**Beaver Valley Power Station**
Units 1 & 2
Docket Nos. 50-334 & 50-412
Operating License Nos. DPR-66 & NPF-73

**Davis-Besse Nuclear Power Station**
Docket No. 50-346
Operating License No. NPF-3

**Perry Nuclear Power Plant**
Docket No. 50-440
Operating License No. NPF-58

**Approved By:** _____ **Date:** 10/29/15
Vice President – Fleet Oversight

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## A. MANAGEMENT

### 1. Methodology

a. The Quality Assurance Program Manual (QAPM) provides a consolidated overview of the quality program controls which govern the operation and maintenance of FirstEnergy Nuclear Operating Company's (FENOC's) quality related items and activities. This includes nuclear plant and FENOC fleet locations, as well as FirstEnergy corporate locations that provide safety related services. The QAPM describes the quality assurance organizational structure, functional responsibilities, levels of authority, and interfaces.

b. The requirements and commitments contained in the QAPM are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations. Employees are expected to actively participate in the continued development of the QAPM as well as its implementation. Changes are promptly communicated when identified.

c. The QAPM implements 10CFR50, Appendix B and applies to all activities associated with structures, systems, and components which are safety related. The requirements of the QAPM are applied to these items and activities to an extent commensurate with their importance to safety.

d. The QAPM also applies to the packaging and transportation of radioactive waste activities controlled by 10CFR71, as the quality assurance program required by 10CFR71, Subpart H.

e. The QAPM also applies to the independent storage of spent nuclear fuel and high-level radioactive waste activities controlled by 10CFR72, as the quality assurance program required by 10CFR72, Subpart G.

f. The QAPM sections B.13, Corrective Actions, and B.14, Document Control, also apply to non-safety related Structures, Systems and Components subject to aging management for the period of extended operations following issuance of the renewed operating license.

Section B.13 and the listed references also address the confirmation process described in NRC RIS 2014-09, Maintaining the Effectiveness of License Renewal Aging Management Programs, to ensure preventive actions are adequate and appropriate corrective actions are completed and effective.

Section B.14 and the listed references address administrative controls described in NRC RIS 2014-09, to ensure formal review and approval processes are provided.

g. The applicability of the requirements of the QAPM to other items and activities is determined on a case-by-case basis.

h. The QAPM is implemented through the use of approved procedures (i.e., policies, directives, procedures, or other documents) which provide written guidance for the control of quality related activities and provide for the development of documentation to provide objective evidence of compliance.

## 2. Organization

The organizational structure responsible for implementation of the QAPM is described below. The specific organization titles for the quality assurance functions described are identified in procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility.

a. The President FENOC and chief nuclear officer (CNO) is responsible for establishing expectations and providing top level direction of all activities associated with the safe and reliable operation of FENOC's nuclear power plants and activities of corporate functions. The FENOC President and CNO provides guidance with regards to the company quality assurance policy.

1. The executive responsible for oversight reports to the President FENOC and chief nuclear officer and is responsible for the audit and assessment of the quality assurance program of FENOC's nuclear activities, both site and corporate, and maintaining this QAPM in accordance with regulatory requirements. This executive is also responsible for establishing the quality assurance program policies, goals and objectives, for implementation of the quality assurance program, and for maintaining the Quality Assurance Program Manual. This executive also has overall responsibility for the quality assurance and independent off-site safety review committee functions, as well as supplier auditing.

a) The individual responsible for quality assurance reports to the executive responsible for oversight and has overall authority and responsibility for verifying the implementation and adequacy of the quality assurance program (auditing) as described in this QAPM. The individual responsible for quality assurance has the authority and responsibility to report matters directly to the president and chief nuclear officer when needed. This individual is also responsible for the quality control function, and receipt and supplier source inspections.

b) These individuals above may be responsible for a single unit/location or for multiple units/locations and may fulfill more than one function described. Conversely, responsibilities may be fulfilled by more than one individual. Individuals may be located at the nuclear plant or FirstEnergy corporate locations.

b. The following management positions report to the President FENOC and chief nuclear officer:

1. The executive responsible for operations provides a singular point of contact with respect to the operation of the four FENOC power plants, and provides operational oversight of the four plants.

a. The executives responsible for overall plant nuclear safety and operations support at each site report to the executive responsible for operations. These executives may report through an additional layer of management but shall maintain sufficient authority and organizational freedom to implement the assigned responsibilities. These executives are responsible for establishing and implementing the quality assurance program at the respective site.

2. The executive responsible for engineering is responsible for providing engineering services at all sites.

3. A management position responsible for licensing, regulatory affairs and laboratory services.

c. The individuals fulfilling the following management functions report to the appropriate management position identified in Paragraphs 2.b.1.a or 2.b.2. above. These individuals may report through an additional layer of management but shall maintain sufficient authority and organizational freedom to implement the assigned responsibilities. These individuals may be responsible for a single unit/location or for multiple units/locations and may fulfill more than one function described below. Conversely, responsibilities may be fulfilled by more than one individual. The functions described below may also be implemented by non-FENOC organizations within the FirstEnergy Corporation however, FENOC maintains responsibility and authority.

1. The individual responsible for plant operations assures the safe, reliable, and efficient operation of the plant within the constraints of applicable regulatory requirements and the operating license.

2. The individual responsible for plant modification provides direction, control, and overall supervision of the implementation of plant modifications and assigned maintenance.

3. The individual responsible for training provides direction, control, and overall supervision of all training of personnel required by regulations.

4. The individual responsible for records management provides direction, control, and overall supervision of the records management program and associated activities.

5. The individual responsible for document control provides direction, control, and overall supervision of the document control program and associated activities.

6. The individual responsible for the corrective action program provides direction, control, and overall supervision of the corrective action program and associated activities.

7. The individual responsible for engineering is responsible for the development and maintenance of engineering programs, policies, and procedures and for providing engineering services.

8. The individual responsible for materials, purchasing, and contracts is responsible for supplier evaluations, procurement, services, receipt, storage, and issue of materials, parts, and components.

d. The on-site and off-site safety review committees independently review activities to provide additional assurance that the units are operated and maintained in accordance with the Operating License and applicable regulations which address nuclear safety. (Refer to Table 1, Item C.2 for additional details.)

**3. Responsibility**

a. FENOC has the responsibility for the scope and implementation of an effective quality assurance program.

b. FENOC may delegate all or part of the activities of planning, establishing, and implementing the quality assurance program to others, but retains the responsibility for the program's effectiveness.

c. The adequacy of the QAPM's implementation is continually assessed by the individual(s) responsible for quality assurance and the associated executive for overall plant nuclear safety, and is reported to the executive responsible for oversight and to the president and chief nuclear officer.

d. FENOC is responsible for ensuring that the applicable portion(s) of the quality assurance program is properly documented, approved, and implemented (people

are trained and resources are available) before an activity within the scope of the QAPM is undertaken by FENOC or by others.

e. Responsible individuals are to ensure that personnel working under their management cognizance are provided the necessary training and resources to accomplish their assigned tasks within the scope of the QAPM.

f. Procedures that implement the QAPM are approved by the management responsible for the applicable quality function. These procedures are to reflect the QAPM and work is to be accomplished in accordance with them.

**4. Authority**

a. When FENOC delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibilities is delegated.

b. The individual responsible for quality assurance has the responsibility and the authority to stop unsatisfactory work (including reactor operation through proper channels) and control further processing, delivery, installation, or use of non-conforming items or services. Cost and schedule considerations will not override safety considerations.

**5. Personnel Training and Qualification**

a. Personnel assigned to implement elements of the quality assurance program are capable of performing their assigned tasks.

b. Training programs are established and implemented to ensure that personnel achieve and maintain suitable proficiency.

c. Personnel training and qualification records are maintained in accordance with procedures.

d. Additional details concerning personnel training and qualification may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.8, 1.58, and 1.146).

**6. Corrective Action**

a. It is the responsibility of each individual to promptly identify and report conditions adverse to quality. Management at all levels encourages the identification of conditions that are adverse to quality.

b. A corrective action program is established and implemented that includes prompt identification, documentation, significance evaluation, and correction of conditions adverse to quality. For significant conditions adverse to quality, the cause is determined and corrective action to preclude repetition is identified and tracked until it is completed and verified.

c. Specific responsibilities within the corrective action program may be delegated, but FENOC maintains responsibility for the program's effectiveness.

d. Non-conforming items are properly controlled to prevent their inadvertent test, installation, or use. They are reviewed and either accepted, rejected, repaired, or reworked.

e. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to the appropriate level of management.

f. Additional details concerning corrective action activities may be found in Section B.13 and the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.33 and 1.144).

**7. Regulatory Commitments**

a. Except where alternatives are identified, FENOC complies with the QA guidance documents listed on Table 1. If the guidance in any of these documents is in conflict with the QAPM, the guidance provided in the QAPM is the controlling guidance. Additionally, the following clarifications apply to all guidance documents listed in Table 1:

1. For modifications and nonroutine maintenance, guidance applicable to construction-like activities is applicable to comparable plant activities, except that the inspection of modifications, repairs, rework, and replacements shall be in accordance with the original design and inspection requirements or a documented approved alternative.
2. The definitions provided by Regulatory Guide 1.74 apply wherever the defined term is used in the QAPM and associated guidance documents.
3. Clarifications and alternatives to a guidance document apply wherever the guidance document is invoked.
4. In each of the ANSI Standards, other documents (e.g., other Standards, Codes, Regulations, tables, or appendices) are referenced or described. These other documents are only quality assurance program requirements if explicitly committed to in the QAPM. If not explicitly committed to, these documents are not considered as quality assurance program requirements, although they may be used as guidance.

5. Regulatory guidance originally intended to apply to design or construction phase activities will be applied to activities during the operations phase that are comparable in nature and extent to construction phase activities.

b. The NRC is to be notified of QAPM changes in accordance with 10CFR50.54(a).

c. In cases where license requirements differ from the QAPM, the most stringent requirements apply.

## B. PERFORMANCE/VERIFICATION

### 1. Methodology

a. Personnel performing work activities such as design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, modification, operation, and decommissioning are responsible for achieving acceptable quality.

b. Personnel performing verification activities are responsible for verifying the achievement of acceptable quality.

c. Work is accomplished and verified using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

d. Criteria that define acceptable quality are specified, and quality is verified against these criteria.

### 2. Design Control

a. The design control program is established and implemented to assure that the activities associated with the design of systems, components, structures, and equipment and modifications thereto, are executed in a planned, controlled, and orderly manner.

b. The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.

c. Design inputs (e.g., performance, regulatory, quality, and quality verification requirements) are to be correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions).

d. The final design output is to relate to the design input in sufficient detail to permit verification.

e. The design process is to ensure that items and activities are selected and independently verified consistent with their importance to safety to ensure they are suitable for their intended application.

f. Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair are to be subjected to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designee.

g. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are defined in procedures.

h. Design documentation and records, which provide evidence that the design and design verification process was performed in accordance with this program, shall be collected, stored, and maintained in accordance with documented procedures. This documentation includes final design documents, such as drawings and specifications, and revisions thereto and documentation which identifies the important steps, including sources of design inputs that support the final design.

i. Additional details concerning design control activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.64).

**3. Design Verification**

a. A program is established and implemented to verify the acceptability of design activities and documents for the design of items. The selection and incorporation of design inputs and design processes, outputs, and changes are verified.

b. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. The extent of this verification will be a function of the importance to safety of the item, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Standardized or previously proven designs will be reviewed for applicability prior to use.

c. When a test program is used to verify the acceptability of a specific design feature, the test program is to demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are expected to be encountered.

d. Independent design verification is to be completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is to be identified and controlled. In all cases, the design verification is to be completed before relying on the item to perform its function.

e. Individuals or groups responsible for design reviews or other verification activities shall be identified in procedures and their authority and responsibility shall be defined and controlled. Design verification shall be performed by any competent individuals or groups other than those who performed the original design but who may be from the same organization. The designer's immediate supervisor may perform the design verification provided: the supervisor is the only technically qualified individual capable of performing the verification, the need is individually documented and approved in advance by the supervisor's management, and the frequency and effectiveness of the supervisor's use as a design verifier are independently verified to guard against abuse.

f. Design verification procedures are to be established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, the verification is satisfactorily accomplished, and the results are properly recorded.

g. Additional details concerning design verification activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.64).

**4. Procurement Control**

a. A program is established and implemented to ensure that purchased items and services are of acceptable quality.

b. The program includes provisions for evaluating prospective suppliers and selecting only qualified suppliers.

c. The program includes provisions for ensuring that qualified suppliers continue to provide acceptable products and services.

d. The program includes provisions (e.g., source verification, receipt inspection, pre-installation and post-installation tests, and certificates of conformance) for accepting purchased items and services.

e. Applicable technical, regulatory, administrative, and reporting requirements (e.g., specifications, codes, standards, tests, inspections, special processes, and 10CFR21) are invoked for procurement of items and services.

f. The program includes provisions for ensuring that documented evidence of an item's conformance to procurement requirements is available at the site before the item is placed in service or used unless otherwise specified in procedures.

g. The program includes provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used unless otherwise specified in procedures.

h. The procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service.

i. Appropriate controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and quality evaluation of commercial grade items are to be imposed to ensure that the items will perform satisfactorily in service.

j. Additional details concerning procurement control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.33 and 1.123).

**5. Procurement Verification**

a. A program is established and implemented to verify the quality of purchased items and services at intervals and to a depth consistent with the item's or service's importance to safety, complexity, and quantity and the frequency of procurement.

b. The program is executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier.

c. Additional details concerning procurement verification may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.123 and 1.144).

**6. Identification and Control of Items**

a. A program is established and implemented to identify and control items to prevent the use of incorrect or defective items.

b. Identification of each item is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. Traceability is maintained to an extent consistent with the item's importance to safety.

c. Additional details concerning identification and control of items may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.33).

**7. Handling, Storage, and Shipping**

a. A program is established and implemented to control the handling, storage, shipping, cleaning, and preserving of items to ensure the items maintain acceptable quality.

b. Special protective measures (e.g., containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are specified and provided when required to maintain acceptable quality.

c. Specific procedures are developed and used for cleaning, handling, storage, packaging, shipping, and preserving items when required to maintain acceptable quality.

d. Items are marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the items' integrity and indicate the need for special controls.

e. Additional details concerning handling, storage, and shipping activities may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.38).

**8. Test Control**

a. A test control program is established and implemented to demonstrate that items will perform satisfactorily in service.

b. Criteria are defined that specify when testing is required.

c. The test control program includes, as appropriate, proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests.

d. Test procedures are developed that include:

1. instructions and prerequisites to perform the test,

2. use of proper test equipment,

3. acceptance criteria, and

4. mandatory inspections as required.

e. Test results are evaluated to assure that test objectives and inspection requirements have been satisfied.

f. Unacceptable test results shall be evaluated.

g. Additional details concerning test control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.33).

**9. Measuring and Test Equipment Control**

a. A program is established and implemented to control the calibration, maintenance, and use of measuring and test equipment. Measuring and test equipment does not include permanently installed operating equipment or test equipment used for preliminary checks where data obtained will not be used to determine acceptability or be the basis for design or engineering evaluation. Additionally, calibration and control measures are not required for rulers, tape measures, levels and other such devices if normal commercial manufacturing practices provide adequate accuracy.

b. The types of equipment covered by the program (e.g., instruments, tools, gages, and reference and transfer standards) are defined in procedures.

c. Measuring and test equipment is calibrated at specified intervals or immediately before use on the basis of the item's required accuracy, intended use, frequency of use, and stability characteristics and other conditions affecting its performance.

d. Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

e. Measuring and test equipment is calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.

f. If nationally recognized standards exist, calibration standards are to be traceable to them. Except where calibration standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.

g. Measuring and test equipment found out of calibration is tagged or segregated. The acceptability shall be determined of items measured, inspected, or tested with an out-of-calibration device.

h. Additional details concerning measuring and test equipment control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.30, 1.33, 1.94, 1.116, and 1.123).

**10. Inspection, Test, and Operating Status**

a. The status of required inspections and tests and the operating status of items is verified before release, fabrication, receipt, installation, test, and use, as applicable. This verification is to preclude inadvertent bypassing of inspections and tests and to prevent inadvertent operation of controlled equipment.

b. The application and removal of inspection, test, and operating status indicators are controlled in accordance with procedures.

c. Additional details concerning inspection, test, and operating status control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.33).

**11. Special Process Control**

a. A program is established and implemented to ensure that special processes are properly controlled.

b. The criteria that establish which processes are special are described in procedures.

c. Special processes are accomplished by qualified personnel, using appropriate equipment, and procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

d. Additional details concerning special process control may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.33).

**12. Inspection**

a. A program is established and implemented for inspections of activities in order to verify conformance to the documented instructions, procedures and drawings

for accomplishing the activity. The inspection program may be implemented by or for the organization performing the activity to be inspected.

b. Provisions to ensure inspection planning is properly accomplished are to be established. Planning activities are to identify the characteristics and activities to be inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspection.

c. Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization, are to be defined.

d. Inspection results are to be documented by the inspector and reviewed by qualified personnel.

e. Unacceptable inspection results shall be evaluated and resolved in accordance with procedures.

f. Inspections are performed by qualified personnel other than those who performed or directly supervised the work being inspected. While performing the inspection activity the inspectors functionally report to the associated individual responsible for quality control or an individual responsible for materials, purchasing, and contracts as appropriate.

g. Additional details concerning inspections may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.33 and 1.58).

**13. Corrective Action**

a. Procedures shall provide for identification, evaluation, and resolution of conditions adverse to quality.

b. Reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

c. Additional details concerning corrective action activities may be found in Section A.6, Section A.1.f, and the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.33 and 1.144).

**14. Document Control**

a. A program is established and implemented to control the development, review, approval, issue, use, and revision of documents.

b. The document control program shall be applied to documents that prescribe activities affecting quality of safety-related structures, systems or components. Such activities include design, procurement, material control, installation, inspection, testing, maintenance, modification, operation, refueling and decommissioning.

c. Revisions of controlled documents are reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable.

d. Controlled documents are available to and used by the person performing the activity.

e. The distribution of new and revised controlled documents is in accordance with procedures. Superseded documents are controlled to prevent inadvertent use.

f. Additional details concerning document control may be found in Section A.1.f and the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.33).

**15. Records**

a. A program is established and implemented to ensure that sufficient records of items and activities (e.g., design, engineering, procurement, manufacturing, construction, inspection and test, installation, preoperation, startup, operations, maintenance, modification, decommissioning, and audits) are generated and maintained to reflect completed work.

b. The program provides provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of records.

c. Additional details concerning record requirements may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guide 1.88).

## C. ASSESSMENT

### 1. Methodology

a. Personnel responsible for carrying out audits are maintained cognizant of day-to-day activities by the ongoing involvement in the quality assurance program requirements so that they can act in a management advisory function.

b. Organizations performing audits are to be technically and performance oriented commensurate with the activity being reviewed.

c. Personnel performing audits have no direct responsibilities in the area they are assessing.

d. Audits are accomplished using procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

**2. Audit**

a. A program of planned and periodic audits is established and implemented to confirm that activities affecting quality comply with the QAPM and that the QAPM has been implemented effectively. Audits will be conducted as required by the applicable Code of Federal Regulations, Technical Specifications, safety analysis reports, and commitments by various correspondence to the NRC. Audits will be conducted at a frequency in accordance with either Section C.2.a.1 or Section C.2.a.2 below.

1. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (± 25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management.

This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.

2. Audit schedules assure that the following areas are audited at the indicated frequencies, or more frequently as performance dictates.

   a. The conformance of unit operation to provisions contained within the Technical Specifications and applicable license conditions at least once per 24 months.

   b. The performance, training and qualification of the station staff at least once per 24 months.

   c. The results of actions taken to correct deficiencies occurring in unit equipment, structures, systems or method of operation that affect nuclear safety at least once per 24 months.

   d. The performance of activities required by the QAPM to meet the requirements of 10CFR50, Appendix B at least once per 24 months.

   e. The fire protection program controls and implementing procedures at least once per 24 months.

   f. The fire protection equipment and program implementation at least once per 24 months utilizing either qualified licensee personnel or an outside fire protection consultant.

   g. The fire protection equipment and program implementation at least once per 36 months utilizing a qualified outside fire protection consultant.

   h. The Radiological Environmental Monitoring Program (REMP) and radiological effluents monitoring activities and implementing procedures at least once per 24 months.

   i. The Offsite Dose Calculation Manual and implementing procedures at least once per 24 months.

   j. The Process Control Program and implementing procedures for processing and packaging of radioactive wastes at least once per 24 months.

3. A grace period of 90 days may be applied to the 24 month frequency for internal audits. For activities deferred in accordance with the 90 day grace period, the next performance due date will be based on their originally scheduled date.

4. Audits shall provide an objective evaluation of quality related practices, procedures, instructions, activities, and items and a review of documents and records, as applicable.

5. Audits shall be performed in accordance with approved written procedures or checklists. Items from previous audits shall be reviewed and reaudited, as appropriate. The checklists are used as guides to the auditor.

6. Scheduling and resource allocation are based on the status and safety importance of the activity or process being assessed.

7. Scheduling is dynamic and resources are supplemented when the effectiveness of the quality assurance program is in doubt.

8. Audit reports are written and distributed to the appropriate levels of management for review. Follow-up action can be accomplished through written communication, re-audit, or other appropriate means, as deemed necessary.

9. Implementation of delegated portions of the quality assurance program is assessed.

10. Audits are conducted using predetermined acceptance criteria, which are the individual requirements within the QAPM, applicable Regulatory Guides and ANSI Standards, procedures, and documents that are used to perform the audited activity or process.

11. Additional details concerning audits may be found in the Regulatory Guides and associated Standards as committed to in Section A.7 and Table 1 (e.g., Regulatory Guides 1.33 and 1.144).

## D. INDEPENDENT SAFETY REVIEW

### 1. Description

a. Independent safety review is performed to meet the individual unit's commitment to perform the functions described in NUREG-0737, Section I.B.1.2, "Independent Safety Engineering Group."

**Table 1 – Regulatory Commitments**

**A. Regulatory Guide 1.8 (Revision 1) [September 1975], *Personnel Selection and Training***

1. FENOC commits to the regulatory position of this Guide with the following clarifications:

   a. Regulatory Guide 1.8 states "The RPM should have a bachelor's degree or the equivalent in a science or engineering subject including some formal training in radiation protection and at least 5 years of professional experience in applied radiation protection." It is FENOC's position that equivalent as used in this Regulatory Guide for the bachelor's degree means (a) four years of post secondary schooling in science or engineering, or (b) four years of applied experience at a nuclear facility in the area for which qualification is sought, or (c) four years of operational or technical experience or training in nuclear power, or (d) any combination of the above totaling four years. The years of experience used to meet the education requirements as allowed by this exception shall not be used to also meet the experience requirements.

2. FENOC commits to the requirements of ANSI N18.1-1971 as modified by plant-specific Technical Specifications.

**B. Regulatory Guide 1.30 (Revision 0) [August 1972], *Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.4-1972 with the following clarifications:

   a. Section 1.1 specifies equipment to which this Standard applies. In lieu of this, requirements of this Standard shall apply to those systems and components that are within the scope of the QAPM. Each plant maintains a list of equipment subject to QAPM requirements. This Standard is also applied to other systems and components when required by approved procedures, engineering specifications, or other work controlling documents.

   b. Section 2.2 requires that evidence of compliance by the manufacturer with purchase requirements, including quality assurance requirements, be available at the site prior to applying the requirements of ANSI N45.2.4. In lieu of this requirement, installation, inspection, and testing activities of equipment lacking its quality documentation may proceed provided that this equipment has been identified and released in accordance with non-conforming material procedures and that all required quality documentation has been received and accepted prior to the item being placed in service.

c. Section 3 requires that records of protective measures maintained during storage for conformance to storage requirements be checked to verify that items are in satisfactory condition for installation. This check shall be made only if equipment requires special storage or handling as specified in procurement documents.

d. Sections 5.2 and 6.2 list the tests which are to be conducted during construction and post-construction activities. In lieu of these tests, FENOC shall conduct only those tests necessary to verify that work activities specified by work controlling documents have been satisfactorily accomplished during maintenance or modification activities. The requirements of Sections 5.2 and 6.2 of ANSI N45.2.4 shall be used as guidelines in determining these testing requirements.

e. Section 6.2.1 states in part that "Items requiring calibration shall be tagged or labeled on completion indicating date of calibration and identity of person that performed the calibration." In lieu of this requirement, FENOC may alternatively implement programs that require the equipment to be suitably marked to indicate the date of the next calibration and the identity of the person that performed the calibration. In addition, installed plant equipment that is used as measuring and test equipment (M&TE) may be controlled to indicate its calibration status and to ensure traceability to calibration test data by alternate means in lieu of physically tagging or labeling (e.g., preventive maintenance program).

**C. Regulatory Guide 1.33 (Revision 2) [February 1978], *Quality Assurance Program Requirements (Operations)***

1. FENOC commits to the regulatory position of this Guide with the following alternatives:

   a. Regulatory Position C.4 specifies audit frequencies for several audit topics. QAPM Section C.2 (Audit) describes alternatives to these frequencies.

2. FENOC commits to the requirements of ANSI N18.7-1976/ANS 3.2 with the following clarifications and alternatives:

   a. Section 1 requires that this Standard "apply to all activities affecting the safety-related functions of nuclear power plant structures, systems, and components." FENOC shall apply the requirements of this Standard to those structures, systems, and components identified as safety-related in the respective plant's USAR.

   b. Section 5.1 states in part that "a summary document should be compiled by each owner organization to identify the sources, to index such sources to the requirements of this Standard, and to provide a consolidated base for the description of the program." In lieu of this requirement, a method of cross-referencing these requirements to the implementing procedures will be maintained.

   c. Section 5.2.2 requires that "temporary changes which clearly do not change the intent of the approved procedure shall, as a minimum, be approved by two members of the

plant staff knowledgeable in the areas affected by the procedure. At least one of these shall be the supervisor in charge of the shift and hold a senior operating license on the unit affected." Such changes shall be documented and if appropriate, incorporated into the next revision of the affected procedure. In lieu of these requirements, FENOC commits to the following:

1) Temporary changes to procedures which do not change the intent of the approved procedure shall be approved for implementation by two members of the plant management staff, at least one of whom holds a Senior Reactor Operating License for the unit affected. The temporary procedures shall be approved by the original approval authority within 14 days. For changes to procedures which may involve a change in intent of the procedure, the original approval authority shall approve the change prior to implementation. OR

2) Temporary changes to procedures will be approved by two knowledgeable members of the plant staff prior to implementation. At least one of these persons will be a member of supervision. If the change affects operations procedures, at least one of these persons will hold a senior reactor operator license for the unit affected. Prior to implementation, the OSC (PORC) shall review and recommend approval of temporary changes to procedures which require a 10CFR50.59 safety evaluation. Within 14 days of implementation, temporary changes will be reviewed by an independent qualified reviewer and approved by the Responsible Discipline Manager or his designee.

d. Section 5.2.6 requires that a log be maintained to identify the current status of temporary modifications such as bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings. FENOC takes exception to this requirement when the installation and removal of such temporary modifications is specifically addressed in approved procedures. These procedures ensure that the circuitry is returned to its original configuration when the operation is completed.

e. Section 5.2.7 – Since certain emergency situations could arise which might prevent preplanning activities, FENOC complies with an alternative to the first sentence in the second paragraph as follows: "Except under 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 approved procedures. When written procedures would be required and are not used, the activities that are accomplished are documented after-the-fact and receive the same degree of reviews as if they had been preplanned."

f. Section 5.2.13 (1) establishes the requirement for identifying quality assurance program requirements applicable to the items or services being procured. When purchasing commercial grade services from certain accredited calibration laboratories, the procurement documents are not required to impose a quality assurance program consistent with ANSI N18.7. Alternative requirements described

in this QAPM for Regulatory Guide 1.123 may be implemented in lieu of imposing a quality assurance program consistent with ANSI N18.7.

g. Section 5.2.15 contains a requirement for biennial review of plant procedures. In lieu of this requirement, FENOC may use one of the following methods as alternatives:

1) Implement process controls that ensure procedures are reviewed for possible revision upon identification of new or revised source material potentially affecting the intent of procedures.

2) Implement process controls related to procedure review, a maximum six year review period and biennial audits of operating organizations that include a review of their procedures to assure that controls result in timely procedure revision in response to operations experience deficiencies and procedure deficiencies identified by users.

h. Section 4.3.4 (3) discusses the requirement for the on-site and off-site independent review bodies to review license amendments and technical specification changes. As an alternative to the requirements for the off-site review body to review license amendments and technical specification changes, FENOC will utilize the on-site review body for these reviews. To ensure that the on-site review body maintains independence during these reviews, any voting member that has a potential conflict of interest in a change under review will be replaced by another member to achieve a quorum. In addition, the off-site review body will review on-site review body meeting minutes and independent oversight (QA) audit and assessment results of on-site review body activities to evaluate their effectiveness.

**D. Regulatory Guide 1.37 (Revision 0) [March 1973],** *Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants*

1. FENOC commits to the regulatory position of this Guide with the following clarifications:

a. Regulatory Position C.3 requires that water quality for final flushes of fluid systems and associated components be at least equivalent to the quality required for normal operation. This requirement is not applied to dissolved oxygen or nitrogen nor does it infer that additives normally in the system water shall be added to the flush water.

b. Regulatory Position C.4 requires that chemical components that could contribute to intergranular cracking or stress corrosion cracking should not be used with austenitic stainless steel and nickel-based alloys. It is FENOC's position that materials such as inks, temperature indicating crayons, labels, wrapping materials (other than polyethylene), water soluble materials, desiccants, lubricants, and NDE penetrant materials and couplants, which contact stainless steel or nickel-based alloy material surfaces contain no more than trace amounts of lead, zinc, copper, or lower melting

alloys or compounds. Maximum allowable levels of water leachable chloride ions, total halogens and sulfur compounds shall be defined and imposed on the aforementioned materials. These materials will be controlled through administrative procedures that are, in part, designed to minimize their effects on intergranular cracking or stress corrosion cracking.

2. FENOC commits to the requirements of ANSI N45.2.1-1973 with the following clarifications:

   a. During maintenance and modification activities, FENOC shall control the opening of clean systems and shall conduct inspections to verify that affected system cleanliness levels shall not be adversely affected by the maintenance or modification activity. When system cleanliness is affected, specific cleaning procedures which incorporate the applicable portions of this Standard shall be developed and implemented to maintain system cleanliness.

   b. Section 2.4 requires that personnel who perform inspection, examination or testing activities required by this Standard be qualified in accordance with ANSI N45.2.6. In lieu of this, personnel who perform cleanliness inspections may alternatively be qualified in accordance with Regulatory Guide 1.8.

**E. Regulatory Guide 1.38 (Revision 2) [May 1977], *Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.2-1978 with the following clarifications:

   a. Sections 3 and 4 specify a four level classification system for the packaging and shipping of items. In lieu of these requirements, commercial grade items shall be packaged and shipped in accordance with standard commercial practices.

   b. Section 5.2.1 requires preliminary visual inspection or examination for shipping damage to be performed prior to unloading. In lieu of this requirement, visual inspection shall be performed during unloading and unpacking.

   c. Section 5.5 provides for "rework" and "use-as-is" dispositions for nonconforming items. As an alternative, the "repair" disposition (as defined by ANSI N45.2.10-1973) may also be used.

   d. Section 6.5 requires that items released from storage and placed in their final locations within the power plant be inspected and cared for in accordance with the requirements of Section 6 of this Standard and other applicable Standards. In lieu of this requirement, FENOC shall, whenever feasible, store items within their

appropriate storage area and move the equipment to the plant areas for staging only in sufficient time to support its installation. Within the plant, the equipment shall be staged at locations which provide equivalent environmental conditions under which it is designed to operate. Materials placed in staging areas shall be stored in accordance with the applicable requirements of Paragraphs 6.1, 6.3 and 6.4.2 of ANSI N45.2.2.

e. Various Sections of ANSI N45.2.2 address the use of non-halegenated materials when in contact with austenitic stainless steel or nickel-based alloys. The exceptions applicable to Regulatory Guide 1.37 regarding this subject also apply to ANSI N45.2.2.

f. Section A.3.4.2 addresses inert gas blankets. There may be cases involving large or complex shapes for which an inert or dry air purge flow is provided rather than static gas blankets in order to provide adequate protection due to difficulty of providing a leak-proof barrier. In these cases, a positive pressure purge flow may be used as an alternative to a leak-proof barrier.

**F. Regulatory Guide 1.39 (Revision 2) [September 1977], *Housekeeping Requirements for Water-Cooled Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.3-1973 with the following alternative.

   a. The ANSI five level zone designation system may not be utilized, but the intent of the standard will be met for the areas of housekeeping, plant and personnel safety, and fire protection.

**G. Regulatory Guide 1.58 (Revision 1) [September 1980], *Qualification of Nuclear Power Plant Inspection, Examination and Testing Personnel***

1. FENOC commits to the regulatory position of this Guide with the following clarifications:

   a. The guidance of this Regulatory Guide shall be followed as it pertains to the qualification of personnel who verify conformance of work activities to quality requirements.

   b. Personnel will not be certified as stated in this Guide in the following areas:

      1) Individuals that handle test results or perform document control activities.

      2) Quality assurance and staff personnel responsible for the review of documents for clarity and completeness.

3) Test personnel utilizing gas test methods for information or data collection activities (this includes those personnel performing local leak rate testing (LLRT) as stated in 10CFR50 Appendix J). The qualifications of these personnel shall conform to the requirements of Regulatory Guide 1.8.

4) Plant operation personnel concerned with day-to-day operation, maintenance, and certain technical services (the qualifications of these personnel shall conform to the requirements of Regulatory Guide 1.8).

c. Regulatory Position C.2 indicates that SNT-TC-1A-1975 is to be used for the qualification of nondestructive examination (NDE) personnel who apply various NDE methods. It also indicates that personnel performing nondestructive examinations required by Section III and Section XI of the ASME Code should be qualified to SNT-TC-1A-1975 as well as additional provision of the Code. For the qualification of NDE personnel, FENOC commits to the ASME Section XI requirements specified within the applicable code year edition(s) as defined by 10CFR50.55a. This alternative may be applied regardless of whether examinations are of a type required by the Code.

2. FENOC commits to the requirements of ANSI N45.2.6-1978 as modified by the commitments to Regulatory Guide 1.58 with the following clarifications:

a. Section 2.5 of this Standard discusses special physical characteristics. FENOC commits to the following: Examinations to verify that personnel have the required physical characteristics will be scheduled on an annual basis with a maximum allowable extension of 90 days.

b. Section 3.5 of this Standard discusses education and experience. FENOC commits to the following: The initial qualifications of individuals to Level I, II, or III will generally be to the education and experience recommendations in the Standard. However, in certain instances as determined by appropriate management, qualifications may be alternatively determined through test results and/or demonstration of capabilities. For Level I, FENOC will also accept a four year college degree plus one month of related experience or equivalent inspection, examination or testing activities. Individual requalification will meet or exceed the recommendation of this Standard.

c. Section 2.3 of this Standard discusses evaluating personnel who have not performed inspection activities for more than a year. A 90 day grace period is applied to this evaluation.

**H. Regulatory Guide 1.64 (Revision 2) [June 1976], *Quality Assurance Requirements for the Design of Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide with the following clarifications:

a. Regulatory Position C.2(1) addresses the use of a supervisor in design verification. If, in exceptional circumstances, the supervisor is the only technically qualified individual available, the design verification or checking shall be conducted by the supervisor with the following provisions:

1) The other requirements of Regulatory Position C.2 of this Guide shall be met.

2) The justification shall be individually documented and approved by the next level of supervision.

3) Quality assurance audits shall include review of frequency and effectiveness of the use of the immediate supervisor to assure that this provision is used only in exceptional circumstances.

b. An individual who contributed to a given design may participate in a group verification of that design provided that the individual who contributed to the design does not (1) verify his contribution to the design, or (2) serve as chairman or leader of the group verification activity.

2. FENOC commits to the requirements of ANSI N45.2.11-1974 with the clarifications as noted above for the use of an immediate supervisor for design verification activities and conduct of group verification activities.

**I. Regulatory Guide 1.74 (Revision 0) [February 1974], *Quality Assurance Terms and Definitions***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.10-1973.

**J. Regulatory Guide 1.88 (Revision 2) [October 1976], *Collection, Storage and Maintenance of Nuclear Power Plant Quality Assurance Records***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.9-1974 with the following alternatives:

a. Section 5.6 addresses records storage facilities. In lieu of this, the design and construction of quality assurance record storage facilities will follow the guidance of ANSI/ASME NQA-1-1983, Supplement 17S-1, Section 4.4. When temporary storage of records is required, the guidance of ASME NQA-1-1989, Supplement 17S-1, Section 4.4.3 will be followed. For storage of special processed records (such as radiographs and microfilm), humidity and temperature controls shall be provided so as to maintain an environmental condition as prescribed in Paragraph 6.1.1 of ANSI PH 1.43-1979 (Also required by Section 5.4).

b. Appendix A of ANSI N45.2.9, requires that records of measuring and test equipment calibration be maintained "until recalibration." This implies that the full storage requirements of this Standard apply until the equipment is recalibrated. In lieu of this requirement, FENOC may store measuring and test equipment calibration records in one-hour fire rated containers. This exception does not apply to records of calibration required by the Technical Specifications.

c. For managing QA records in electronic media FENOC commits to the guidance of RIS-2000-018. This NRC Regulatory Issue Summary (RIS) endorses:

- NIRMA Technical Guide (TG) 11-1998, Authentication of Records and Media
- NIRMA TG 15-1998, Management of Electronic Records
- NIRMA TG 16-1998, Software Configuration Management and Quality Assurance
- NIRMA TG 21-1998, Electronic Records Protection and Restoration

**K. Regulatory Guide 1.94 (Revision 1) [April 1976], *Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.5-1974 with the following clarifications and alternatives:

a. Section 2.2 requires that installation, inspection, and test procedures be kept current with the latest information. This Standard was written to address requirements associated with construction phase activities. However, during the operations phase, activities associated with installation, inspection, and testing of structural concrete and structural steel are very minor in frequency and extent. Consequently, procedures for these activities shall only be reviewed or updated prior to commencing the activity. The procedures for structural concrete and structural steel installation, inspection, and testing activities will be developed using the provisions of ANSI N45.2.5 – 1974.

b. Alternatives to this Standard are taken with respect to frequency of calibration of impact wrenches and bolt projection criteria. Impact and torque wrenches shall be checked at least once daily per shift, and at least one full thread of all bolts shall project beyond the nut of all tightened connections. These criteria comply with the recommendations of the Research Council on Riveted and Bolted Structural Joints.

c. Section 4.9.1 discusses the qualification requirements for mechanical (cadweld) splice operators. In lieu of this, Davis-Besse and Beaver Valley will comply with qualification requirements of ASME Section III, 1995 Edition, subparagraph CC-4333.4.

d. Section 4.9.3 discusses tensile testing of mechanical (cadweld) splices. In lieu of this, Davis-Besse and Beaver Valley will comply with the requirements of ASME Section III, 1995 Edition, subparagraph CC-4333.5.2.

e. Section 4.9.4 discusses tensile testing frequency. In lieu of this, Davis-Besse and Beaver Valley will comply with ASME Section III, 1995 Edition, subparagraph CC-4333.5.3.

f. Section 4.9.4 discusses testing of both production and sister mechanical (cadweld) splices. In lieu of this, Davis-Besse and Beaver Valley will test sister mechanical (cadweld) splices as described in ASME Section III, 1995 Edition, subparagraph CC-4333.5.2.

g. Section 5.5 discusses inspection of structural steel welding. In lieu of this, Davis-Besse and Beaver Valley will comply with inspection requirements of the applicable welding codes and any exceptions.

h. The mechanical splice personnel qualification, testing and testing frequency requirements for mechanical (cadweld) splices addressed in K.2.c through K.2.f apply to other full positive connection technologies that meet the design code of record. The frequency of shear screw and sleeve splice testing shall meet the same requirements as swaged splices.

**L. Regulatory Guide 1.116 (Revision 0) [May 1977], *Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.8-1975 with the following clarifications:

   a. Sections 2.4 and 2.6 require that procedures define system restoration requirements as needed to prevent contamination after cleanliness class is achieved in accordance with commitments to ANSI N45.2.1 and ANSI N45.2.3.

   b. Section 2.9 requires that evidence of compliance by the manufacturer with purchase requirements, including quality assurance requirements, be available at the site prior to applying the requirements of this Standard. In lieu of this requirement, section B.4 (Procurement Control) of this manual describes the controls for equipment lacking quality documentation.

c. Section 4.5.1 provides requirements for the cleaning, flushing, and conditioning of installed systems. FENOC's position on Regulatory Guide 1.37 and ANSI N45.2.1 also apply to this Section and take precedence over the requirements of ANSI N45.2.8 when conflicts exist.

**M. Regulatory Guide 1.123 (Revision 1) [July 1977], *Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.13-1976 with the following clarifications, exceptions and alternatives:

   a. Subsection 3.2.3 discusses quality assurance program requirements for procurement documents. For the purchasing of commercial grade calibration services from domestic calibration laboratories accredited by a nationally recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with ANSI N18.7.

      In such cases, accreditation may be acceptable in lieu of the purchaser imposing a QA program consistent with ANSI N18.7, provided all the following are met:

      1) The accreditation is to ISO/IEC 17025.

      2) The calibration laboratory holds a domestic accreditation by one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

         - National Voluntary Laboratory Accreditation Program (NVLAP), administered by NIST
         - American Association for Laboratory Accreditation (A2LA)
         - ACLASS Accreditation Services (ACLASS)
         - International Accreditation Service (IAS)
         - Laboratory Accreditation Bureau (L-A-B)

      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 FENOC QA Program and technical requirements. This will include requiring that the supplier identify the laboratory equipment/standards used and the as-found and as-left data in the calibration certificate/report.

      5) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

b. The alternative method is applicable to sub-suppliers of calibration service suppliers, provided the above conditions are met.

c. Section 4 provides for the selection of procurement sources. For "commercial grade" items and for non-safety related items within the scope of the Quality Assurance Program for which there are no quality assurance program or quality documentation requirements, the requirements of this Section need not be adhered to. However, the procurement documents shall specify requirements specific to the item being procured, sufficient to provide adequate certification or other records to ensure that items and activities meet the specified requirements.

d. Section 8.2 provides requirements for the control of nonconformances. Suppliers qualified by FENOC as design agents in accordance with Regulatory Guides 1.64 and 1.123 may be permitted under specific contractual provisions to disposition nonconformances as "use-as-is" or "repair" on behalf of FENOC. All nonconformances dispositioned "use-as-is" or "repair" by suppliers qualified by FENOC as design agents on behalf of FENOC are required to be submitted to FENOC for engineering approval at the time equipment is received on site. If FENOC determines that a disposition has been incorrectly made, a nonconformance report is generated on site to document the problem and effect resolution.

e. Section 10.2.d is interpreted as follows: The person attesting to a certificate shall be an authorized and responsible employee of the supplier and shall be identified by the supplier.

**N. Regulatory Guide 1.144 (Revision 1) [September 1980], *Auditing of Quality Assurance Programs for Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide with the following alternatives:

   a. Section C.3.b (2) outlines the requirements for triennial audits and annual evaluations of suppliers. A 90 day grace period may be applied to these activities. For triennial audits and annual evaluations that are deferred, the next performance due date will be based on the originally scheduled date.

   b. Section C.3.b (2) outlines the requirements for triennial audits and annual evaluations of suppliers. When purchasing commercial grade calibration services from domestic 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.

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

1) The accreditation is to ISO/IEC 17025.

2) The calibration laboratory holds a domestic accreditation by one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

- National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology (NIST)
- American Association for Laboratory Accreditation (A2LA)
- ACLASS Accreditation Services (ACLASS)
- International Accreditation Service (IAS)
- Laboratory Accreditation Bureau (L-A-B)

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

c. The alternative method is applicable to sub-suppliers of calibration service suppliers, provided the above conditions are met.

d. Section C.3.b (2) outlines the requirements for triennial audits and annual evaluations of suppliers. Instead of documenting evaluations of suppliers on an annual basis, FENOC may document evaluations of suppliers on an ongoing basis, using the guidance of Section C.3.b of this Regulatory Guide. The results of these ongoing evaluations are reviewed and appropriate corrective actions taken. Adverse findings resulting from these evaluations are periodically reviewed in order to determine if, as a whole, they result in a significant condition adverse to quality and to provide input to support supplier audit activities conducted by the licensee or a third party auditing entity.

2. FENOC commits to the requirements of ANSI N45.2.12-1977 with the following clarification:

a. Section 4.5.1 of this Standard discusses follow-up and corrective actions. FENOC may utilize the provisions of the corrective action program outlined in Section A.6 instead of these requirements, as long as the appropriate time limits are applied to significant conditions adverse to quality. Also, no additional documentation is necessary if needed corrective actions are taken and verified prior to audit report issuance.

b. Sections 4.3.1 and 4.3.3 of this Standard discuss pre-audit and post-audit conferences. Pre-audit and post-audit conferences may be fulfilled by a variety of communications, such as telephone conversation.

c. Section 4.3.1 and 4.3.3 of this Standard discuss pre-audit and post-audit conferences. Pre-audit and post-audit conferences are only held when deemed necessary by quality assurance or when requested by the audited organization.

d. Section 4.4 discusses audit reporting. Audit reports shall be issued within thirty working days after the last day of the audit. The last day of an audit shall be considered to be the day of the post-audit conference. If a post-audit conference is not held because it was deemed unnecessary, the last day of the audit shall be considered to be the date the post-audit conference was deemed unnecessary as documented in the audit report.

**O. Regulatory Guide 1.146 (Revision 0) [August 1980], *Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants***

1. FENOC commits to the regulatory position of this Guide.

2. FENOC commits to the requirements of ANSI N45.2.23-1978 with the following alternatives.

   a. Section 2.3.1.3 discusses other credentials of professional competence. Holders of NRC issued Reactor Operator/Senior Reactor Operator Licenses comply with the requirements of this section and may be awarded two credits.

   b. Section 2.3.4 discusses audit participation. Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and lead an audit team. They shall have participated in at least one nuclear audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively lead audits, licensee management may designate a prospective lead auditor as a lead auditor.

   c. Section 3.2 requires an annual evaluation of lead auditors. A 90 day grace period may be applied to the annual evaluation. For those evaluations that are deferred, the next performance due date will be based on the originally schedule date.

   d. Section 5.3 requires that records for lead auditors be maintained and updated annually. A 90 day grace period may be applied to the annual update. For those updates that are deferred, the next performance due date will be based on the originally schedule date.