CALLAWAY NUCLEAR PLANT

OPERATING QUALITY ASSURANCE MANUAL

(OQAM)

Rev. 027

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OQAP POLICY/INTRODUCTIONS

It is the policy of Union Electric Company (AmerenUE[1]) to develop, implement, and maintain an Operating Quality Assurance Program (OQAP) for Callaway Plant as required by provisions of a Nuclear Regulatory Commission (NRC) operating license and amendments thereto. The QA Program shall be applied to those activities affecting quality (safety-related) regarding structures, systems, and components necessary to assure:

1) The integrity of the reactor coolant pressure boundary,

2) The capability to shut down the reactor and maintain it in a safe shutdown condition, or

3) The capability to prevent or mitigate the consequences of accidents which could result in off-site exposures comparable to the guideline exposures of NRC Regulations 10 CFR 100.

These activities include operational testing, operations, maintenance, refueling, and modifications. Control over these activities as they affect quality shall be to the extent consistent with their importance to safety.

AmerenUE[1] has established an organization to implement the OQAP as documented in policies, manuals, and procedures. Specific OQAP requirements and corresponding organizational responsibilities are specified in the Operating Quality Assurance Manual (OQAM).

The OQAP involves the proper functioning of many disciplines and activities. Functions, departments, groups, committees and other organizational subdivisions shall control activities affecting quality through implementation of appropriate written procedures or instructions. Documentation shall be maintained to provide objective evidence of program implementation and effectiveness.

The OQAP shall comply with 10 CFR 50, Appendix B - "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" and follow the guidance of the Regulatory Position of Regulatory Guide 1.33. Clarifications, alternatives, and exceptions to this Regulatory Position are described in Appendix A of the OQAM. An eighteen (18) section format is employed with a discussion of how corresponding criteria of 10 CFR 50, Appendix B are satisfied.

The responsibility for formulating, authorizing, and assuring implementation of the AmerenUE[1] OQAP rests with the Senior Vice President and Chief Nuclear Officer. The policy and resultant QA Program are mandatory for

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[1] Effective December 31, 1997, Union Electric (UE) and Central Illinois Public Services Company (CIPSCO) completed a merger into a new operating company – Ameren Corporation. With this merger, some reorganization has occurred with several of the functions and divisions previously within Union Electric being redistributed either to AmerenUE (new operating company for the power generation portion of the company previously within UE) or Ameren Services (new operating company for the non-power generation side of the newly created Ameren Corporation).

Callaway Plant operational phase activities. Accordingly, personnel shall be made cognizant of QA Program requirements and responsibilities applicable to their individual activities and interfaces.

By the signatures of the undersigned, this OQAM is approved and those Ameren[1] personnel whose activities are within the purview of the OQAP are responsible for its implementation in accordance with the requirements described herein.

Les H. Kanuckel — 5/11/09

Les H. Kanuckel
Manager, Quality Assurance

Date

Adam C. Heflin — 5/13/09

Adam C. Heflin
Senior Vice President and Chief Nuclear Officer

Date

1. ORGANIZATION

1.1 AmerenUE 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). AmerenUE 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 Plant 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. He is responsible for directing activities within Nuclear Generation[3] which support the engineering, construction, testing, and operation of the Callaway Plant and coordinating support activities performed by others who are not under his direct administrative control. He has corporate responsibility for the operation and physical control of the Callaway Plant. He reports to the President and Chief Executive Officer – AmerenUE, who in turn reports to the Chairman and Chief Executive Officer. The Chairman and Chief Executive Officer has ultimate responsibility for the Callaway Plant. (**COMN** 371)

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 also directs the Supervising Engineer, Fuel Cycle Management, who is responsible for aspects of the nuclear fuel cycle including procurement, enrichment, fabrication, reprocessing, high level waste management, and fuel economics studies.

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[3] 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 Manager, Quality Assurance reports to the Senior Vice President and Chief Nuclear Officer (CNO) on Quality Assurance Program and administrative matters. The Manager QA has direct access to the Senior Vice President and CNO on significant QA matters. The Manager, Quality Assurance 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 AmerenUE including Program development, maintenance, and verification of implementation; and providing a constant independent overview of nuclear plant safety. The Manager, Quality Assurance has sufficient authority, organizational freedom, and independence to effectively assure compliance with OQAP requirements as they control Callaway Plant 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 Manager, Quality Assurance, Supervising Engineers, QA, 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 Manager, Quality Assurance are at least equivalent to those specified in ANSI/ANS-3.1-1978, "Selection and Training of Nuclear Power Plant Personnel," Sections 4.2.4 and 4.4.5. The Manager, Quality Assurance is located at Callaway Plant and provides technical direction and administrative guidance, to the Quality Assurance staff. (**COMN** 1790, 1799, 2012)

1.4 The Manager, QA directs Supervising Engineers QA, 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 QA staff assure implementation of the OQAP. The Manager, Quality Assurance is responsible to evaluate Callaway Plant operations from a safety perspective.

1.4.1 The Quality Control Group reports to the QA Manager. They are responsible for work activities, inspections, receipt inspections as described in Section 7.0 and non-destructive examinations.

1.5 The Manager, Supervisor QC and Supervising Engineers QA in the Quality Assurance 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 Plant Director 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 Quality Assurance Department. The Manager, Quality Assurance has no duties or responsibilities unrelated to QA that would prevent his full attention to QA matters.

1.6 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. (**COMN** 1790, 2255)

1.7 The Vice President, Nuclear Operations reports directly to the Senior Vice President and Chief Nuclear Officer and has overall responsibility for site activities and supervision of plant operations, business operations, and training personnel.

1.8 The Vice President, Engineering, reports directly to the Senior Vice President and Chief Nuclear Officer, and has direct responsibility for, and provides supervision of Nuclear Engineering (Plant Engineering and Engineering Services) and other technical support activities.

1.8.1 The Manager, Plant Engineering and Manager Engineering Services report directly to the Vice President, Engineering, and direct staffs of assistant managers, supervisors, and supervising engineers, whose primary function is to provide technical support to the operation of Callaway Plant. This support includes, but is not necessarily limited to design; modification; configuration control; system and equipment performance; reliability, and testing; technical programs administration; incore fuel management; reactor design and radiological engineering; and contractor support. They control those activities and implement the OQAP through the assistant managers Superintendents, Design Engineering, System Engineering, Technical Support Engineering and Major Projects. Within the Plant Engineering organization, NDE Specialists perform inspections or examinations which provide quality verification of Nuclear Engineering work activities. They perform radiographic testing of welds when required by ASME Section III, B 31.1 or Section XI Code. They also perform UT examinations when required by Section XI repair and replacement plans.

1.9 The Manager, Regulatory Affairs reports directly to the Vice President, Engineering, and has overall responsibility for coordination of licensing, site Access Control, Security, Emergency Preparedness, Performance Improvement and Regional Regulatory Affairs.

1.9.1 The Superintendent, Protective Services is responsible for security, emergency preparedness, and industrial safety program. The Emergency Preparedness staff has overall responsibility for the development and maintenance of the Emergency Preparedness Program. This includes onsite and offsite emergency preparedness, coordination of the Plant Radiological Emergency Response Plan with State and local emergency plans, and the planning and execution of emergency drills and emergency plan exercises.

1.9.2 The Superintendent, Protective Services, supervises the Security staff and has overall responsibility for development, maintenance, and implementation of the Security Plan.

1.9.3 The Superintendent, Protective Services is responsible for the Fitness for Duty, Access Authorization, and Medical Physical Programs.

1.10 The Plant Director reports to the Vice President, Nuclear Operations, and is responsible for the safe, legal and efficient operation and maintenance of the Callaway Plant. He has overall responsibility for the execution of administrative controls and the quality assurance program to assure safety. He is also responsible for implementing and maintaining the effectiveness of the ALARA program. The Plant ALARA Review Committee (PARC) provides oversight for the Callaway Plant ALARA program to ensure effective implementation and consistency with plant operation. The PARC responsibilities are defined in Radiation Protection procedures.

1.10.1 The Plant Director is the individual with the authority and responsibility of "plant manager" as described in technical specification administrative controls.

1.11 The Radiation Protection Manager, who reports to the Plant Director, supervises Radiation Protection staff and has responsibility for developing, implementing, and maintaining the Radiation Protection and ALARA programs.

1.11.1 The Superintendent, Performance Improvement reports directly to the Manager, Regulatory Affairs and is responsible for review of Operating Experience, Corrective Action Program administration, and other activities as assigned.

1.12 The Manager, Nuclear Operations reports directly to the Plant Director, and controls Plant functions and implements the OQAP through the Assistant Operations Managers and the Superintendent, Chemistry. He has the primary responsibility for reactor operation and safety, fire marshal monitoring and procedure development. (**COMN** 1799)

1.12.1 The Manager, Nuclear Operations or the Shift Assistant Operations Manager, respectively, meet the qualifications for "operations manager" or "assistant operations manager" as described in technical specification administrative controls. The on-shift Shift Manager is the individual having the qualifications, responsibility and authority of "Shift Supervisor" as described in technical specification administrative controls.

1.13 The Manager, Maintenance reports directly to the Plant Director and is responsible for the plant maintenance work activities. He controls maintenance activities through the Superintendents of Mechanical, Electrical, I&C and Facilities, and other staff.

1.13.1 The Manager, Planning, Scheduling, and Outages reports directly to the Plant Director and is responsible for planning and implementation of outages and planning and scheduling of work activities. The position controls outage activities through the Outage Manager and Superintendent, Work Management.

1.14 The Manager, Training reports directly to the Vice President, Nuclear Operations and is responsible for plant learning activities. General Quality Assurance indoctrination and training for Nuclear Generation is responsibility of the Training Department. The Quality Assurance Department is responsible for specific QA training as requested by Nuclear Generation organizations.

1.15 The Manager, Business Operations reports to the Vice President, Nuclear Operations and is responsible for organizational support, personnel development, administration, strategic planning, cost forecasting, status reporting and budget matters. The Manager, Business Operations also functions as the site contact for the Information Technology, Supply Chain Operations, and Human Resources corporate organizations and is responsible for providing oversight for the implementation of the Software Quality Assurance Program.

1.15.1 The Manager, Information Technology Customer Services - Field Operations reports to the Director, Operations, who reports to the Vice President, Information Technology, who in turn reports to the Ameren Services Senior Vice President – Administration. The Manager, Information Technology Customer Services - Field Operations is responsible for providing information technology services to Callaway Plant, and for implementing the Software Quality Assurance Program elements that relate to information technology.

1.16 The Manager, Supply Chain Operations reports directly to the Ameren Services Vice President-Supply Services who in turn reports to the Ameren Services Senior Vice President - Administration. The Manager, Supply Chain Operations is responsible for procurement of materials, systems, components, and services (excluding engineering services and certain nuclear fuel cycle-related procurements) not delegated to others which are employed in support of Callaway Plant.

1.17 The Manager, Human Resources (HR) Business Services reports to the Vice President, HR Business Services, who in turn reports to the Ameren Senior Vice President and Chief HR Officer, and is responsible for assisting in the areas of industrial relations and other matters under the guidance of Corporate, AmerenUE and Nuclear Generation policies.

1.18 The Manager, Missouri Substation / Relay Construction & Maintenance reports to the Ameren Services Vice President-Energy Delivery Technical Services who in turn reports to the Ameren Services Senior Vice President – Administration and is responsible for providing qualified engineers, technicians and equipment to maintain Callaway Plant relays. The Ameren Services Vice President-Energy Delivery Technical Services also provides engineering and other support services when requested by the Senior Vice President and Chief Nuclear Officer.

1.19 The Manager, Distribution Operating Department reports to the AmerenUE Vice President, Energy Delivery – Distribution Services who in turn reports to the AmerenUE Senior Vice President – Missouri Energy Delivery and is responsible for providing qualified engineers, technicians and equipment for Callaway Plant battery testing and technical support.

1.20 The Vice President, Transmission reports to the Ameren Services Senior Vice President – Administration, and is responsible for directing all activities related to the operation and planning of Transmission facilities.

1.21 Other Ameren Services or AmerenUE 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.

1.22 Safety review committees shall be established to provide an independent review of those items required below. These committees are the Onsite Review Committee (ORC -- refer to Section 1.22.1 and the Nuclear Safety Review Board (NSRB -- refer to Section 1.22.2)

1.22.1 The ORC shall function to advise the Plant Director on all matters related to nuclear safety. The Plant Director shall be Chairman of the ORC.

1.22.1.1 ORC membership shall include a minimum of six additional members appointed by the Chairman and an additional member appointed by the Manager, Quality Assurance. Selected members shall include, at a minimum, management responsible for the following areas of expertise:

a) Operations
b) Maintenance
c) Chemistry
d) Radwaste
e) Health Physics
f) Nuclear Engineering
g) Quality Assurance

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

1.22.1.3 The alternate for Quality Assurance is appointed by the Manager, Quality Assurance.

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

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

1.22.1.6 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 and the NSRB.

1.22.1.7 The ORC shall be responsible for:

a) Review of all Administrative Procedures;

b) Review of 10CFR50.59 evaluations for:

- procedures,
- change to procedures, equipment, systems or facilities, and
- tests or experiments completed under the provision of 10CFR50.59 to verify that such actions did not require a license amendment.

c) Review of proposed procedures and changes to procedure, equipment, systems or facilities which may involve a license amendment as defined in 10CFR50.59 or involves a change in Technical Specifications;

d) Review of proposed test or experiments which may involve a license amendment as defined in 10CFR50.59 or requires a change in Technical Specifications;

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 and to the NSRB;

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 and shall submit recommended changes to the NSRB;

j) Review of the Radiological Emergency Response Plan and shall submit recommended changes to the NSRB;

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 Plant Director and to the NSRB;

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

n) Investigations or analysis of special subjects as requested by the Chairman of the NSRB;

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

p) Review of the Fire Protection Program and submitting recommended changes to the NSRB.

1.22.1.8 The ORC shall:

a) Recommend in writing to the Plant Director approval or disapproval of the PROCESS CONTROL PROGRAM and the OFFSITE DOSE CALCULATION MANUAL and changes thereto, considered under Sections 1.22.1.7.a and 1.22.1.7.k above.

b) Recommend in writing to the Plant Director approval or disapproval of other Administrative Procedures considered under Section 1.22.1.7.a above.

c) Recommend in writing to the Plant Director, Callaway Plant approval or disapproval of items considered under Sections 1.22.1.7.b through 1.22.1.7.e, 1.22.1.7.i, 1.22.1.7.j, 1.22.1.7.k, 1.22.1.7.l, 1.22.1.7.o, and 1.22.1.7.p above.

d) Render determinations in writing with regard to whether or not each item considered under Sections 1. 22.1.7.b through 1.22.1.7.e, and 1.22.1.7.m, above, require a license amendment per 10 CFR 50.59; and

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

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

1.22.2 The NSRB shall function to provide independent review and audit of designated activities in the areas of:

a) Nuclear power plant operations,
b) Nuclear engineering,
c) Chemistry and radiochemistry,
d) Metallurgy,
e) Instrumentation and control,
f) Radiological safety,
g) Mechanical and electrical engineering, and
h) Quality assurance practices

1.22.2.1 The NSRB shall report to and advise the Senior Vice President and Chief Nuclear Officer on those areas of responsibility stated in OQAM Sections 1.22.2.10 and 18.8.

1.22.2.2 The NSRB shall be composed of at least the following members:

Chairman:	Manager, Regulatory Affairs
Member:	Manager, Engineering Services
Member:	Manager, Quality Assurance
Member:	Plant Director
Member:	Manager, Nuclear Operations

1.22.2.3 Additional members and Vice Chairman may be appointed by the Chairman.

1.22.2.4 The NSRB members shall hold a Bachelor's degree in an engineering or physical science field, or equivalent experience, and a minimum of 5 years of technical experience of which a minimum of 3 years shall be in one or more of the disciplines of Section 1.22.2. NSRB shall be composed of no less than five persons.

1.22.2.5 All alternate members shall be appointed in writing by the NSRB Chairman to serve on a temporary basis; however, no more than two alternates shall participate as voting members in NSRB activities at any one time.

1.22.2.6 Consultants shall be utilized as determined by the NSRB Chairman to provide expert advice to the NSRB.

1.22.2.7 The NSRB shall meet at least once every 6 months.

1.22.2.8 The quorum of the NSRB necessary for the performance of the NSRB review and audit functions herein, and shall consist of not less than a majority of the members or duly appointed alternates. No more than a minority of the quorum shall have line responsibility for operation of the unit.

1.22.2.9 Minutes of each NSRB meeting, including reports of reviews encompassed by Section 1.22.2.10, shall be prepared, approved and forwarded to the Senior Vice President and Chief Nuclear Officer within 15 working days following each meeting.

1.22.2.10 The NSRB shall be responsible for the review of:

a) The 10 CFR 50.59 evaluations for:

- changes to procedures, equipment, systems or facilities; and
- tests or experiments completed under the provision of Section 10 CFR 50.59, to verify that such actions did not require a license amendment;

b) Proposed changes to procedures, equipment, systems or facilities which involve a license amendment as defined in 10 CFR 50.59;

c) Proposed tests or experiments which involve a license amendment as defined in 10 CFR 50.59,

d) Proposed changes to Technical Specifications or the Operating License;

e) Violations of Codes, regulations, orders, Technical Specifications, license requirements, or of internal procedures or instructions having nuclear safety significance;

f) Significant operating abnormalities or deviations from normal and expected performance of unit equipment that affect nuclear safety;

g) ALL REPORTABLE EVENTS;

h) All recognized indications of an unanticipated deficiency in some aspect of design or operation of structures, systems or components that could affect nuclear safety; and

i) Reports and meeting minutes of the ORC.

1.23 INDEPENDENT TECHNICAL REVIEW

1.23.1 Independent technical reviews shall be used to examine plant operating characteristics, NRC issuances, industry advisories, REPORTABLE EVENTS and other sources of plant design and operating experience information, including plants of similar design, which may indicate areas for procedures, equipment modifications, maintenance activities, operations activities or other means of improving plant safety.

1.23.2 Several personnel performing independent technical reviews will be required to have a degree in engineering or related science and at least 2 years of professional level experience in their field.

1.23.3 Independent technical reviews shall be used to observe and verify that activities are performed correctly and that human errors are reduced as much as practical. Personnel performing independent technical reviews should be independent of performance function, signoff function, and the plant management chain while performing this oversight activity.

1.23.4 The results of independent technical reviews will be periodically transmitted to appropriate line and senior management, the Nuclear Safety Review Board, and the Senior Vice President and Chief Nuclear Officer for review and/or action and advise management on the overall quality and safety of operations.

1.23.5 Conditions adverse to quality and recommendations identified during the performance of independent technical reviews shall be subject to the requirements of OQAM Section 15 and 16.

2. QUALITY ASSURANCE PROGRAM

2.1 AmerenUE has established an OQAP which controls activities affecting quality. The Program encompasses those quality activities necessary to support the operating phase of the Callaway Plant and shall comply with 10CFR50, 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. 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 AmerenUE for establishing and implementing the Quality Assurance Program requirements.
(**COMN** 1799, 2974)

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 position guides 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. (**COMN** 1788)

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) and 10 CFR 50.71.

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 Manager, Quality Assurance and the Manager, Engineering Service 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. (**COMN** 1824, 1853, 20200)

2.5 The OQAP shall be implemented throughout the operating life of the Callaway Plant. 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.
(**COMN** 1879, 1947)

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: (**COMN** 1788, 1879)

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.

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 Manager, Quality Assurance. (**COMN** 1823)

3) Callaway Plant Operating Procedures

The Callaway Plant 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. (**COMN** 1947)

Administrative procedures which apply to the entire staff, and revisions thereto, shall be reviewed by the Callaway Plant Onsite Review Committee (ORC). The final approval of the PROCESS CONTROL PROGRAM and the OFFSITE DOSE CALCULATION MANUAL, and revisions thereto shall be by the Plant Director. The final approval of other Administrative Procedures and revisions thereto shall be by the Plant Director.

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 AmerenUE may employ the safety-related services of architect engineers, NSSS suppliers, fuel fabricators, constructors, and others, which provide or augment AmerenUE 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 AmerenUE OQAP. The quality assurance program of outside organizations shall be subject to review, evaluation and acceptance by the Quality Assurance Department prior to the initiation of safety-related work. Vendor programs and procedures shall also meet AmerenUE's commitment to USNRC Generic Letter 83-28. (**COMN** 679, 1746, 1787, 2460)

2.8 Disputes which may arise between QA 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 Callaway Plant personnel are described in Section 13.2 of the Callaway-SA FSAR. The training of permanent Plant personnel is the responsibility of the Manager, 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 AmerenUE'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.
(**COMN** 1795, 1916, 2188)

2.10.1 A retraining and replacement training program for the unit staff shall be maintained under the direction of the Manager, 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 shall meet or exceed the requirements and recommendations of Section 5 of ANSI/ANS 3.1-1978.

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 Manager, Quality Assurance 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. He 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. (**COMN** 1799)

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 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 AmerenUE management representatives. In addition, various reports are issued to the Senior Vice President and Chief Nuclear Officer on a periodic basis to assist his independent assessment of the OQAP (e.g., semiannual trend analysis, and periodic QA audit reports). (**COMN** 1799, 1800)

2.13 Implementation of OQAP controls over activities affecting quality assures achieving the objective of the AmerenUE OQAP to provide management with adequate confidence that activities affecting quality regarding the design, installation, modification, and operation of the Callaway Plant 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 AmerenUE Management has established standards of performance, which exceed those set forth by the Regulatory Agencies. As a management initiative in this area, AmerenUE 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 AmerenUE 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 QA 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.

2.15 COLA Development

The OQAM provides the basis for control and performance of safety-related and quality-related activities associated with combined Construction and Operating License Application (COLA) activities. Controls, as currently stated in the OQAP, will be extended to associated activities commensurate with their importance for safety. These QA program controls remain effective until the Nuclear Regulatory Commission approves a Quality Program specific to the new unit, and associated implementing procedures are in place.

3. DESIGN CONTROL

3.1 The design, modification, addition, and replacement of safety-related structures, systems, and components shall be controlled to assure appropriate design control measures are implemented. Procedures, Design Guides and Policies shall establish requirements; assign responsibilities; and provide control of activities regarding design in a planned, controlled, and orderly manner.
(**COMN** 1850, 2070, 2072, 2096, 2168, 2185, 2187, 2188, 2222, 1864, 2183, 2974)

3.2 The Plant design is defined by those NSSS, A/E and selected supplier design drawings and specifications which illustrate the general arrangement and details of safety-related structures, systems, and components and define the requirements for assuring their continued capability to perform their intended operational or safety design function. (**COMN** 2188)

3.3 As the result of operating experience, or as necessitated by regulatory requirements, Plant systems and equipment may have to be changed. Design changes and configuration changes are modifications in Plant design or operation and are accomplished in accordance with requirements and limitations of applicable codes, standards, specifications, licenses, and predetermined safety restrictions. (**COMN** 2664)

3.3.1 A design change is a modification where a function changes or a new failure mode is introduced.

3.3.2 A configuration change is a change in configuration that can be either physical or in documentation that preserves the design functions and does not introduce new failure modes. This includes a change to the configuration of a replacement item which is not a like-for-like replacement of the present design.

3.4 Maintenance or modifications which may affect functioning of safety-related structures, systems, or components shall be performed in a manner to ensure quality at least equivalent to that specified in original design bases and requirements, materials specifications and inspection requirements. A suitable level of confidence in structures, systems, or components on which maintenance or modifications have been performed shall be attained by appropriate inspection and performance testing.
(**COMN** 1850, 2100, 2101, 2105, 2111)

3.5 Design, including related procurement efforts, may be carried out by Nuclear Engineering, Fuel Cycle Management Department, or outside organizations. (**COMN** 2184, 2188, 2222)

3.6 Control of design shall be specified in procedures, design guides and policies. These documents shall include instructions for defining typical design requirements; communicating needed design information across internal and external interfaces; preparing, reviewing, approving, releasing, distributing, revising, and maintaining design documents; performing design reviews and reviews of design; and controlling field changes.
(**COMN** 2071, 2074, 2164, 2188, 2221, 2222, 2223, 2225, 2243)

3.7 Design control shall involve measures which include a definition of design requirements; a design process which includes design analysis and delineation of requirements through the issuance of drawings, specifications, and other design documents (design outputs); and design verification or review of design to verify the adequacy of design or to become acquainted with design features. (**COMN** 2164)

3.8 Design requirements and changes thereto shall be identified, documented, reviewed and approved to assure incorporation of appropriate quality standards in design documents and to control departures from these standards. Modifications to structures, systems, and components shall consider, as a minimum, the design bases described in the Callaway-SP and the Callaway-SA FSAR and the Technical Specifications. Design criteria documents, which are newly issued or modified in the course of design or design/configuration changes, shall be reviewed by a Supervising Engineer in the Engineering Services Department for seismic and quality group classification and selection of quality standards. Design criteria documents consist of original Plant design criteria, system descriptions and other documents defining design input which changes the Plant as described in the FSAR. The design input shall be specified on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.
(**COMN** 1850, 2188, 2203, 2204, 2205, 2207, 2222, 2664)

3.9 Design activities shall include the correct translation of regulatory requirements and design bases into specifications, drawings, written procedures, and instructions (design outputs) that define the design. Design analyses regarding reactor physics, stress, thermal, hydraulic, radiation, and accident analyses used to produce design output documents, shall be sufficiently detailed to permit an independent review by a technically qualified person. Analyses shall specify purpose, method, assumptions, design requirements, references, and units. When computer codes are employed, only codes that have been verified and/or validated (V&V) shall be used in safety-related design and design/configuration changes.
(**COMN** 2207, 2209, 2210, 2212, 2974, 2170)

3.10 Procedures shall specify requirements for the review and approval of design changes by the organizations or individuals that performed the original design or Engineering Services. Design control activities, including design/configuration changes, may be delegated to others provided they have access to background and technical information. Design control measures for design revisions shall be commensurate with those applied to the original design. (**COMN** 2165, 2166, 2168, 2169, 2243)

3.11 Design activities shall also include: 1) reviewing the applicability of standards; 2) reviewing commercial or previously approved materials, parts or equipment for suitability of application; 3) reviewing the compatibility of materials used in the design; 4) reviewing the accessibility of equipment and components for inservice inspection, maintenance, and repair; 5) specifying criteria for inspection and test/retest; and 6) reviewing and approving procedures for special processes. (**COMN** 1934)

3.12 The design process shall establish controls for releasing design documents which are technically adequate and accurate in a controlled manner with a timely distribution to responsible individuals and groups. Design control procedures govern the design documents that reflect the commitments of the FSAR, which include, but are not limited to, calculations, computer programs, FSAR system descriptions, SAR when used as a design document, and drawings including piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Engineering change control procedures also establish controls for maintaining other as-built drawings, such as flow diagrams, and for maintaining software configuration. Procurement specifications are maintained in accordance with Section 4. Documents are controlled and used in accordance with Section 6.
(**COMN** 2164, 2168, 2188, 2220, 2243)

3.13 The design interfaces between AmerenUE organizations performing work affecting quality of design and between AmerenUE and outside organizations shall be identified and controlled by procedures. These procedures shall address control of the interface, responsibilities, lines of communication, and documentation of internal and external interface activities. (**COMN** 2164, 2188, 2217, 2218, 2219, 2223, 2231)

3.14 Design changes and calculations shall include design verification. Configuration change shall include a design review. Design verification assures that design is adequate and meets specified design inputs. Design control procedures shall specify requirements for the selection and accomplishment of a design Verification program. The program depth shall be commensurate with the importance of the system or component to safety, complexity of the design, and similarity of the design to previously proven designs. Design verification shall be conducted in accordance with procedures, which identify the responsibilities of the verifier and the documentation required and which, through adherence to the procedures, provide for the identification of the areas, features, and pertinent considerations to be verified. Design verification shall be by either design review, alternate calculation, qualification testing, or by a combination of these. Where alternate calculations are performed to verify the correctness of a calculation, a review shall be performed to address the appropriateness of assumptions, input data, and the code or other calculation method used. AmerenUE shall perform "reviews of design" of selected documents for subcontracted design to become familiar with design features. An independent third-level review must be employed as an additional verification when AmerenUE judges that the design involves unique or special design features. The organization performing design shall have the responsibility for design control unless specified otherwise. Design verification shall be performed by competent personnel other than those who performed the original design and who shall not have specified a singular design approach, have ruled out certain design considerations, or have established the design inputs for the particular design aspect being verified. A designer's supervisor may perform design verification when he is the only technically qualified individual and in such instances the need for design verification by the designer's immediate supervisor shall be individually documented and approved in advance by the supervisor's management. Quality Assurance Department audits shall examine the frequency and the effectiveness of use of supervisors as design verifiers to guard against abuse. (**COMN** 1934, 2182, 2209, 2234, 2188, 2227, 2231)

3.15 Design verification, if other than by qualification testing of a prototype or lead production unit, shall be completed prior to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing the justification for this action is documented and the portions of the design output documents based on the unverified data are appropriately identified and controlled. Without verification, site activities associated with a design or design change must not proceed past the point where the installation would become irreversible (i.e., require extensive demolition and rework). The design verification shall be complete prior to relying upon the component, system, or structure to perform its safety-related function. (**COMN** 1934, 2227)

3.16 Action shall be initiated to correct errors found in the design process. Errors and deficiencies identified in approved design documents shall be documented and the process of their correction (i.e., review and approval) shall be controlled. These actions shall assure that changes to design or installed components are controlled. (**COMN** 2188, 2172)

3.17 Requests for design/configuration changes affecting safety-related structures, systems, and components may be originated by Nuclear Generation personnel. Design changes shall be processed by Engineering. Design/configuration changes engineered by Nuclear Engineering organizations shall be the responsibility of Nuclear Engineering. Design/configuration changes engineered by the Fuel Cycle Management Department shall be the responsibility of Fuel Cycle Management.

3.18 Independent of the responsibilities of the design organization, the requirements of the Onsite Review Committee (ORC) and the Nuclear Safety Review Board (NSRB) as defined in OQAM Section 1.0 shall be satisfied.

Safety Related Design changes shall be reviewed by the ORC and approved by the Plant Director. In addition, design/configuration changes, which require a change in the Callaway Plant Technical Specifications or a License Amendment per 10CFR50.59 require review and approval by the NSRB and the Nuclear Regulatory Commission prior to implementation.

When design is performed by an outside organization, AmerenUE shall perform or coordinate a review of the design for operability, maintainability, inspectability, FSAR commitment compatibility, test and inspection acceptance criteria acceptability, and design requirements imposed by Plant generating equipment.

3.19 10CFR50.59 evaluations, which consider the effect of the design as described in the design documents, shall be performed by the responsible AmerenUE engineering organization or outside organization(s). These evaluations shall include the basis for the determination that the design/configuration change does not involve License Amendment. As deemed necessary by the evaluating organization, detailed analyses shall be performed to support the bases of 10CFR50.59 evaluations. All 10CFR50.59 evaluations are submitted to the ORC. Changes involving the substitution of equivalent hardware require the 10CFR50.59 process (in addition to the appropriate requirements of this OQAM) to assure that the design requirement changes are consistent with and do not alter the design criteria specified in existing design documents. When an outside organization performs the 10CFR50.59 process or prepares design documents under its QA program, review and approval per ANSI N45.2.11 will be included. AmerenUE will approve all outside organizations' design documents and 10CFR50.59 evaluations, and will perform appropriate reviews necessary for final approval.

3.20 Design/configuration changes which require an amendment of the license, shall be submitted on an application to the Nuclear Regulatory Commission for approval in accordance with 10CFR50.90.

3.21 Procedures and instructions related to equipment or systems that are modified shall be reviewed and updated in accordance with Appendix A to this OQAM (Regulatory Guide 1.33, Section 5.2.15 of ANSI N18.7), to reflect the modification prior to placing the equipment or systems in operation to perform safety-related functions. Plant personnel shall be made aware of changes affecting the performance of their duties through procedure revisions, or specific training in the operation of modified equipment or systems, or other appropriate means. (**COMN** 1911, 2164)

3.22 Records of design and configuration control activities are maintained in accordance with Section 17. (**COMN** 2039, 2132, 2173)

3.23 Drawings shall be prepared under a drawing control system which provides for checking methods and review and approval requirements. Drawings shall be subject to reviews by the responsible design organization for correctness, conformance to design criteria, and compliance with applicable codes and standards.

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. (**COMN** 679, 975, 1876, 1887, 1875, 3541, 3548)

4.2 Written procedures shall include controls, as applicable, for preparation, content, review, approval, and processing of the following related procurement documents: (**COMN** 3559)

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. (**COMN** 3560)

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 AmerenUE. 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. (**COMN** 3572, 3580, 3582, 3584, 3607, 3874)

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 (**COMN** 1892, 3572, 3582, 3584)

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 Quality Assurance Department; Nuclear Engineering; Fuel Cycle Management Department; or the unit staff. (**COMN** 1875)

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. (**COMN** 975, 1876)

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. (**COMN** 1876)

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. (**COMN** 1864, 1890, 2416, 3550, 3551, 3552)

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. When procuring commercial grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, such accreditation may be accepted in lieu of procuring such services from a supplier with a QA Program consistent with ANSI N45.2-1977, provided all the following are met:

   - The accreditation is to ANSI/ISO/IEC 17025.
   - The accrediting body is either the National Voluntary Laboratory Accreditation Program (NVLAP), or the American Association for Laboratory Accreditation (A2LA), as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).

- The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges and uncertainties.
- The procurement documents impose additional technical and administrative requirements, as necessary, to satisfy AmerenUE QA program and technical requirements.
- The procurement documents require reporting as-found and as-left calibration data, and identification of the standards used during calibration. (**COMN** 1888, 1890, 3542, 3550, 3553, 42668)

3) Requirements for supplier surveillance, audit, and inspection including provisions for AmerenUE or agent access to facilities and records and for identification of witness and hold points. (**COMN** 1890, 3550, 3555, 3573, 3582, 3867, 3874)

4) Requirements for extending applicable requirements of AmerenUE procurement documents to lower-tier suppliers and subcontractors. These requirements shall include right-of-access to subsupplier facilities and records by AmerenUE. (**COMN** 1890, 3542, 3550, 3554, 3555)

5) Requirements for suppliers to obtain AmerenUE approval of nonconformances to procurement document requirements dispositioned "use-as-is" and "repair" and conditions of their disposition including identification of those subject to AmerenUE approval prior to further processing. (**COMN** 3550, 3558, 3597)

6) Applicability of 10 CFR 21 reporting requirements. (**COMN** 3484)

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. (**COMN** 1890, 2132, 3550, 3556, 3574)

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 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. (**COMN** 3559, 3560, 3562, 3563)

4.10 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 4.10.1, 4.10.2, 4.10.3, and 4.10.4: (**COMN** 3563, 3564, 3567, 3568, 3569)

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

4.10.1 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. (**COMN** 3560)

4.10.2 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. (**COMN** 3560)

4.10.3 The Quality Assurance 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. (**COMN** 3560)

4.10.4 The Fuel Cycle Management Department shall evaluate bids or proposals for fuel cycle goods or services in the above areas. (**COMN** 3560)

4.11 Bids or proposals with alternates or exceptions identified in Section 4.10 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. (**COMN** 3560, 3561, 3567, 3568, 3570)

4.12 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.

4.13 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. (**COMN** 3563)

4.14 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. (**COMN** 975, 3543, 3548, 3563, 3575, 42587)

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 The activities affecting quality associated with the operating phase shall be accomplished and controlled by: (**COMN** 1830, 1858, 1867, 1916, 1948, 2073, 2074, 2091, 2974)

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 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 Callaway Plant 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. (**COMN** 1833, 1830)

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 Plant Director 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. Procedures other than Administrative Procedures shall be approved by the appropriate Department Head as designated in writing by the Vice President, Nuclear Operations. The Plant Director shall approve the PROCESS CONTROL PROGRAM and the OFFSITE DOSE CALCULATION MANUAL. The Plant Director shall approve other Administrative Procedures and Radiological Emergency Response Plan implementing procedures. The Superintendent, Protective Services, 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 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 Plant Director. 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 Plant Director.

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 10CFR50.59. 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 Plant Director.

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. **(CTSN 2783)**

5.6.4 Each review shall include a determination of whether or not a license amendment is involved. Pursuant to Section 50.59, 10 CFR, NRC approval of items involving license amendments shall be obtained prior to the Plant Director, approval for implementation; and

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 Plant Director. 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 Plant Director, ORC and/or NSRB 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.

6. DOCUMENT CONTROL

6.1 Documents and their revisions which control all activities affecting safety-related structures, systems, and components shall be prepared, reviewed by knowledgeable individuals, and approved by authorized personnel prior to release or issuance in accordance with written approved procedures. (**COMN** 1916, 1908)

6.2 Divisions, departments, and organizations responsible for OQAP implementing documents shall be required to provide the necessary review and approval for instructions, procedures, specifications, and drawings. Reviews and approvals shall assure that issued documents are adequate, authorized, include proper quality and technical requirements, and are correct for intended use. Individuals or groups responsible for preparing, reviewing, and approving documents and revisions thereto shall be identified in written procedures. Specifically, QC personnel shall review maintenance and modification procedures; [1] and QC personnel are responsible for the preparation of inspection procedures and/or checklists to support maintenance and modification activities. These reviews by QC personnel determine: (**COMN** 1908, 1916, 1917, 2262, 4616)

1) The need for inspection, identification of inspection personnel, and documentation of inspection results; and

2) That the necessary inspection requirements, methods, and acceptance criteria have been identified.

6.3 Changes to documents shall be reviewed and approved by the same function, department, group, or organization that performed the original review and approval; however, AmerenUE may assume or delegate this responsibility. The reviewing organizations shall have access to pertinent background information upon which to base their approval and shall have adequate understanding of requirements and intent of the original document. (**COMN** 1908, 1914, 1915, 2170)

6.4 Documents relating to the AmerenUE OQAP shall be controlled to an extent which considers the document type, its importance to safety, and the intended use of the document. The preparation, review, approval and revision of procedures, instructions and drawings shall adhere to the OQAP.

6.5 The controls governing the issuance of documents shall provide for the availability of documents at the point of use prior to commencing an activity and the prompt transmittal of approved changes for incorporation into subsequent revisions. Measures shall be established to prevent the inadvertent use of superseded documents. (**COMN** 1828, 1833, 1908, 1917)

6.6 Types of documents which shall be controlled include the FSAR, specifications, Operating Quality Assurance Manual, other manuals, procurement documents, policies, work authorizing documents, design documents (e.g., calculations, drawings, analyses) including documents related to computer codes, nonconformance reports, as-built drawings, the Callaway Plant Operating Procedures, and topical reports.

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[1] Work authorizing documents, such as Jobs may contain instructions to workers. However, Jobs are not considered "Maintenance procedures" which require QC review. When required, the assignment of inspection points for work authorizing documents is performed by QC or Work Management Department personnel based on established criteria. Work authorizing documents with assigned inspection points are routed to QC before work starts and after completion for tracking of inspection point assignments.

6.7 The issuance of controlled documents at the General Office and Callaway Plant is coordinated by the Regulatory Affairs and the Administration organizations. The Administration organization shall be responsible for assuring the issuance of controlled documents at the Plant Site. Regulatory Affairs shall be responsible for assuring the issuance of controlled documents at the General Office, and for transmittal of documents to the Administration organization for entry into the document control system.

6.8 Document control methods shall be defined consistent with the importance of the document to safety. Selected documents shall receive a control number. A serialized distribution list shall identify selected document holders by name and control number. Acknowledgment of receipt of selected documents, incorporation of revisions, and destroying or voiding of superseded documents shall be required by the distributor. In addition the distributing organization for documents controlled by a system of control numbers shall periodically compose a master list of the documents showing the effective revision date of each.

6.9 Procedures shall specify the requirements for the processing and maintenance of records. Procedures shall also be established to control instructions, procedures, and drawings governed by the OQAP. These procedural controls shall provide for the prompt transmittal of document revisions to work locations and the removal, destruction, or voiding of obsolete/superseded documents. The unit staff and other AmerenUE organizations shall assure that current documents are distributed to and used at the location where the prescribed activity is performed. It is recognized that, in certain instances, activities are controlled via the communication of documented procedural instructions from a remote location, (i.e., separated from the location where the prescribed activity is being performed). Identified, controlled copies of documents shall be used to perform an activity. Uncontrolled copies shall be identified. (**COMN** 1872, 2132, 2136, 2164)

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: (**COMN** 1875, 3541)

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 (**COMN** 3565)
4) Verification activities (surveillance, inspection, and audit) required by the purchaser
5) Control of nonconformances as described in Section 15 (**COMN** 3597, 3576)
6) Corrective action as described in Section 16
7) Material, equipment, and service acceptance
8) Control of quality assurance records (**COMN** 2416)
9) Audits of the procurement program as described in Section 18

7.2 AmerenUE 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: 1) 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 AmerenUE OQAP, do not require pre-award source evaluation or post-award audits which attest to their capability as a procurement source. (**COMN** 1891, 3564, 3565, 3596, 3874)

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 AmerenUE 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. (**COMN** 2337, 2977, 3564, 3874)

7.4 Code certified material may be obtained from an ASME accredited Material Manufacturer or Material Supplier for repair or replacement applications. However AmerenUE 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 Quality Assurance 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. (**COMN** 1891, 1894, 3564, 3565)

7.6 Procurement source selection and evaluations shall consider one or more of the following: (**COMN** 3565, 3566, 3604)

1) Experience of users of identical or similar products of the prospective supplier. NRC Licensee Contractor and Vendor Inspection Program (LCVIP) reports, ASME Certificates of Authorization (C of A), audit reports, AmerenUE records accumulated in previous procurement actions, and AmerenUE 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 LCVIP 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. (**COMN** 3564)

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. (**COMN** 3564)

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. (**COMN** 1892, 3571)

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 AmerenUE 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. AmerenUE hold and witness points shall be documented as early as practicable in the procurement process. (**COMN** 3572, 3573, 3580)

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. (**COMN** 3571, 3574)

7.11 Supplier monitoring activities may be performed by personnel from Quality Assurance, 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: (**COMN** 3565, 3584)

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. (**COMN** 2337)

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 AmerenUE receiving inspection activities. (**COMN** 975, 2337, 2416)

7.14 Acceptance of items and services shall include one or more of the following: (**COMN** 975, 1891, 1892, 3608)

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 on one or more of the following: (**COMN** 1892, 3565, 1876)

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 AmerenUE organization or their designated agent prior to acceptance. (**COMN** 1891, 1893, 3603, 3605, 3607)

7.16.1 For suppliers of commercial-grade calibration services with accreditation by a nationally recognized accrediting body, a documented review of the supplier's accreditation by the purchaser may be used in lieu of inspections or tests following delivery or in-process surveillances during performance of the service. This review shall include, at a minimum, all the following:

- The accreditation is to ANSI/ISO/IEC 17025.
- The accrediting body is either the National Voluntary Laboratory Accreditation Program (NVLAP), or the American Association for Laboratory Accreditation (A2LA), as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).
- The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges and uncertainties.

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. (**COMN** 1876, 3606)

7.18 Receiving inspection shall be performed by personnel certified to ANSI N45.2.6 - 1978, (as clarified in OQAM Appendix A Regulatory Guide 1.58) under the direction of the Quality Control organization. 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). (**COMN** 2483)

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. (**COMN** 2337)

7.20 Receiving inspection activities shall include: (**COMN** 975, 2337)

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. (**COMN** 2326, 2329, 2328)
5) Verifying that received items which do not conform to procurement documents are segregated (if practicable) and processed in accordance with Section 15. (**COMN** 2327)

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 AmerenUE. (**COMN** 3608)

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 The identification and control of materials, parts, and components shall be accomplished in accordance with documented procedures and apply to safety-related materials, parts, and components during fabrication, storage, installation or use. Materials, parts, and components identified as nonconforming shall be controlled as described in Section 15. (**COMN** 975)

8.2 The identification and control requirements shall address traceability to associated documents, as appropriate; specification of the degree of identification and control necessary; location and method of identification to preclude a degradation of the item's functional capability or quality; and proper identification of materials, parts, and components prior to release for manufacturing, shipping, construction, or installation. Materials, parts, and components manufactured or modified by AmerenUE shall be controlled and identified during manufacture. (**COMN** 1897, 2089, 2090, 2093, 2333, 2337)

8.3 Documented procedures shall assure that specifications and other procurement documents include or reference appropriate requirements for the identification and control of materials, parts, and components including partially fabricated assemblies. Procedures shall also specify measures for material control including storing and controlling accepted items; controlling the issuance of accepted items from storage while maintaining item identity; controlling the return to storage of issued materials, parts, or components received, stored, installed, modified, or used at the Plant site. These procedures shall assure that correct identifications are verified and documented prior to release. (**COMN** 1876, 2088)

8.4 Physical identification shall be employed to the maximum possible extent for relating an item at any point in time to applicable design or other pertinent specifying documents including drawings, specifications, purchase orders, manufacturing and inspection documents, nonconformance reports, and physical and chemical mill test reports. Physical identification or marking shall not affect the form, fit, or function of the item being identified. Where physical identification is not employed, physical separation, procedural control, tags, or other means shall be utilized. Identification shall be maintained on items or records traceable to items through fabrication, erection, and installation. When unique traceability is impractical, bulk traceability may be employed consistent with the relative importance of the item to safety. When tags are used, the stock shall be made from material which will not deteriorate during storage. Tags shall be securely affixed to the items, and displayed in an area that is readily accessible.
(**COMN** 1895, 1896, 2318, 2331, 2333, 2337, 2346)

8.5 Changing or correcting any marking on a code stamp name plate is prohibited, unless authorized by the manufacturer whose serial number is applied. (**COMN** 2336)

8.6 In the event the identification or traceability of an item is lost, it shall be handled as nonconforming in accordance with Section 15, if the disposition is other than to scrap or to retain for non-safety related applications. (**COMN** 1895)

9. CONTROL OF SPECIAL PROCESSES

9.1 Special processes are fabrications, tests, and final preparation processes which require in-process controls in addition to final inspections to assure quality. Special processes also require the qualification of procedures, techniques, and personnel in accordance with the requirements of applicable codes, standards, specifications, or other special requirements to which AmerenUE is committed. Special processes include such activities as welding, heat treating, nondestructive examination, the application of specialized coatings, and chemical cleaning. For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established Codes or standards; the necessary qualifications of personnel, procedures, or equipment shall be defined by Nuclear Engineering.
(**COMN** 1851, 1937, 2098)

9.2 Procedures for special processes shall be qualified as part of their approval process, and shall also provide for recording evidence of acceptable accomplishment of the special processes. Personnel qualifications shall be certified and equipment shall be qualified prior to use.

9.3 The responsible Plant Department Head shall assure that personnel performing special processes are qualified and are employing approved procedures. QA audits shall be performed to assure special processes are performed by qualified and certified personnel. Nondestructive examination (NDE) personnel shall be qualified in accordance with procedures established to meet the requirements of the Code Edition and Addenda to which AmerenUE is committed at the time the NDE is performed. When non-code NDE is performed, personnel shall be qualified to the version of SNT-TC-1A or CP-189 used to meet AmerenUE's current commitment to the ASME B&PV Code.

9.4 Special process equipment that may require periodic adjustment and whose performance cannot be verified through direct monitoring of appropriate parameters shall be subject to the controls described in Section 12.

9.5 Planning for maintenance shall include evaluation of the use of special processes, equipment and materials in performance of the task, including assessment of potential hazards to personnel and equipment.
(**COMN** 1857)

9.6 Qualified outside organizations may be employed to perform special processes onsite and shall be required to conform to the requirements described herein. Special process procedures submitted by these organization(s) in accordance with the procurement document requirements shall receive a technical review by the responsible engineering organization.

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. (**COMN** 1851, 1926, 1927, 2094, 2095, 2974, 42430, 42431)

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 Callaway Plant 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. (**COMN** 1850, 1937)

10.4 Plant Engineering 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 Plant Engineering 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, Plant Engineering 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. (**COMN** 2049)

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 Manager, Training shall be responsible for providing related technical and quality training appropriate to the certification/qualification of AmerenUE personnel. (**COMN** 2483, 2484, 2485)

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. Other personnel performing "inspection" activities shall have appropriate experience, training, and retraining to assure competence in accordance with ANSI/ANS-3.1 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, AmerenUE shall demonstrate by documented results of written examinations and evaluations of actual work proficiency that individuals possess comparable or equivalent competence.
(**COMN** 1851, 2079, 2263, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2994)

10.8 Personnel from outside organizations performing QC inspection activities associated with safety-related items at the Callaway Plant shall be certified as required by ANSI N45.2.6. (**COMN** 2079, 2097, 2263, 2480, 2482, 2483, 2484, 2485, 2994)

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 Callaway Plant shall meet one or more of the following for the activities which they are performing:

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

10.9 When contractors or vendors are retained to perform work activities or to provide services associated with safety-related items at the Callaway Plant, 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 Callaway Plant 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. (**COMN** 2482, 2484, 2485)

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. (**COMN** 1930, 1931, 1935, 2073, 2075)

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. (**COMN** 1928, 1929, 1973, 2039, 2979)

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. (**COMN** 1935, 1936)

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. (**COMN** 1932)

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. (**COMN** 1934, 1973, 2125, 2262, 42479)

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, ISI 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. (**COMN** 1850, 1934, 2052, 3577, 2974, 42430, 42431)

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. (**COMN** 1853, 1865)

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. (**COMN** 1851, 2053)

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. (**COMN** 3577)

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. (**COMN** 1938, 2055, 2056)

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. (**COMN** 1930, 1938, 2075, 2132)

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.
(**COMN** 1848, 1934, 1973, 2075, 2125, 42479)

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

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 Manager, Training shall be responsible for providing related technical and quality training for AmerenUE personnel who perform testing. (**COMN** 2039, 2481, 2482, 2483, 2484, 2485)

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. Other personnel performing "testing" activities shall have appropriate experience, training, and retraining to assure competence in accordance with ANSI/ANS-3.1 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, AmerenUE shall demonstrate by documented results of written examinations and evaluations of actual work proficiency that individuals possess comparable or equivalent competence. (**COMN** 2263, 2479, 2480, 2482, 2483, 2484, 2485)

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 Callaway Plant shall meet one or more of the following for the activities which they are performing: (**COMN** 2263, 2480, 2482, 2483, 2484, 2485)

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

11.13 When contractors or vendors are retained to perform work activities or to provide services associated with safety-related items at the Callaway Plant, 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 Callaway Plant, 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. (**COMN** 2483, 2484, 2485)

12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Measuring and test equipment utilized in activities affecting quality shall be controlled in accordance with written procedures or instructions. The procedures or work instructions for calibration and control shall address the identification of test equipment, calibration techniques, calibration frequencies, maintenance control, and storage requirements. The equipment subject to these controls includes: (1) M&TE (portable measuring instruments, test equipment, tools, gages, and non-destructive test equipment used in measuring and inspecting safety-related structures, systems, and components); (2) reference standards (primary, secondary, transfer, and working); and (3) permanently installed process instrumentation (PI) when it is used to provide quantitative calibration and test data (i.e., in lieu of using M&TE).
(**COMN** 1919, 1920, 1969, 2042, 2081, 2083, 2264)

12.2 Tools, instruments, testing equipment and measuring devices used for measurements, tests, and calibration shall be of the proper range and type; and shall be controlled, calibrated, adjusted and maintained at specified intervals or prior to use to assure the necessary accuracy of calibrated devices. M&TE and reference standards shall be tagged or labeled indicating the date of calibration and the due date for recalibration. (**COMN** 1920, 1851, 2295, 2044, 2060, 2080)

12.3 Permanently installed process instrumentation shall be afforded the control measures described herein consistent with the surveillance testing program and preventive maintenance program.

12.4 The calibration and control program established at the Callaway Plant shall assure that M&TE, reference standards, and PI maintain their required accuracy. The Manager, Maintenance is responsible for assuring the program establishment. Program implementation is the responsibility of the appropriate Department Heads.

12.5 M&TE, reference standards, and PI shall be utilized by various organizations as required to perform tests or other special operations. Each organization shall be responsible for assuring that the M&TE or reference standards it uses have been calibrated. Outside organizations using M&TE or reference standards at the Callaway Plant in activities affecting quality shall be required to implement calibration and control measures consistent with the applicable requirements of this section. Vendors activities performed offsite, other than calibration services for Callaway Plant M&TE or PI, do not need to meet the requirements of item 8 and 9 of OQAM Section 12.6 unless specified in procurement documents. Vendor-provided calibration services for Callaway Plant M&TE or PI are required to be consistent with the requirements of item 8 and 9 of OQAM Section 12.6. Other Ameren organizations (e.g. relay testing, battery testing) using M&TE or reference standards at the Callaway Plant in activities affecting quality shall be required to implement a calibration and control program consistent with the requirements described herein, or control their activities relating to M&TE or reference standards via the Callaway Plant calibration and control program.
(**COMN** 1920, 2084)

12.6 The calibration and control program shall provide for: (**COMN** 2082)

1) The assignment of specific calibration intervals, calibration procedures, or work instructions which specify calibration methods, and instrument accuracy requirements. Interval selection shall be a function of the equipment type, inherent stability and reliability, intended use, required accuracy, and other conditions which may affect calibration. Records shall be maintained to permit a determination of calibration intervals. A calibration shall be performed when the accuracy is suspect. (**COMN** 1923)

2) The unique identification of items.

3) The traceability to calibration test data.

4) The traceability of reference standards and thereby M&TE and PI, to nationally recognized standards and the periodic revalidation of reference standards.

5) The maintenance of records which indicate the status of each item, maintenance history, calibration results, anomalies, and most recent and next scheduled calibration dates. A recall system shall be established to assure that calibration intervals are not exceeded.

6) The maintenance and control of items not in use.

7) Provisions to control the purchase requirements and acceptance tests for items sent out for calibration and for new or replacement items including the requirements for accuracy, stability, and repeatability.

8) M&TE shall be calibrated from reference standards with an accuracy ratio of at least four-to-one (Reference standard to M&TE). Calibration accuracy ratios of less than 4.0 but equal to or better than 1.0 (Reference standard to M&TE) shall be acceptable when equipment to meet specified requirements is not commercially available. The basis of acceptance in these cases shall be documented.

9) M&TE used for calibrating Plant PI shall have calibration ranges, precisions, and accuracies such that the PI can be calibrated and maintained to achieve its specified accuracy. PI shall be calibrated from M&TE with an accuracy ratio of at least two-to-one (M&TE to PI). Calibration accuracy ratios of less than 2.0 but equal to or better than 1.0 shall be acceptable when equipment to meet specified requirements is not commercially available. The basis of acceptance in these cases shall be documented.

12.7 Calibration shall be performed against certified equipment or reference standards having known relationships to nationally recognized standards. Where no national standard exists, provisions shall be established to document the basis for calibration. Calibration and control measures shall not apply to rulers, tape measures, levels, and other devices when normal commercial practice affords adequate accuracy.

12.8 M&TE and reference standards found to be out of calibration shall require an investigation to evaluate the validity of previous measuring, test, inspection, and calibration results and the acceptability of impacted items. Investigations shall evaluate the necessity of repeating original measurements, inspections, tests, or calibrations to establish the acceptability of such items. When the calibration history of an item shows it to be consistently out of calibration, the item shall be repaired, replaced, or the calibration interval modified. (**COMN** 2044)

13. HANDLING, STORAGE, AND SHIPPING

13.1 Safety-related items including safety-related parts of structures, systems, and components and related consumables shall be handled, stored, shipped, cleaned, and preserved in accordance with procedures, instructions or drawings, to assure that the quality of items is preserved from fabrication until incorporation in the Callaway Plant. The procedures shall also establish responsibilities for determining applicable requirements for packaging, shipping, receiving, storage, and handling activities. (**COMN** 975, 2093, 2417)

13.2 Generic procedures or instructions shall be prepared for application to these activities; however, detailed procedures or instructions shall be prepared for the handling, cleaning, storing, maintaining while stored, or shipping of certain items and types of equipment or material. (**COMN** 2349, 2416, 41668)

13.3 Applicable manufacturer instructions and recommendations, or procurement requirements shall be reviewed and invoked in governing procedures when determined appropriate based on an engineering review. Deviations which relax manufacturer's recommendations shall involve an engineering evaluation. This may be appropriate when unrealistic requirements are recommended and such recommendations are not reasonably necessary to preclude equipment degradation. (**COMN** 2354, 2105)

13.4 The requirements for activities described in this Section shall be divided into levels with respect to protective measures to prevent damage, deterioration, or contamination of items. These levels are based upon the important physical characteristics and not the important functional characteristics of the item with respect to safety, reliability, and operation. The specific environmental, special measures or other conditions applicable to each level shall be described in implementing procedures. (**COMN** 2416)

13.5 The Maintenance Manager shall establish an inspection program for Plant material handling equipment that provides for routine maintenance and inspection in accordance with documented procedures which specify acceptance criteria. Routine inspections shall determine the acceptability of equipment and rigging. Routine inspections shall be supplemented by nondestructive examinations and proof tests as delineated in procedures for items requiring special handling. Personnel performing nondestructive examination and proof testing shall be qualified.

13.6 Procedures shall be prepared for items that require special handling and shall be available prior to the time items are to be handled. Items not specifically addressed by procedures shall be handled in accordance with sound material handling practice. Fuel assemblies, which require unique equipment and handling, shall be handled under the direction of a Licensed Senior Reactor Operator during core alterations. Other material handling activities may involve personnel from various Plant organizations. Operators of special handling and lifting equipment shall be experienced or trained in the use of equipment. (**COMN** 2325, 2356, 2416, 2984)

13.7 Procurement documents or procedures shall address packaging requirements which afford protection from the possible degradation of quality during shipping, handling, or storing. The packaging protection specified may vary in degree consistent with the item's protection classification. Similarly, the mode of transportation employed shall be consistent with the protection classification of items. (**COMN** 2416, 2304)

13.8 Measures shall also be established to control the shipping of licensed radioactive materials in accordance with 10 CFR 71.

13.9 Procedures shall provide instructions for the storage of materials and equipment to minimize the possibility of damage from the time an item is stored following receiving inspection, until the time the item is removed from storage and placed in its final location. Periodic inspections shall be performed to assure that storage areas are being properly maintained. Material and equipment shall be placed in a storage level commensurate with the protection level of items. The various levels of storage shall correspond to prescribed environmental conditions which are procedurally defined. (**COMN** 2341, 2981, 2984)

14. INSPECTION, TEST, AND OPERATING STATUS

14.1 Safety-related items that are received, stored or installed at the Callaway Plant shall be identified and controlled in accordance with documented procedures.

14.2 Items received at or installed in the Plant shall be identified in accordance with procedures as to their status regarding required inspections and tests before the items are stored, issued or operated. Prior to storage or installation, items shall be identified by means of stamps, tags, labels, routing cards, segregation, or other means traceable to manufacturers' and receiving inspection documentation. In the event traceability is not available, the item(s) shall be considered nonconforming and handled in accordance with Section 15, if the disposition is other than to scrap or retain for non-safety related applications. (**COMN** 1847, 2116, 2331)

14.3 Plant procedures shall provide instructions relating to the manner of indicating the operational status of safety-related structures, systems, and components, including temporary modifications, and shall require independent verifications, where appropriate, to assure necessary measures, such as tagging equipment, have been implemented correctly. These procedures shall address measures for the release and control of equipment during periods of maintenance; thereby maintaining personnel and reactor safety and avoiding the unauthorized operation of equipment. Equipment and systems in a controlled status to prevent unauthorized operation shall be identified. (**COMN** 1841, 1842, 1844)

14.4 Plant procedures shall establish controls to identify the status of inspection and test activities associated with maintenance, repair, modification, refueling, inservice inspection, and instrumentation and control system calibration and testing. The Technical Specifications establish the status required for safe Plant operation, including provisions for periodic and non-periodic tests and inspections of various structures, systems, and components. Periodic tests may be operational tests or tests following maintenance while non-periodic tests may be made following repairs or modifications. (**COMN** 972, 1844, 1846, 1847, 1851)

14.5 Required safety-related inspections, tests, and operations and their sequencing are performed in accordance with Plant operating procedures which are reviewed and approved in accordance with the requirements of the Technical Specifications. In cases where required documentary evidence is not available with respect to whether an item has satisfactorily passed required inspections and tests, the associated equipment or materials must be considered nonconforming in accordance with Section 15. Except in the case of temporary changes (non-intent changes) which are allowed by the Technical Specifications and which are administratively controlled, any deviations from procedural requirements shall be subject to the original or equivalent review and approval controls. (**COMN** 1848)

15. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

15.1 Material nonconformances include material deficiencies (including inoperative and malfunctioning structures, systems, and components). Material nonconformances identified under the AmerenUE OQAP shall be controlled to prevent the inadvertent use of material, parts, or components which are defective or of indeterminate quality and to identify documentation inadequacies. Measures shall be established regarding identification, documentation, status control, disposition, and notification of affected organizations. (**COMN** 1848, 1861, 1862, 1870, 1907, 2045, 2112)

15.2 Under the AmerenUE OQAP, Nonconforming Material Reports (NMRs), nonconformance logs, or other administrative controls shall be employed to identify and control nonconformances. Nonconformance logs may be employed to control deficiencies of a minor nature or to control documentation deficiencies both of which can be corrected by bringing the deficiency into compliance with the original requirements. Material nonconformances shall be controlled, as appropriate, by documentation, tagging, marking, logging, or physical segregation. The programs describing the administrative nonconformance controls shall delineate the methods of identifying corrective action to be taken for a nonconforming item or series of nonconforming items. Until suitable documentary evidence is available to show the equipment or material is in conformance, affected systems shall be considered inoperable and reliance shall not be placed on such systems to fulfill their intended safety function. (**COMN** 1848, 1876, 1903, 1907, 2328, 2334, 3600)

15.3 Plant and other Ameren organization's procedures shall prescribe measures for the control and disposition of AmerenUE purchased items and services identified by outside organizations as nonconforming. Procurement documents shall specify those nonconformances to be submitted to AmerenUE for approval of the recommended disposition. As specified in procurement documents, actions taken in response to these nonconformances shall be documented and forwarded to AmerenUE along with the hardware and accompanying quality verification documentation. Nuclear Engineering shall be responsible for assuring the processing of supplier- recommended dispositions for Plant-initiated procurements. Similarly, other Ameren or outside organizations shall approve or be requested to provide a technical evaluation regarding supplier-recommended dispositions of nonconformances regarding procurements they initiate. (**COMN** 1906, 3558, 3598, 3599, 3600)

15.4 Material nonconformance shall be processed in accordance with documented procedures and shall identify the specifics of the nonconformance stating the particular drawing, specification or other requirement; shall record the disposition; and shall register the signature of an approval authority. Procedures shall prescribe the individuals or groups assigned the responsibility and authority to approve and verify the implementation of the disposition of material nonconformance. (**COMN** 1904, 1905, 1907)

15.5 Material nonconformance disposition categories shall include: (**COMN** 1907, 2334)

1) "Use-as-is" or "acceptable" (including conditional releases)
2) "Reject" or "not acceptable, scrap, or return to vendor"
3) "Rework" in accordance with approved procedures
4) "Repair" in accordance with approved procedures

Material nonconformance's shall be reviewed and accepted, rejected, repaired, reworked, or conditionally released in accordance with documented procedures. An approved disposition of a nonconformance which allows a reduction in the requirements of a safety-related structure, system, or component, shall be treated as a design/configuration change subject to the controls prescribed in Section 3.

15.6 The design/configuration change process is used in the Nonconformance Program to carry out dispositions of "use-as-is" or "repair". This process ensures that all aspects of plant operation are considered in light of the fact that the dispositioned item is now not exactly per original design. These considerations include revision of applicable drawings, possible revisions to operation, test, maintenance and inspection procedures; training of affected personnel, changes to spare parts inventory; reviews per 10 CFR 50.59; and review of licensing documents.

15.7 Nuclear Engineering shall be responsible for approving material nonconformance dispositions of "use-as-is" and "repair". Fuel Cycle Management may also approve material nonconformance dispositions of "use as is" and "repair" on nuclear fuel which are generated prior to the arrival of such fuel at the Callaway Plant. Regarding material nonconformances identified on-site, QC personnel shall be responsible for verification that approved dispositions have been implemented and for the final sign-off.
(**COMN** 1848, 1905, 1907, 2335)

15.8 Nonconformance documents which record defects in basic components shall be reviewed for reporting applicability under 10CFR21 and other Federal reporting requirements. Significant nonconforming conditions involving a defect or material noncompliance in a receipt accepted component or a service which has commenced which could create a substantial safety hazard shall be reported to the Nuclear Regulatory Commission pursuant to the requirements of 10CFR21. (**COMN** 1862)

15.9 Material nonconformance which would impact the conduct of a test shall be corrected or resolved prior to initiation of the test on the item. The decision to proceed with the testing of a system or subsystem with outstanding material nonconformances shall consider the nature of the nonconformance, its effect on test results, and the need for supplemental tests or inspections after correction of the nonconformance. The evaluations shall be documented. (**COMN** 1906)

15.10 Repaired and reworked items shall be reinspected or tested. Measures may be established to conditionally release nonconforming items whose disposition is pending, provided that an evaluation indicates that further work or activity will not contribute adversely to the material nonconformance or preclude identification and correction. (**COMN** 1848, 1904, 1906, 2053, 2328, 2332)

15.11 Material nonconformance summaries shall be prepared and analyzed for potential adverse quality trends semiannually in accordance with Section 16.

16. CORRECTIVE ACTION

16.1 Measures shall be established to assure that conditions adverse to quality are promptly identified, reported, and corrected. Such measures shall be established in a program or programs which are proceduralized. These procedures, as a minimum, shall:
(**COMN** 1870, 1871, 1903, 2970, 2973, 2978, 3599, 3600, 42244)

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

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

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

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

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

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

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

8) Provide for developing and analyzing trends on at least a semiannual basis. Trending of conditions adverse to quality identified at suppliers' facilities is performed as part of the annual supplier evaluation per OQAM, Section 18.12. (**COMN** 1800)

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

16.3 Conditions adverse to quality which impede the implementation or reduce the effectiveness of the Operating QA Program shall be considered significant conditions adverse to quality. Significant conditions adverse to quality may include, but are not limited to, noncompliance with procedural requirements which impact nuclear or personnel safety; reportable occurrences required by regulations; adverse nonconformance trends; deficiencies identified in the OQAP; recurring conditions for which past corrective action has been ineffective; and managerial controls which could result in the failure of a plant system to perform its intended function. Examples of such conditions include those which match the descriptions in Sections 1.22.1.7.f, g, h, l, m (potential hazards to nuclear safety) of this OQAM and National Pollutant Discharge Elimination System (NPDES) violations.

16.4 Conditions adverse to quality which involve defects in basic components shall be reviewed for reporting applicability under 10CFR21 and other Federal reporting requirements. Reportable conditions adverse to quality are classified as significant.

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

16.6 Engineering Services personnel shall review conditions adverse to quality which involve design deficiencies or which involve recommending design/configuration changes as corrective action. Fuel Cycle Management should review conditions adverse to quality for fuel related issues. The ORC shall review significant conditions adverse to quality. (**COMN** 1871, 2171, 2172)

16.7 Corrective action documents shall be closed by verifying the implementation and adequacy of corrective action. The closure of corrective action documents shall be accomplished as promptly as practicable after the corrective action taken has been verified. Verification may be accomplished through direct observations, written communications, re-audit, surveillances, or other appropriate means. (**COMN** 3870)

16.8 Copies of completed corrective action documents shall be available for management review (hard copy or electronic media). The Quality Assurance Department shall periodically review corrective action documents and identify significant conditions. Summaries of significant conditions adverse to quality shall be submitted to the NSRB and appropriate levels of management. (**COMN** 1871)

16.9 Corrective action documents shall be reviewed for the effectiveness of the corrective actions taken and analyzed for potential adverse quality trends. Quality Assurance shall evaluate the analyses, the identification of adverse trends, and the acceptability of actions taken on these trends through routine audit and surveillance activities. The results of these assessments shall be reported to management. (**COMN** 1800)

17. QUALITY ASSURANCE RECORDS

17.1 Quality assurance record systems governing the collection, storage, and maintenance of records shall be established by AmerenUE. They shall apply to records associated with startup testing, operation, maintenance, repair, refueling, and modification of safety-related structures, systems, and components at the Callaway Plant. (**COMN** 1851, 2126, 2127, 2130, 2173, 3002)

17.2 During the operating phase, quality assurance records shall be maintained to furnish documentary evidence of the quality of items and activities affecting quality. Applicable design specifications, procurement documents, test procedures, operational procedures or other documents shall specify the quality assurance records to be generated by, supplied to, or held by AmerenUE. Documents shall be considered quality assurance records when completed. Records may be maintained for varying periods and shall be identified as lifetime or nonpermanent records in that a lifetime or finite retention period shall be specified. Records shall provide sufficient information to permit identification to the item or activity to which it applies, and be retrievable. (**COMN** 1851, 2128, 2132, 2133, 2137, 2138, 2173)

17.3 Quality assurance records include, but are not limited to, operating logs; maintenance and modification procedures and inspection results; reportable occurrences; results of reviews; ORC meeting minutes; inspections, tests, audits and material analyses; qualification of personnel, procedures, and equipment; and other documentation including drawings, specifications, procurement documents, nonconformance documentation, corrective action documents, calibration procedures or work instructions and results, and the results of monitoring work performance (e.g., surveillance). (**COMN** 2140, 2258, 2259, 2337, 2364, 3002, 40635)

17.4 Inspection and test records shall contain the following as a minimum: (**COMN** 1936)

1) A description of the type of observation
2) The date and results of the inspection or test
3) Identification of the inspector or data recorder
4) Evaluation of the acceptability of the results
5) Action taken in connection with any deficiencies noted

17.5 Quality assurance records generated by others are transferred or made accessible to AmerenUE as systems and equipment or services are transferred or delivered from A/E's, NSSS suppliers, fuel fabricators, constructors, or others. Records maintained by an outside organization prior to and subsequent to final transfer are required to be accessible to AmerenUE. Records generated internally shall be processed in a timely manner in accordance with documented procedures.

17.6 Record systems shall be established by the Administration organization for Nuclear Generation and shall be controlled in accordance with written procedures. The implementing procedures shall address records administration; receipt of records; storage, preservation and safekeeping of records; record retrieval; and the disposition of records. The Regulatory Affairs organization is responsible for assuring the handling and maintenance of quality assurance records generated, received, and temporarily stored at the General Offices. The Administration organization shall provide for the administration of the quality assurance record system at the Callaway Plant. (**COMN** 2129, 2130, 2136, 2145)

17.7 The requirements regarding hard-copy records administration shall require that quality assurance records be listed in an index. The index shall be established prior to the receipt of records and shall indicate the location of records. Microfilm or optical disk records shall be controlled as indicated in AmerenUE's commitment to ANSI N45.2.9 as stated in Appendix A. The distributing and handling of records, the correcting or supplementing of quality assurance records, and specifying the retention period of record types shall be delineated in written procedures. The retention period of records generated prior to commercial operation shall begin on [2] December 19, 1984; the date of commercial operation. (**COMN** 2135, 2149, 2150)

17.8 The requirements regarding receipt of records shall define the requirements for the receipt of documentation generated by others during the operation of the Callaway Plant. These requirements shall assure that records are submitted and that designated authorities are responsible for organizing and implementing a system of records receipt control. The records' receipt control shall permit an assessment of the status of records during the receiving process. (**COMN** 2145, 2148)

17.9 The requirements regarding storage, preservation, and safekeeping of records shall establish storage requirements for the maintenance, preservation, and protection of quality assurance records. These requirements shall include methods for maintaining control of, access to, and accountability for records; storing records in a manner to preclude deterioration; and providing record storage facilities which protect contents from possible destruction by causes such as fire. An alternative to the establishment of a single record storage facility shall be the maintenance of a duplicate copy of records in a remote location. Where duplicate storage is employed, the storage environment need not be uniquely controlled in each storage area, but may be the prevailing building temperature and humidity. (**COMN** 2150, 2151, 2153, 2155)

17.10 Record storage systems shall provide for an accurate retrieval of information without undue delay. Those records maintained by an outside organization shall be required to be accessible to the buyer or AmerenUE; in the case of lifetime records for the life of the items involved, or for designated retention times for nonpermanent records. (**COMN** 2157)

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[2] Callaway was declared available for unrestricted loading by the UE Load Dispatcher on December 19, 1984. The PSC Commercial Operation date is April 9, 1985. The PM and EQ programs use the PSC date. Refer to UO 86-107.

17.11 Record disposition practices shall establish requirements for the transfer of records from others to AmerenUE. Upon final transfer, records shall be inventoried against any transmittal forms and processed in accordance with written procedures. Nonpermanent records shall be retained for the specified retention period; after the specified retention period they are no longer required to be maintained as records. (**COMN** 2160)

In addition to the applicable record retention requirements of Title 10, Code of Federal Regulations, the following records shall be retained for at least the minimum period indicated.

17.11.1 The following records shall be retained for at least 5 years:

a. Records and logs of unit operation covering time interval at each power level;
b. Records and logs of principal maintenance activities, inspections, repair and replacement of principal items of equipment related to nuclear safety;
c. All REPORTABLE EVENTS;
d. Records of surveillance activities; inspections and calibrations required by these Technical Specifications;
e. Records of changes made to the procedures required by Specification 5.4.1;
f. Records of radioactive shipments;
g. Records of sealed source and fission detector leak tests and results; and
h. Records of annual physical inventory of all sealed source material of record.

17.11.2 The following records shall be retained for the duration of the unit Operating License:

a. Records and drawing changes reflecting unit design modifications made to systems and equipment described in the Final Safety Analysis Report;
b. Records of new and irradiated fuel inventory, fuel transfers and assembly burnup histories;
c. Records of radiation exposure for all individuals entering radiation control areas;
d. Records of gaseous and liquid radioactive material released to the environs;
e. Records of transient or operational cycles for those unit components identified in FSAR (Table 3.9(N)-1 A.);
f. Records of reactor tests and experiments;
g. Records of training and qualification for current members of the unit staff;
h. Records of in-service inspections performed pursuant to these Technical Specifications;
i. Records of quality assurance activities required by the QA Program;
j. Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59;
k. Records of meetings of the ORC and the NSRB;
l. Records of the service lives of all hydraulic and mechanical snubbers including the date at which the service life commences and associated installation and maintenance records;
m. Records of secondary water sampling and water quality;
n. Records of analysis required by the Radiological Environmental Monitoring Program that would permit evaluation of the accuracy of the analysis at a later date. This should include procedures effective at specified times and QA records showing that these procedures were followed; and
o. Records of reviews performed for changes made to **APA-ZZ-01003**, the OFFSITE DOSE CALCULATION MANUAL and **APA-ZZ-01011**, the PROCESS CONTROL PROGRAM.

18. AUDITS

18.1 A comprehensive audit program shall be established and implemented by AmerenUE 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.
(**COMN** 2037, 2186, 2188, 2978, 2988, 3865, 3867, 3883, 2180, 3869, 41639)

18.2 The AmerenUE audit system shall include the performance of audits and surveillances by the Quality Assurance (QA) 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). QA 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. (**COMN** 1800, 2037, 2245)

18.3 The Manager, Quality Assurance shall establish a program which provides for the qualification and training of QA 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 QA 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 QA 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 QA personnel training, evaluations, qualification, certifications, and retraining.
(**COMN** 1818, 2037, 2244, 2245, 2247, 2248, 2250, 2252, 2253, 2254, 2255, 2257, 2968, 3001, 3866, 3877, 3892, 40635)

18.4 QA Department personnel who perform audit and surveillance activities shall be qualified in accordance with the requirements prescribed in QA Department procedures. Lead Auditor qualification requirements shall include education or professional status, previous work experience or training, training received through AmerenUE, 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 Manager, Quality Assurance. 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 Manager, Quality Assurance 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 anytime 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.
(**COMN** 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2257, 2259, 2969, 3866, 40862)

18.5 The Manager, Quality Assurance shall be responsible for assuring the implementation of a comprehensive system of planned audits to verify compliance with the OQAP. The Manager, Quality Assurance has sufficient authority and organizational freedom to schedule and perform both internal and external audits. He 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 Manager, Quality Assurance has direct access to the Senior Vice President and Chief Nuclear Officer.
(**COMN** 3865, 1790)

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 QA Department for quality trends and results reported to the appropriate management. The Manager, Quality Assurance 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 NSRB shall selectively review audit reports of onsite audits. The NSRB shall also periodically review the onsite audit program as developed by the QA Department, 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.
(**COMN** 1790, 1799, 1800, 3871)

18.7 Internal audits shall be conducted by the QA 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.
(**COMN** 1792, 1816, 2188, 3873)

18.8 Supplementary to the biennial requirements to audit safety-related functions, audits of Unit activities (listed below) SHALL be: (**COMN** 2666, 2681, 2847, 3873, 41777)

- performed under the cognizance of the NSRB, and
- conducted on a performance based frequency by the QA 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, 10CFR Part 50;
  e) Fire Protection will be audited using NRC Generic Letter 82-21 audit scope as follows:
     1) The Fire Protection equipment, programmatic controls, and implementing procedures utilizing either a qualified offsite Ameren Fire Protection Engineer or an outside independent Fire Protection Consultant (non-Ameren). However, an outside independent Fire Protection Consultant (non-Ameren) SHALL be used at least every third year.
     2) Fire Protection Quality Assurance Program (FSAR-SA, Appendix 9.5A);
  f) The Radiological Environmental Monitoring Program and the results thereof;
  g) The OFFSITE DOSE CALCULATION MANUAL and implementing procedures;
  h) The PROCESS CONTROL PROGRAM and implementing procedures for processing and packaging of radioactive wastes;
  i) The performance of activities required by the Quality Assurance Program for effluent and environmental monitoring; and
  j) Any other area of Unit operation considered appropriate by the NSRB or 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 excluding the third year Fire Protection Consultant audit, provided the 24 month frequency for the following audit performance is not set forward.

18.8.1 In addition to audits conducted under the cognizance of the NSRB, the following areas shall be reviewed or audited per the frequency specified in applicable regulations:

⇒ Special Nuclear Material Accountability program
⇒ Radiological Protection program
⇒ Security program
⇒ Access Authorization
⇒ Fitness-For-Duty program
⇒ Radiological Emergency Response Plan

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. (**COMN** 1799, 1800, 3873)

18.10 External audits shall be conducted by or for the QA 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 AmerenUE performed audits and may not necessarily audit specific items furnished to AmerenUE. These audits and surveillances shall utilize personnel qualified in accordance with this OQAM and shall be conducted in accordance with this OQAM and QA 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. (**COMN** 3577, 3584, 3596)

18.10.1 When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, in lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade supplier survey, a documented review of the supplier's accreditation shall be performed by or for the QA Department. This review shall include, at a minimum, verification of all of the following:

- The accreditation is to ANSI/ISO/IEC 17025.
- The accrediting body is either the National Voluntary Laboratory Accreditation Program (NVLAP), or the American Association for Laboratory Accreditation (A2LA), as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).
- The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

18.11 Applicable elements of suppliers' quality assurance programs shall be audited (post-award) on a triennial basis. 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 QA 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. (**COMN** 1780, 3565, 3596, 3878, 3872)

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 services, continued maintenance of laboratory accreditation. (**COMN** 3565, 3566, 3596)

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. (**COMN** 3565, 3872, 3874, 3883)

18.14 Audits shall be conducted using written plans in accordance with QA 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. (**COMN** 3876, 3878, 3881, 3889)

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. (**COMN** 3877, 3889)

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 under the cognizance of the NSRB in accordance with Section 18.8.

OQAM CONFORMANCE TO APPLICABLE NRC REGULATORY GUIDES

This Appendix briefly discusses the extent to which AmerenUE's Operating Quality Assurance Program (OQAP) conforms to NRC published Regulatory Guides for the Callaway Plant. 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 AmerenUE 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. AmerenUE'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 AmerenUE 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 18.1-1971 for all other positions).

DISCUSSION:

AmerenUE 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, in accordance with the Callaway Plant Technical Specifications. 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.

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.

AmerenUE 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. 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. As an alternative, these personnel can be qualified for assigned tasks either by AmerenUE through its systematic approach to training or by Vendors with AmerenUE 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 AmerenUEs commitment to ANSI N45.2.6-1978 given elsewhere in this Appendix.

With regard to Section 5.6 of ANSI/ANS 3.1 - 1978 titled Documentation: AmerenUE 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:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

For maintenance and modification activities AmerenUE 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 and modifications 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.

Specific clarifications for ANSI N45.2.4 - 1972 are indicated below by sections.

Section 1.4 - 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 AmerenUE's commitment to Regulatory Guide 1.74.

Section 2.1 - Planning requirements, as determined by engineering, shall be incorporated into modification procedures. Engineering actions performed in accordance with this Section of the Standard are conducted with QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

Section 2.3 - Procedures and Instructions shall be implemented as set forth in OQAM Sections 2, 3, 5, 10 and 11 and by compliance with the Callaway Plant Technical Specifications and Regulatory Guide 1.33 (ANSI N18.7) as set forth in this Appendix in lieu of the requirements set forth here. When compliance with an NRC accepted program (e.g., Callaway Plant Technical Specifications) is referenced, AmerenUE has substituted the NRC accepted program for applicable regulatory requirements in lieu of the general requirements of the Quality Assurance program standards.

Section 2.4 - Results shall be implemented as set forth in OQAM Sections 10, 11 and 17 and by compliance with ANSI N18.7 as set forth in this Appendix in lieu of the requirements set forth here. In every case either identical or equivalent controls are provided in the sections of the referenced Standards or documents.

Section 2.5.2 - Calibration and Control covers three classes of instrumentation used by AmerenUE:

(1) M&TE (portable measuring instruments, test equipment, tools, gages, and non-destructive test equipment used in measuring and inspecting safety-related structures, systems, and components);

(2) reference standards (primary, secondary, transfer, and working); and

(3) permanently installed process instrumentation (PI).

With respect to the first sentence, M&TE and reference standards shall be included in a calibration program and shall either be calibrated at prescribed intervals or shall be calibrated prior to use. With respect to the last sentence, personnel shall be trained and procedures shall require that the calibration label or tag shall be reviewed to determine calibration status prior to use: This label or tag shall be considered to clearly identify equipment which is out of calibration. Lack of a label or tag shall require the organization responsible for calibrating the M&TE to review records and affix a new label or tag based on calibration data. M&TE and reference standards shall comply with sentences 2, 3 and 4.

With respect to the 3rd sentence, AmerenUE uniquely identifies each safety-related item of permanently installed process instrumentation. This identification provides traceability to calibration data. These actions are AmerenUE's alternative to the tagging or labeling of items to indicate the calibration date and the identity of the person who performed the calibration. Permanently installed process instrumentation shall comply with sentences 1, 2, and 5.

Section 3 - Preconstruction Verification shall be implemented as follows:

(1) shall be required only for modifications;

(2) shall be implemented with the clarification that "approved instruction manuals" shall be interpreted to mean the manuals provided by the supplier as required by the procurement order - these manuals are not necessarily reviewed and approved, per se, by AmerenUE;

(3) no special checks shall be required to be made by the person withdrawing a replacement part from the warehouse - equivalent controls are assured by compliance with Regulatory Guide 1.38 (ANSI N45.2.2) as set forth in this Appendix; and,

(4) shall be complied with as determined by engineering or by individual technicians as part of the modification process. Engineering actions performed in accordance with this Section of the Standard are conducted with QA/QC involvement and are subject to QA audit.

Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

Section 4 - Installation shall be implemented as stated and as follows: Engineering actions performed in accordance with this Section of the Standard are conducted with QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

Section 5.1 - Inspections, including subsections 5.1.1, 5.1.2, and the first sentence in 5.1.3, shall be implemented as set forth in OQAM Section 10. The inspection program shall incorporate, as determined by engineering and QC, those items listed in these subsections. The remaining sentence in 5.1.3 is covered in equivalent detail in AmerenUE's commitment to Regulatory Guide 1.33 (ANSI N18.7), Section 5.2.6; the requirements as set forth in that commitment shall be implemented in lieu of the requirements stated here. In every case either identical or equivalent controls are provided in the Sections of the referenced Standards or documents.

Section 5.2 - Tests, including subsections 5.2.1 through 5.2.3, shall be implemented as set forth in OQAM Sections 3 and 11. In some cases Surveillance testing may be used to meet the appropriate requirements of this Section.

Section 6 - Post-Construction Verification is not generally considered applicable at operating facilities because of the scope of the work and the relatively short interval between installation and operation. Where considered necessary by engineering or QC, the elements described in this Section shall be used in the development and implementation of inspection and testing programs as described in OQAM Sections 3, 10 and 11.

Section 7 - Data Analysis and Evaluation shall be implemented as stated herein after adding the clarifying phrase "Where used" at the beginning of the paragraph. This clarification accounts for the fact that some testing will not generate "Data" as such.

Section 8 - Records shall be implemented by conformance with OQAM Section 17 and Regulatory Guide 1.88 (ANSI N45.2.9) as set forth in this Appendix.

REGULATORY GUIDE 1.33 REVISION 2 DATED 2/78

Quality Assurance Program Requirements (Operation) (Endorses ANSI N18.7-1976/ANS 3.2)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

Paragraph C.3 of Regulatory Guide 1.33 (and Section 4.3.4 of ANSI N18.7 which it references) shall be implemented as required by OQAM Section 1 which defines "Subjects Requiring Independent Review."

When the term "safety evaluation" is used, it should be replaced by "10CFR50.59 evaluation". In addition, the term "unreviewed safety question" should be replaced with "license amendment". Where 10CFR50.59(a)(2) is cited, the corresponding part of the revised rule is 10CFR50.59(c)(2).

Paragraph C.4.a, b & c of Regulatory Guide 1.33 (and Section 4.5 of ANSI N18.7 which it references) shall be implemented as required by OQAM Section 18 which defines the "audit program" to be conducted. The audit program is further defined and shall be implemented as required by the commitment to Regulatory Guide 1.144 (ANSI N45.2.12) as stated in this Appendix.

Paragraph C.5.d of Regulatory Guide 1.33 (and Section 5.2.7.1 of ANSI N18.7 which it references) shall be implemented by adding the clarifying phrase "When determined by engineering" in front of the fourth sentence of the fifth paragraph. It is not always practicable to test parts prior to use. For modifications where these requirements are not considered practicable, a review in accordance with the provisions of 10 CFR 50.59 shall be conducted and documented. Engineering actions performed in accordance with this Section of the Regulatory Guide are conducted with QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of ORC). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

Paragraph C.5.e of Regulatory Guide 1.33 and Section 5.2.13.4 of ANSI N18.7 which it references shall be implemented subject to the same clarifications made for Regulatory Guide 1.38 (ANSI N45.2.2).

Paragraph C.5.f of Regulatory Guide 1.33 (and Section 5.2.19(2) of ANSI N18.7 which it references) shall be implemented with the substitution of the word "practicable" for the word "possible" in the last sentence. The action referenced in this Section is the responsibility of the Callaway Plant Operating Organization, and includes QA/QC involvement. QA is involved through audit and surveillance activities. QC is involved in maintenance inspection activities.

Paragraph C.5.g of Regulatory Guide 1.33 (and Section 5.2.19.1 on ANSI N18.7 which it references) shall be implemented with the addition of the modifier "normally" after each of the verbs (should) which the Regulatory Guide converts to "shall." It is AmerenUE's intent to fully comply with the requirements of this paragraph, and any conditions which do not fully comply shall be documented and approved by management personnel. Management personnel includes QA through cross-disciplinary reviews and through QA permanent membership on the Callaway Onsite Review Committee. QA has and shall conduct audits or surveillances of preoperational testing. In cases where conditions do not fully comply, the reason for the exception shall also be documented. The documentation shall be retained as lifetime records.

With regard to Section 3.4.2 of ANSI N18.7 - 1976 titled Requirements for the Onsite Operating Organization:

Some of AmerenUE's technical support organizations are physically located at the Callaway site. Therefore the second sentence of this Section shall be implemented as follows:

> "Initial incumbents or replacements for members of the onsite or offsite technical support organizations shall have appropriate experience, training and retraining to assure that necessary competence is maintained in accordance with the provisions of ANSI/ANS 3.1 - 1978 as committed to in the OQAM."

In the third sentence, AmerenUE interprets "QA" to be "QC", consistent with the intent of Regulatory Guide 1.58 (ANSI N45.2.6-1978) and the OQAM.

Training standards referenced in this Section are implemented as described in this Appendix's commitments to Regulatory Guide 1.8 (ANSI/ANS 3.1) and Regulatory Guide 1.58 (ANSI N45.2.6-1978) or as otherwise included as part of the Callaway operating license. AmerenUE's methods of documenting and otherwise meeting the remainder of the requirements of this Section are set forth in OQAM Section 2, in the Callaway Plant Technical Specifications, and in other licensing commitments.

With regard to Section 4.1 of ANSI N18.7 - 1976 titled General: The AmerenUE 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 Section 18.

With regard to Section 4.2 of ANSI N18.7 - 1976 titled Program Description: Two aspects are addressed in this Section: audits and independent reviews. The independent review program shall be implemented as required by the OQAM. The AmerenUE audit program shall be described in accordance with and to meet the requirements of Regulatory Guide 1.144 (ANSI N45.2.12) as endorsed in this Appendix, and OQAM Section 18.

With regard to Section 4.3 of ANSI N18.7 - 1976 titled Independent Review Process: The requirements of this Section, including of its subparts, shall be met by compliance with the OQAM.

With regard to audit frequency specified in Section 4.5 of ANSI N18.7 – 1976 titled Audit Program: The AmerenUE audit program shall be implemented in accordance with the frequencies specified in OQAM Sections 18.7 and 18.8.

With regard to Section 4.5 of ANSI N18.7 - 1976 titled Audit Program: The AmerenUE 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 Section 18.

With regard to Section 5.1 of ANSI N18.7 - 1976 titled Program Description: The fourth sentence in this Section requires a "summary document." AmerenUE's OQAM is organized in accordance with the 18 criteria of 10 CFR 50, Appendix B. AmerenUE interprets this OQAM and applicable Regulatory Guides as endorsed in this Appendix to fulfill the requirements for a "summary document."

With regard to Section 5.2.2 of ANSI N18.7 - 1976 titled Procedure Adherence: The temporary change requirements of this Section are delineated in the OQAM for activities occurring after the Operating License (OL) is issued; the requirements of the OQAM shall be used to control temporary changes.

With respect to Section 5.2.6 of ANSI N18.7 - 1976 titled Equipment Control: AmerenUE shall comply with the "independent verification" requirements based on the definition of this phrase as given under our commitment to Regulatory Guide 1.74 in this Appendix.

Since AmerenUE sometimes uses descriptive names to designate equipment, the sixth paragraph, second sentence is replaced with:

> "Suitable means include identification numbers or other descriptions which are traceable to records of the status of inspections and tests."

The first sentence in the seventh paragraph shall be met after clarifying "operating personnel" to mean trained employees assigned to, or under the control of, Plant management at Callaway.

With regard to Section 5.2.7 of ANSI N18.7 - 1976 titled Maintenance and Modification: AmerenUE shall interpret the word "original" in the first sentence of this Section to modify ONLY the words "design bases." This interpretation is to assure that original inspection requirements are not imposed, without appropriate review, on modifications or maintenance activities which are similar in nature to original construction activities. In developing means to assure the quality of maintenance or modification activity, inspection requirements from associated construction activities shall be considered. Operational inspection requirements shall assure quality at least equivalent to the original quality.

Since some emergency situations could arise which might preclude preplanning of all activities, AmerenUE shall comply with an alternate to the first sentence in the second paragraph which reads:

> "Except in emergency or abnormal operating conditions where immediate actions are required to protect the health and safety of the public, to protect equipment or personnel, or to prevent the deterioration of Plant conditions to a possibly unsafe or unstable level, maintenance or modification of equipment shall be preplanned and performed in accordance with written procedures. Where written procedures would be required and are not used, the activities that were accomplished shall be documented after-the-fact and receive the same degree of review as if they had been preplanned."

With regard to Section 5.2.7.1 of ANSI N18.7 - 1976 titled Maintenance Programs: AmerenUE shall comply with the requirements of the first sentence of the fifth paragraph, where practical. This clarification is needed since it is not always possible to promptly determine the cause of the malfunction. AmerenUE shall initiate proceedings to determine the cause, and shall make such determinations promptly, where practical. QA is involved via both audits and surveillances, and QC is involved in inspection of maintenance inspection activities.

With regard to Section 5.2.8 of ANSI N18.7 - 1976 titled Surveillance Testing and Inspection Schedule: In lieu of a "master surveillance schedule," the following requirement shall be met: "Schedules shall be established reflecting the status of in-plant surveillance tests and scheduled inspections."

With regard to Section 5.2.9 of ANSI N18.7 - 1976 titled Plant Security and Visitor Control: The requirements of the Security Plan shall be implemented in lieu of these general requirements. When compliance with an NRC accepted program (e.g., Callaway Security Plan) is referenced, AmerenUE has substituted the NRC accepted program for applicable regulatory requirements in lieu of the general requirements of the Quality Assurance program standards.

With regard to Section 5.2.10 of ANSI N18.7 - 1976 titled Housekeeping and Cleanliness Control: The requirements of this Section, beginning with the last sentence of the first paragraph and continuing through the end of the Section, shall be implemented as described in AmerenUE's commitments to Regulatory Guide 1.39 (ANSI N45.2.3) and Regulatory Guide 1.37 (ANSI N45.2.1) as set forth in this Appendix. In every case either identical or equivalent controls are provided in the Sections of the reference standards or documents.

With regard to Section 5.2.13.1 of ANSI N18.7 - 1976 titled Procurement Document Control: AmerenUE shall comply with the following sentences in lieu of the last sentence of the referenced Section.

"When procuring commercial-grade items (products or services), the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2. Alternative requirements described in AmerenUE's commitment to Regulatory Guide 1.123 as set forth in this Appendix may be implemented in lieu of imposing a quality assurance program consistent with ANSI N45.2. Where changes are made to the technical or quality requirements on procurement documents, they shall be subject to an equivalent level of review and approval as the original document by the originating organization."

With regard to Section 5.2.15 of ANSI N18.7-1976 titled Review, Approval and Control of Procedures; in lieu of the wording starting with the second sentence in the third paragraph of this section beginning with "The frequency of ...," through the end of the fourth paragraph, which ends "... a procedure review.", AmerenUE provides the following alternative guidance:

> "Procedures shall be revised as necessary. These revisions will generally be initiated through reviews conducted by knowledgeable personnel during routine performance of activities. Examples of such reviews include evaluations of problems encountered during performance of a procedure, evaluation of corrective actions for self-identified deficiencies or events, evaluation of events occurring at other plants, evaluation of procedure changes necessary to implement modifications, evaluation of procedure changes necessary to implement License, Technical Specification, FSAR or OQAM revisions as well as evaluations of changes necessary to resolve Regulatory Issues. Such changes shall be implemented as necessary. In some situations such implementation will be completed prior to completion of the in-process activity. Guidance on the need to revise procedures shall be provided in plant administrative controls."

With regard to Section 5.2.17 of ANSI N18.7 - 1976 titled Inspection: The third paragraph is replaced with the following:

Inspections for modifications and nonroutine maintenance shall be conducted as indicated in our reference to Section 5.2.7 of this standard.

The following is a clarification to the sixth paragraph:

Inspections may not require generation of a separate inspection report. Inspection requirements may be integrated into appropriate procedures or other documents with the procedure or document serving as the record. However, records of inspections shall be identifiable and retrievable.

With regard to Section 5.2.18 of ANSI N18.7 - 1976 titled Control of Special Processes: AmerenUE shall comply with the following sentence in lieu of the last sentence of the referenced Section:

> For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, personnel, equipment and procedure qualification shall be defined by engineering.

With regard to Section 5.3.5(4) of ANSI N18.7 - 1976 titled Supporting Maintenance Documents: AmerenUE may choose to include material from vendor manuals in any of three ways.

(1) The applicable section of a manual may be duplicated, referenced in, and attached to the procedure.

(2) The procedure may reference the technical manual or a specific section; the manual may then be used in conjunction with the procedure for performing the activity.

(3) The material, either as originally written or as modified by the procedure's author, may be reproduced within the body of the procedure.

In options (1) and (2) above, the material shall be considered as having received "the same level of review and approval as operating procedures" by virtue of the review and approval of the maintenance procedure. In option (2), the manual shall be available when the procedure is being considered for approval. In option (3), this material receives the same review and approval as the procedure since it is part of the procedure. In any of the options, AmerenUE is NOT reviewing and accepting the entire manual. AmerenUE reviews and accepts that portion of each vendor manual that is used by AmerenUE.

With regard to Section 5.3.9 of ANSI N18.7 - 1976 titled Emergency Procedures: AmerenUE's Emergency Procedures are in the format specified by the NRC in the Callaway Safety Evaluation Report, as required for issuance of the Operating License, in lieu of the requirements given here.

With regard to Section 5.3.9.2 of ANSI N18.7 - 1976 titled Events of Potential Emergency: The licensing FSAR identified natural occurrences which affect the Callaway Plant. Therefore, AmerenUE shall interpret item (11) to mean the natural occurrences which were evaluated in the licensing FSAR.

With regard to Section 5.3.9.3 of ANSI N18.7 - 1976 titled Procedures for Implementing Emergency Plan: AmerenUE's NRC accepted Emergency Plan shall be implemented in lieu of the requirements in this Section. When compliance with an NRC accepted program (e.g., Callaway Plant Radiological Emergency Response Plan) is referenced, AmerenUE has substituted the NRC accepted program for applicable regulatory requirements in lieu of the general requirements of the Quality Assurance Program standards.

REGULATORY GUIDE 1.37 **INITIAL ISSUE** **DATED 3/73**

Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants (Endorses ANSI N45.2.1-1973)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

For maintenance and modification activities AmerenUE 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 maintenance and modifications 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.

The Regulatory Position established in the Regulatory Guide does not apply to establishment of specifications or controls on the quality of the operating system water, or on additives to operating system water.

Specific clarifications for this Regulatory Guide and ANSI N45.2.1 - 1973 are indicated below by Sections.

With regard to Paragraph C.3 of Regulatory Guide 1.37: The water quality for final flushing of fluid systems and associated components shall be at least equivalent to the quality of the operating system water except for the oxygen and nitrogen content; but this does not infer that chromates or other additives, normally in the system water, are added to the flush water.

With regard to Paragraph C.4 of Regulatory Guide 1.37: Expendable materials, such as inks and related products; temperature indicating sticks; tapes; gummed labels; wrapping materials (other than polyethylene); water soluble dam materials; lubricants; NDT penetrant materials and couplants, desiccants, which contact stainless steel or nickel alloy surfaces shall not contain lead, zinc, copper, mercury, cadmium and other low melting points metals, their alloys or compounds as basic and essential chemical constituents. No more than 0.1 percent (1,000 ppm) halogens shall be allowed where such elements are leachable or where they could be released by breakdown of the compounds under expected environmental conditions, except as provided for in approved design documents. No more than 1000 ppm sulfur shall be allowed where such elements are leachable or where they could be released by breakdown of the compounds under expected environmental conditions, except as provided for in approved design documents.

With regard to Section 5 of ANSI N45.2.1 - 1973 titled Installation Cleaning: The recommendation that local rusting on corrosion resistant alloys be removed by mechanical methods is interpreted to mean that local rusting may be removed mechanically, but the use of other removal means is not precluded, as determined by engineering or Chemistry. Engineering actions performed in accordance with this Section of the Standard are conducted with QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

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:

AmerenUE 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 AmerenUE'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 AmerenUE 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: AmerenUE 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 QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/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)), AmerenUE 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)) AmerenUE 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 QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/QC involvement.

With regard to Section 3.3 of ANSI N45.2.2 - 1972 titled Cleaning: (Third sentence) AmerenUE 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) AmerenUE 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 AmerenUE 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, AmerenUE 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 he shall be trained to perform this function, he may not necessarily be certified to Regulatory Guide 1.58 (ANSI N45.2.6) as an Inspector.

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 QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/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 QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/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 QA/QC involvement and are subject to QA audit. Procedures for these activities receive a cross-disciplinary review as well as review by the Onsite Review Committee (QA is a permanent member of this committee). For other activities, QA audits and surveillances, and QC inspection activities assure QA/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: AmerenUE 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:

> "AmerenUE 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 AmerenUE'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 N45.2.3-1975)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

For maintenance and modification activities AmerenUE 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.

Specific clarifications for ANSI N45.2.3 - 1973 are indicated below by Sections.

Section 1.4 - 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 AmerenUE's commitment to Regulatory Guide 1.74.

Section 2.1 - Planning: AmerenUE may choose not to utilize the five-level zone designation system, but shall utilize standard janitorial and work practices to maintain a level of cleanliness commensurate with Program requirements in the areas of housekeeping, Plant and personnel safety, and fire protection.

Cleanliness shall be maintained, consistent with the work being performed, so as to prevent the entry of foreign material into safety-related systems. This shall include, as a minimum, documented cleanliness inspections which shall be performed prior to system closure. As necessary, (e.g. the opening is larger than the tools being used) control of personnel, tools, equipment, and supplies shall be established when the reactor system is opened for inspection, maintenance, refueling, modification or repair.

Additional housekeeping requirements shall be implemented as required for control of radioactive contamination.

Section 3.2 - Control of Facilities: AmerenUE may choose not to utilize the five-level zone designation system, but shall utilize standard janitorial and work practices to maintain a level of cleanliness commensurate with Program requirements in the areas of housekeeping, Plant and personnel safety, and fire protection.

Cleanliness shall be maintained, consistent with the work being performed, so as to prevent the entry of foreign material into safety-related systems. This shall include, as a minimum, documented cleanliness inspections which shall be performed prior to system closure. As necessary, (e.g. the opening is larger than the tools being used) control of personnel, tools, equipment, and supplies shall be established when the reactor system is opened for inspection, maintenance, modification, refueling or repair.

Additional housekeeping requirements shall be implemented as required for control of radioactive contamination.

Section 4 - Records: The requirements of OQAM Section 17 and Regulatory Guide 1.88 (ANSI N45.2.9) as set forth in this Appendix shall be implemented in lieu of the requirements of the Section. In every case either identical or equivalent controls are provided in the sections of the referenced Standards or documents.

REGULATORY GUIDE 1.58 **REVISION 1** **DATED 9/80**

Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel (Endorses ANSI N45.2.6-1978)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

The qualification of AmerenUE QC or contracted QC personnel performing work at the Plant shall be in accordance with Regulatory Guide 1.58 (ANSI N45.2.6-1978). Other personnel performing inspection, examination, and testing activities shall have appropriate experience, training, and retraining to assure competence in accordance with Regulatory Guide 1.8 (ANSI/ANS 3.1-1978). This position is consistent with Regulatory Guide 1.33 (ANSI N18.7-1976/ANS-3.2, Section 3.4.2). (**COMN** 3739, 42434)

In instances where the education and experience recommendations of ANSI N45.2.6-1978 are not met by QC personnel, AmerenUE shall demonstrate by documented results of written examinations and evaluations of actual work proficiency that these individuals possess comparable or equivalent competence. Persons performing Nondestructive Examinations (NDE) as may be required by Section III or XI of the ASME B&PV Code shall be qualified and certified as required by the Edition and Addenda of the Code to which AmerenUE is committed at the time the NDE is performed. However, when qualifying personnel to perform visual examinations in accordance with IWA-2300 of Section XI, Division 1, ANSI/ASME N45.2.6-1978 may be used instead of ANSI N45.2.6-1973 (Code Case N-424). Persons certified to perform NDE for Code work shall also be considered as qualified to perform non-Code NDE (e.g. crane hook inspection) unless more rigorous qualification or certification requirements are imposed by AmerenUE's commitments or government regulations.

With regard to Section 1.2 of ANSI N45.2.6 -1978 titled Applicability: The third paragraph requires that the Standard be used in conjunction with ANSI N45.2; AmerenUE no longer specifically commits to ANSI N45.2 in the Operating QA Manual. The fourth paragraph requires that the Standard be imposed on personnel other than Ameren employees; the applicability of the Standard to suppliers shall be documented and applied, as appropriate, in the procurement documents for such suppliers.

With regard to Section 1.4 of ANSI N45.2.6 - 1978 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 AmerenUE's commitment to Regulatory Guide 1.74.

With regard to Section 2.5 of ANSI N45.2.6 - 1978 titled Physical: AmerenUE shall implement the requirements of this Section with the stipulation that, where no special physical characteristics are required, none shall be specified. The converse is also true: if no special physical requirements are stipulated by AmerenUE, none shall be considered necessary.

REGULATORY GUIDE 1.64 **REVISION 2** **DATED 6/76**

Quality Assurance Requirements for the Design of Nuclear Power Plants (Endorses ANSI N45.2.11-1974)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

When uniqueness or special design considerations warrant or are judged to be appropriate, an independent third-level review may be employed.

With regard to Paragraph C.2(1) of Regulatory Guide 1.64: If the designer's immediate Supervisor is the only technically qualified individual available, this review may be conducted by the Supervisor, provided that:

(a) the other provisions of the Regulatory Guide are satisfied, and

(b) the justification is individually documented and approved in advance by the Supervisor's management, and

(c) quality assurance 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: AmerenUE'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:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications.

AmerenUE 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," AmerenUE shall use the following: "Inspection (when used to refer to activities that are NOT performed by QA 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)." These activities are controlled by the Callaway Plant Operating Procedures.

When AmerenUE 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," AmerenUE 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 AmerenUE'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 AmerenUE 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 Plant Director. 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:

AmerenUE 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, AmerenUE 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: AmerenUE'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 Callaway Plant generated records received are in agreement with procedural guidelines contained in Callaway Plant 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 being duplicated (for dual storage),-being placed on microfilm or optical disk. Open-ended documents --those revised or updated on a more-or-less continuing basis over an extended period of time (e.g. personnel qualification and training documents, equipment history cards, master audit or master surveillance schedules) and those which are cumulative in nature (e.g. nonconforming item logs and control room log books)-- are not considered as QA records since they are not "complete." These types of documents shall become QA records when they are issued as a specific revision (e.g., the master audit schedule); when they are filled-up or discontinued (e.g. log books or equipment history cards); on a predefined periodic basis when the completed portion of the on-going document shall be transferred to document control as a "record" (e.g. training and qualification records).

Paragraph 4, subsection 3 is clarified to require a two-hour minimum fire rating to be consistent with the 1979 version of the Standard and NRC Criteria for Records Storage Facilities (Guidance-ANSI N45.2.9, Section 5.6) issued 7/1/80.

Paragraph 4, subsection 9 is clarified to read:

> "No pipes or penetrations except those providing fire protection, lighting, temperature/ humidity control, or communications are to be located within the facility and they shall comply with a minimum two-hour fire protection rating."

Where duplicate storage is employed, no special precautions or provisions (including vault storage, special humidity and temperature recorders and similar items) are required.

Paragraph 5 is clarified to read the same as our commitment to subsection 5.4.3. Both paragraphs address the same requirement and therefore the commitment must be the same.

With regard to Section 5.7 of ANSI N45.2.9-1974 titled Audits: These specific activities in sub-sections 1, 2 and 3 are accomplished through the establishment of administrative controls by the responsible management.

Audits of these administrative controls are performed in accordance with this OQAM, Section 18 and commitments to Reg. Guide 1.144 in this Appendix.

REGULATORY GUIDE 1.94 **REVISION 1** **DATED 4/76**

Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants. (Endorses ANSI N45.2.5-1974)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

For modification activities AmerenUE 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 modification activities even though such requirements may not have been in effect originally. Technical requirements associated with modifications 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. The recommendations for structural concrete, structural steel, and other Plant components shall be met as indicated by the applicable design documents with the following exceptions:

With regard to Section 2.4 of ANSI N45.2.5-1974 titled Personnel Qualification: AmerenUE will comply with Regulatory Guide 1.58 as endorsed in this OQAM in lieu of the requirements of this standard.

In regard to Section 2.5.2 of ANSI N45.2.5-1974 titled Calibration and Control: The last sentence is clarified as follows: "AmerenUE's inspection or test results conducted with M&TE found to be discrepant are to be evaluated as described in the OQAM, Section 12.8."

With regard to Section 5.4 of ANSI N45.2.5-1974 titled High Strength Bolting: In lieu of the first two sentences in the first paragraph, AmerenUE will comply with the following:

> "Bolts for friction type connections may be tightened using direct tension indicators in accordance with the AISC Specification for Structural Joints Using ASTM A325 or A490 Bolts, approved May 8, 1974."

In lieu of (1) in the second paragraph, AmerenUE will comply with the following:

> "The requirement for the acceptance of tightened bolt assemblies is, the length of the bolts shall be such that the point of the bolt shall be flush with or outside of the face of the nut when completely installed."

REGULATORY GUIDE 1.116 **REVISION 0-R** **DATED 5/77**

Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems (Endorses ANSI N45.2.8-1975)

DISCUSSION:

AmerenUE complies with the recommendations of this Regulatory Guide with the following clarifications:

For maintenance and modification activities AmerenUE shall comply with the Regulatory Position established in this Regulatory Guide in that QA programmatic/administrative requirements included therein shall apply to these maintenance and modification activities even though such requirements may not have been in effect originally. Technical requirements associated with maintenance and modifications 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.

With regard to Section 2.7 of ANSI N45.2.8 - 1975 titled Personnel Qualifications: Personnel performing inspection and testing activities, shall be qualified consistent with the qualification requirements of OQAM Section 10 and, as endorsed in this Appendix, Regulatory Guide 1.58 [ANSI N45.2.6-1978] and Regulatory Guide 1.8 [ANSI/ANS 3.1-1978].

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:

AmerenUE 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 AmerenUE'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 AmerenUE 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 services from calibration laboratories accredited by a nationally-recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2. Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and the American Association for Laboratory Accreditation (A2LA), as recognized by NVLAP through the International Laboratory accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with ANSI N45.2, provided all the following are met:

1. The accreditation is to ANSI/ISO/IEC 17025.

2. The accrediting body is either NVLAP or A2LA, as recognized by NVLAP through the ILAC MRA.

3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges and uncertainties.

4. The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy AmerenUE QA program and technical requirements.

5. The purchase documents require reporting as-found and as-left calibration data, and identification of the standards used during calibration."

With regard to Section 3.4 of ANSI N45.2.13 - 1976 titled Procurement Document Control: AmerenUE 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: AmerenUE 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 QA involvement, Callaway Operations Support is ultimately responsible for the decision. QA 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 AmerenUE 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.

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 as applicable", is subject to the following clarification: Qualification of personnel performing verification activities for the Callaway Plant shall be in accordance with AmerenUE'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:

AmerenUE 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:

"When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, 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 service supplier's quality assurance program.

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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.

Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and the American Association for Laboratory Accreditation (A2LA), as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA).

In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade supplier survey, a documented review of the supplier's accreditation shall be performed by the Purchaser. This review shall include, at a minimum, verification of all the following:

1. The accreditation is to ANSI/ISO/IEC 17025.

2. The accrediting body is either NVLAP or A2LA, as recognized by NVLAP through the ILAC MRA.

3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

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 AmerenUE'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 AmerenUE 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 AmerenUE 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 AmerenUE 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: AmerenUE 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 (AmerenUE), effectiveness shall be reported as required by OQAM Section 18. Other than audit reports, AmerenUE may not directly report on the effectiveness of the quality assurance programs to the audited organization when such organizations are outside of AmerenUE.

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 AmerenUE 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: AmerenUE 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. AmerenUE 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: AmerenUE 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. AmerenUE 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 AmerenUE at the time the audit report is issued.

(b) AmerenUE 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: AmerenUE 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 AmerenUE Operating Quality Assurance Manual.

With regard to Section 4.5.2 of ANSI N45.2.12-1977 titled By Auditing Organization: AmerenUE shall comply with the following clarification of the section: For internal audits, performed by or for the Quality Assurance 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) (**COMN** 2247, 2248, 2249, 2250, 2251, 2252, 2254, 2257, 2258, 2259, 2968, 2969, 2986, 3739)

DISCUSSION:

AmerenUE 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, AmerenUE shall comply with an alternate subsection 2.2.1 which reads: (**COMN** 2246)

> 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 AmerenUE's procedures for implementing audits and reporting results.

With respect to Section 2.3.4 of ANSI N45.2.23-1978, titled Audit Participation: AmerenUE shall substitute the following for this section (COMN 2251):

> The prospective Lead Auditor shall demonstrate his 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 quality assurance 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: AmerenUE 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. (**COMN** 2253)

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

> The Manager, Quality Assurance; Supervising Engineer, QA; 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: AmerenUE shall substitute the following sentence for this Section: (**COMN** 3001)

> 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: AmerenUE shall substitute the following sentence for this Section: (**COMN** 3002)

> 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.