ANSI N45.2.13 - 1976 titled Procurement Document Control: Ameren Missouri shall meet the requirements of OQAM Sections 4 and 7 in lieu of the requirements specified in this Section. In every case either identical or equivalent controls are provided in the sections of the referenced documents.

With regard to Section 5.3 of ANSI N45.2.13 - 1976 titled Preaward Evaluation: Ameren Missouri shall comply with an alternate paragraph which reads:

> "Except in unusual circumstances (e.g. replacement parts are needed to preclude the development of some unsafe or undesirable condition at Callaway), an evaluation of the supplier's acceptability as a procurement source shall be performed as required by the Operating QA Manual."

While it is not the intent to make "unusual circumstances" determinations without Engineering or NOS involvement, Callaway Operations Support is ultimately responsible for the decision. NOS audit and surveillance activities assure against abuse.

With regard to Section 6.4 of ANSI N45.2.13 - 1976 titled Control of Changes in Items of Services: The phrase "the Operating QA Program" is inserted in lieu of "ANSI N45.2, Section 7."

With regard to Section 7.3.1 of ANSI N45.2.13-1976 titled Source Verification Activities and Section 12 of ANSI N45.2.13 - 1976 titled Audit of Procurement Program: The Ameren Missouri audit program shall be implemented in accordance with and to meet the requirements of Regulatory Guide 1.144 (ANSI N45.2.12) as endorsed in this Appendix, and OQAM Sections 16 and 18.

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With regard to Section 7.5 of ANSI N45.2.13 - 1976 titled Personnel Qualifications: The phrase: "Personnel responsible for performing verification activities shall be qualified in accordance with ANSI N45.2.6-1978 as applicable", is subject to the following clarification: Qualification of personnel performing verification activities for the CEC shall be in accordance with Ameren Missouri's position on Regulatory Guide 1.58.

With regard to Section 8.2 of ANSI N45.2.13 - 1976 titled Disposition: The third sentence of item b is revised to read:

> Nonconformances to the contractual procurement requirements or Purchaser approved documents and which consist of one or more of the following shall be submitted to the Purchaser for approval of the recommended disposition prior to shipment when the nonconformance could adversely affect the end use of a module[1] or shippable component relative to safety, interchangeability, operability, reliability, integrity, or maintainability:
>
> 1) Technical or material requirement is violated;
> 2) Requirement in Supplier documents, which have been approved by the Purchaser, is violated;
> 3) Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework; and/or
> 4) The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

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:

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[1] A module is an assembled device, instrument, or piece of equipment identified by serial number or other identification code, having been evaluated by inspection and/or test for conformance to procurement requirements regarding end use. A shippable component is a part of sub-assembly of a device, instrument, or piece of equipment which is shipped as an individual item and which has been evaluated by inspection and/or test for conformance to procurement requirements regarding end use.

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 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~~ or ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."

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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.
4. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

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.

REGULATORY GUIDE 1.146 **INITIAL ISSUE** **DATED 8/80**

Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants (Endorses ANSI N45.2.23-1978)

DISCUSSION:

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

With respect to Section 1.4 of ANSI N45.2.23-1978 titled Definitions: Definitions in this Standard which are not included in ANSI N45.2.10 shall be used: "Audit" which is included in this Standard and ANSI N45.2.10 shall be used as clarified in this Appendix under Regulatory Guide 1.74.

With respect to Section 2.2 of ANSI N45.2.23 - 1978 titled Qualification of Auditors: Subsection 2.2.1 references an ANSI B45.2 (presumed to be standard N45.2); therefore, Ameren Missouri shall comply with an alternate subsection 2.2.1 which reads:

> Orientation to provide a working knowledge and understanding of the Operating QA Manual, including the ANSI standards and Regulatory Guides included in this Appendix and Ameren Missouri's procedures for implementing audits and reporting results.

With respect to Section 2.3.4 of ANSI N45.2.23-1978, titled Audit Participation: Ameren Missouri shall substitute the following for this section:

> The prospective Lead Auditor shall demonstrate the ability to effectively implement the audit process and lead an audit team. This process is described in written procedures which provide for evaluation and documentation. A prospective Lead Auditor shall have participated in at least one nuclear oversight audit within the year preceding the individual's effective date of qualification.

With respect to Section 3.2 of ANSI N45.2.23 - 1978 titled Maintenance of Proficiency: Ameren Missouri shall comply with the requirements of this Section by defining "annual assessment" as one which takes places every 12 + or - 3 months and which uses the initial date of certification (not the calendar year) as the starting date for determining when such annual assessment is due. The combined time interval for any three consecutive assessment intervals shall not exceed 3.25 years.

With respect to Section 4.1 of ANSI N45.2.23 - 1978 titled Organizational Responsibility: Ameren Missouri shall comply with this Section with the substitution of the following sentence in place of the last sentence in the Section:

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The ~~Director~~ Manager, Nuclear Oversight; Supervisor, NOS; or Lead Auditor shall, prior to commencing the audit, assign personnel who collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

With respect to Section 5.3 of ANSI N45.2.23 - 1978 titled Updating of Lead Auditor's Records: Ameren Missouri shall substitute the following sentence for this Section:

> Records for each Lead Auditor shall be maintained and updated during the period of the annual management assessment as defined in Section 3.2 (as clarified).

With respect to Section 5.4 of ANSI N45.2.23 - 1978 titled Records Retention: Ameren Missouri shall substitute the following sentence for this Section:

> Qualification records shall be generated and maintained as required by OQAM Section 17 and by commitment to Regulatory Guide 1.88 (ANSI N45.2.9) as clarified in this Appendix.

In every case either identical or equivalent controls are provided in the sections of the referenced Standards and documents.

Dry Cask Storage System Quality Assurance Program

BACKGROUND

This Appendix is to define the quality program requirements for Callaway Energy Center's Dry Cask Storage System (DCSS). The Dry Cask Storage System in this document includes the Independent Spent Fuel Storage Installation (ISFSI) facility, activities supporting spent fuel dry cask loading, and the associated dry cask storage equipment.

Ameren Missouri is implementing a general license pursuant to 10 CFR 72.210 to store spent fuel in an approved Dry Cask Storage System at an onsite ISFSI facility. The Dry Cask Storage System must comply with the quality assurance requirements of 10 CFR 72 Subpart G, "Quality Assurance". This Appendix addresses the quality program requirements necessary to ensure compliance with 10 CFR 72 Subpart G through the use of existing Ameren Missouri Quality Assurance Program controls specified in the Callaway Energy Center Operating Quality Assurance Manual (OQAM). The quality program requirements to be applied to the Callaway Energy Center Dry Cask Storage System are based on the items or processes "importance to safety".

The quality assurance program requirements for the Dry Cask Storage System are divided into Important To Safety (ITS) categories using the graded approach described in NUREG/CR-6407 "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety". Each component of a Dry Cask Storage System is first identified as either "important to safety" (ITS) or "not important to safety" (NITS). Components classified as "not important to safety" are handled the same as "non-safety related".

As defined in 10 CFR 72.3, the important to safety functions of structures, systems, and components for the storage of spent fuel are:

- To maintain the conditions required to store spent fuel safely;
- To prevent damage to the spent fuel container during handling and storage; or
- To provide reasonable assurance that spent fuel can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

The Dry Cask Storage System structures, systems and components (SSC's) are classified "important to safety" (ITS A, B, or C) in Holtec International "Final Safety Analysis Report on the HI-STORM UMAX Canister Storage System" as follows:

a) Category A (ITS A) – Critical to safe operation

ITS A items include structures, systems and components whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary confinement leading to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.

b) Category B (ITS B) – Major impact to safety

ITS B items include structures, systems and components whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of an ITS B item, in conjunction with failure of an additional item, could result in an unsafe condition.

c) Category C (ITS C) – Minor impact on safety

ITS C items include structures, systems and components whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

1.0. ORGANIZATION

1.1. The Senior Vice President & Chief Nuclear Officer has overall responsibility and authority for the DCSS quality program.

1.2. Overall implementation of the quality program requirements for the Dry Cask Storage System and spent fuel dry cask loading operation resides with each Callaway Energy Center Director for their area of responsibility.

1.3. The ~~Director~~ Manager, Nuclear Oversight, has the responsibility for verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

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2.0. QUALITY ASSURANCE PROGRAM

2.1. The Quality Assurance Program for DCSS complies with the applicable sections of the Callaway Energy Center OQAM, the requirements of Title 10, Code of Federal Regulations, Part 72, Subpart G, "Quality Assurance Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste", and applicable industry codes and standards as identified in the DCSS Final Safety Analysis Report.

2.2. The Ameren Missouri Quality Assurance Program controls established in this manual to meet 10 CFR 50 Appendix B shall be applied to those portions of the Dry Cask Storage System that are classified as ITS A with additional requirements for record retention specified in section 17 of this Appendix.

2.3. References throughout this document to "Callaway Plant", "Callaway Energy Center", "station", or "plant", includes the Dry Cask Storage System structures, systems, and components, unless indicated otherwise. The Dry Cask Storage System includes the Independent Spent Fuel Storage Installation (ISFSI) facility, activities supporting spent fuel dry cask loading, and the associated dry cask storage equipment.

2.4. The NRC Certificate of Compliance (CoC) holder is responsible for the quality assurance requirements as applied to the design, fabrication, and testing of a spent fuel storage cask until possession of the spent fuel storage cask is transferred to the general licensee. The general licensee and the certificate holder are also simultaneously responsible for these quality assurance requirements through the oversight of contractors and subcontractors.

2.5. The quality assurance program shall be documented by written procedures or instructions and the program shall be carried out in accordance with these procedures throughout the period during which the DCSS is licensed or the spent fuel storage cask is certified.

2.6. All necessary training related to DCSS shall be provided. This training will be administered as part of the Callaway Energy Center Training Program.