NEI 06-14A [Revision 5]

Quality Assurance Program Description

May 2008

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Nuclear Energy Institute

Quality Assurance Program Description

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EXECUTIVE SUMMARY

NEI 06-14A, "Quality Assurance Program Description (QAPD)," provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement applicable requirements related to the Quality Assurance Program. The QAPD template includes the methods and QAPD and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR Part 52. The template is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as specified in this document. ASME NQA-1-1994 is the latest NRC approved standard for a Quality Assurance Program as referenced in the Standard Review Plan (NUREG-0800).

NEI 06-14A is structured as a template for use in developing the applicant-specific QAPD required as part of ESP and COL applications. The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for the ESP or COL application. NEI 06-14A includes, following this Executive Summary, a template for a corporate Quality Assurance Policy Statement.

The NRC approved NEI 06-14A in an April 2007 Final Safety Evaluation for use on early site permit, combined license, construction, pre-operation and/or operation activities. The NRC Safety Evaluation is included as an appendix to this document.

NRC staff review of applicant-specific QAPDs based on NEI 06-14A is expected to focus on the specific information provided to replace the bracketed text in the generic template.

[Company Name]

POLICY STATEMENT

[Company Name] ([Company Abbreviation - CA]) shall design, procure, construct and operate nuclear plants in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable laws and regulations of the state and local governments.

The *[CA] [Nuclear Development]* Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) provided in this document and the associated implementing documents. Together they provide for control of *[CA]* activities that affect the quality of safety-related nuclear plant structures, systems, and components and include all planned and systematic activities necessary to provide adequate confidence that such structures, systems, and components will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents *[CA]'s* overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the *[CA]* QAP.

Signed

[NAME]
[President and Chief Executive Officer]
[CA]

[Date]

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PART I INTRODUCTION

SECTION 1 GENERAL

[NOTE: This QAPD can be used for Early Site Permit (ESP)/Combined Operating License (COL)/ construction/pre-operation and/or operations. Appropriate references should be used in the bracketed text.]

[Company (CA)] [Nuclear Development] Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for *[ESP/COL/construction/pre-operation and/or operations]* activities conducted by or for *[CA].* The QAPD describes the methods and establishes QAPD and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as specified in this document.

The QAPD is defined by the NRC approved regulatory document that describes the Quality Assurance Program (QAP) elements, along with the associated implementing documents. Procedures and instructions that control *[Nuclear Development]* activities will be developed prior to commencement of those activities. *[Policies establish high level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all [CA] organizations performing those activities such that the activity is controlled and carried out in a manner that meets QAPD requirements. Site or organization specific procedures establish detailed implementation requirements and methods, and may be used to implement Policies or be unique to particular functions or work activities.]*

1.1 Scope/Applicability

This QAPD applies to *[ESP, COL, construction/pre-operation and/or operations]* activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing	*Handling*	*Startup*	*Storing*	*Decommissioning*
Constructing	*Testing*	*Siting*	*Erecting*	*Modifying*
Procuring	*Pre-operational activities*	*Operating*	*Installing*	*Inspecting*
Fabricating	*(including ITAAC)*	*Maintaining*	*Repairing*	*Refueling*
Cleaning	*Licensing*	*Receiving*	*Training*	*Shipping*

Safety-related systems, structures, and components, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QAPD requirements for activities within their scope.

The policy of *[CA]* is to assure a high degree of availability and reliability of its nuclear plants while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1, 1994 Part I Section I.4 apply to select terms as used in this document.

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This Section describes the *[CA]* organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes *[corporate/support/off-site]* and on-site functions for *[Nuclear Development]* including interface responsibilities for multiple organizations performing quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

[CA management] is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

[The following information will be utility specific but should follow the SRP for the content. It should also include major suppliers of services – NSSS (Applicant for certification or Design Certification Holder (DC)) vendor, A/E, etc. This also includes interface responsibilities for multiple organizations performing quality-related functions. Below is an example of level of detail which illustrates a new plant organization, its independence, and its linking within an existing utility.]

[The [CA] [Nuclear Development (ND)] organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operations development activities. There are several organizations within [CA] which implement and support the QAPD. These organizations include, but are not limited to [Nuclear Development], Technical Services, Corporate Services and Quality Assurance.

Design, engineering and environmental services are provided to the [CA] [Nuclear Development] organization by [two] primary contractors in accordance with their QAPDs. These two contractors are [A/E Firm] and [NSSS vendor].

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the [Nuclear Development] QA Program. The [CA] organization and the [Nuclear Development] organization are shown in Figures II. 1-1 and II. 1-2 respectively.

1.1 President and CEO

The president/CEO is responsible for all aspects of design, construction and operation of [CA]'s nuclear plants. The president/CEO is also responsible for all technical and administrative support activities provided by [CA] and contractors. The president/CEO directs the chief nuclear officer/executive vice president, the [Senior Nuclear Development Officer], the vice president corporate services, and the vice president technical services in fulfillment of their responsibilities. The president/CEO reports to the [CA] Board of Directors with respect to all matters.

1.2 [Nuclear Development]

[Company name], [Nuclear Development] ([ND]) organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operational development activities.

1.2.1 [Senior Nuclear Development Officer]

The Senior Nuclear Development Officer (SNDO) reports to the [CA] President and CEO and is responsible for the administration of the [Nuclear Development] QAPD. The SNDO also directs the planning and development of the [Nuclear Development] staff, and organization resources. The SNDO is also responsible for establishing and managing the NSSS contract for the development of new nuclear generation.

1.3 Technical Services

The Technical Services organization is responsible for support of [Nuclear Development] organization by providing engineering, licensing and document control support where applicable.

1.3.1 Vice President - Technical Services

The Vice President - Technical Services reports to the [CA] President and CEO and is responsible for the administration of engineering, nuclear fuel and nuclear licensing for the existing plants and may provide support activities for [Nuclear Development] under the QAPD.

1.4 Corporate Services

The Corporate Services organization is responsible for supporting the [Nuclear Development] organization through performing activities related to procurement, safety and health and information technology where applicable.

1.4.1 Vice President Corporate Services

The Vice President Corporate Services, reports to the [CA] President/CEO and is responsible for managing the overall Corporate Services organization including assuring that Supply Chain Management, Safety and Health and Information Technology support [Nuclear Development] activities in accordance with the QAPD.

1.5 Executive Vice President

The Executive Vice President is the Chief Nuclear Officer (CNO) and is responsible for the safe, reliable, and efficient operation of [CA] nuclear plants. The CNO directs the operating plants' Vice Presidents - Project (xxxx and yyyy), and the Quality Assurance Manager. The Executive Vice President will support [Nuclear Development] activities through the Vice President - xxxx and the Quality Assurance organization.

1.5.1 Vice President - Project

The Vice Presidents - Project report to the Executive Vice President and are responsible for the overall safe and efficient operation of their operating plant, and for the implementation of quality assurance requirements in the areas specified by the operations QAPD.

For the purposes of this program, the description of the duties of the Vice Presidents - Project and their staff will be limited to those site activities that support the [Nuclear Development] new nuclear generation activities.

1.5.1.1 Site Project Organization

The Site Project Organization is responsible for operations and maintenance of the respective plant site. The Site Project Organization is responsible for operations quality inspection activities of operations on-site work, including any that support [Nuclear Development] ESP and COL application development, as well as controlling interfaces between the operating units and any preconstruction or construction activities.

1.5.2 Quality Assurance

The [CA] Quality Assurance Organization is responsible for independently planning and performing activities to verify the development and effective implementation of the [CA] QAPDs including but not limited to [Nuclear Development], engineering, licensing, document control, corrective action program and procurement that support new nuclear plant generation.

1.5.2.1 Quality Assurance Manager

The Quality Assurance Manager reports to the Executive Vice President for the operations activities and to the Senior Nuclear Development Officer] for the new reactor activities and is responsible for developing and maintaining the [CA] QAPDs, evaluating compliance to the programs and managing the QA organization resources.

1.5.2.1.1 [Nuclear Development] Quality Assurance Project Manager

The [Nuclear Development] Quality Assurance Project Manager (QAPM) reports administratively to the [CA] QA Manager and functionally to the Senior Nuclear Development Officer, and is responsible for the development and verification of implementation of the QAPD described in this document. The QAPM is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; for monitoring organization processes to ensure conformance to commitments and licensing document requirements; for ensuring that vendors providing quality services, parts and materials to [CA] are meeting the requirements of 10 CFR 50, Appendix B through NUPIC or [CA] vendor audits. The QAPM has sufficient independence from other [Nuclear Development] priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding [CA]'s [Nuclear Development] activities. The QAPM may make recommendations to the [Nuclear Development] management regarding improving the quality of work processes. If the QAPM disagrees with any actions taken by the [ND] organization and is unable to obtain resolution, the QAPM shall inform the QA Manager and bring the matter to the attention of the Senior Nuclear Development Officer] who will determine the final disposition.

1.6 NSSS Applicant for Certification or DC Holder

NSSS, Applicant for certification, or DC Holder provides engineering services for plant design and licensing of Plant type plants on CA sites. These engineering services for new nuclear generation include site specific engineering and design necessary to support development of ESP and COL applications, preconstruction and construction activities.

1.7 A/E

A/E Firm provides engineering services for the development of the ESP and COL applications. These engineering services include site specific license engineering, and design activities necessary to support development of the ESP and COL applications, and planning and support for preconstruction and construction of new nuclear generation.]

1.8 Authority to Stop Work

Quality assurance and inspection personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers furnishing safety-related materials and services to *[CA].*

1.9 Quality Assurance Organizational Independence

For the *[ESP/COL and/or construction]*, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.10 NQA-1-1994 Commitment

In establishing its organizational structure, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

Figure II.1-1

[CA] Organization

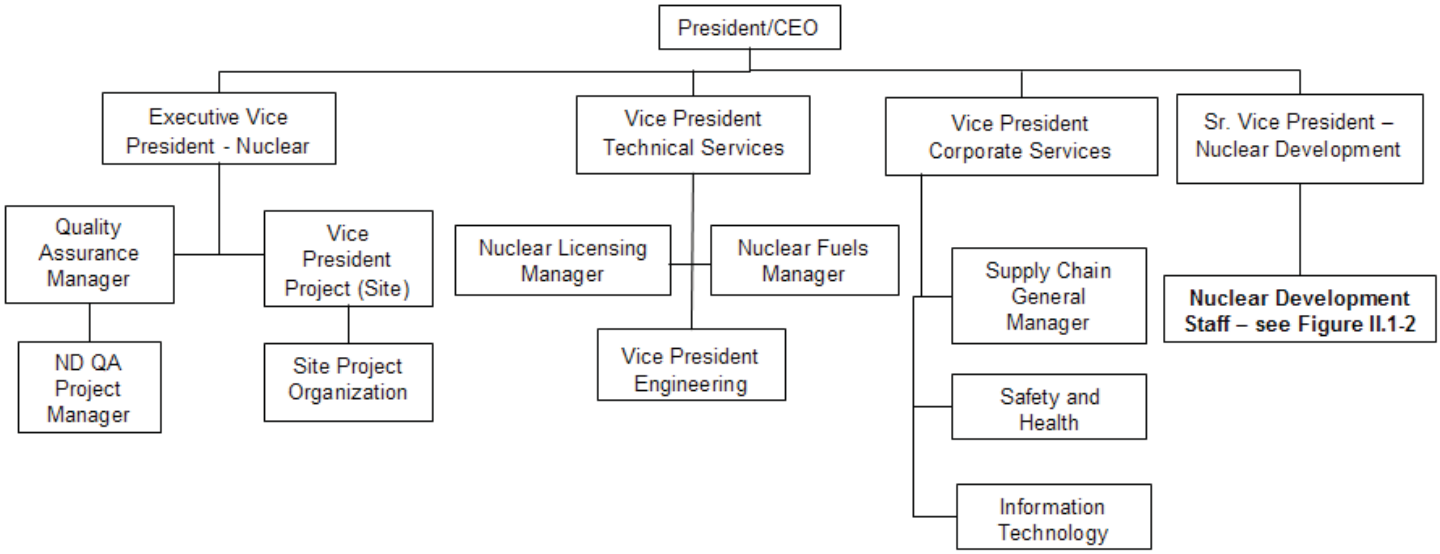
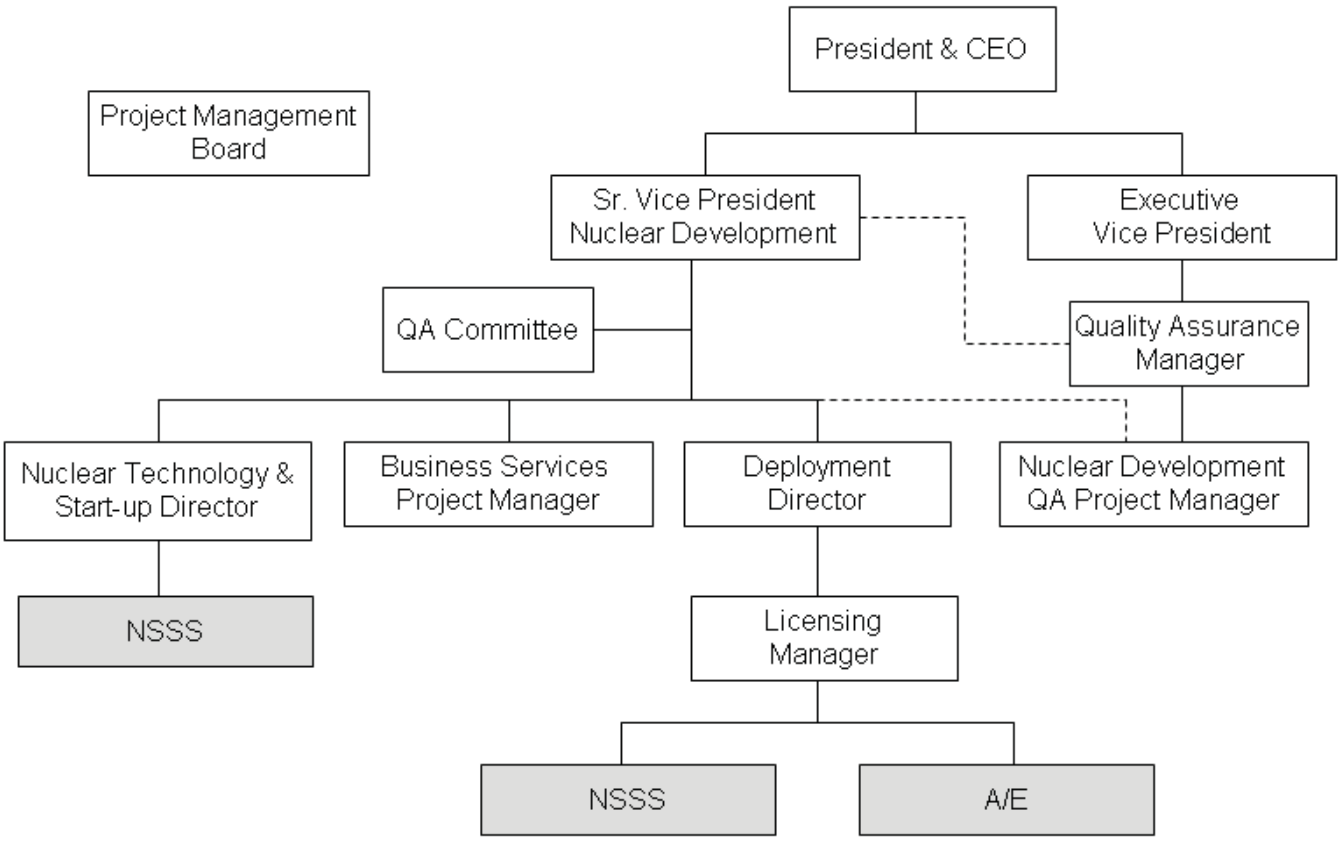


Figure II.1-2

[Nuclear Development] Organization



SECTION 2 QUALITY ASSURANCE PROGRAM

[CA] has established the necessary measures and governing procedures to implement the QAPD as described in the QAPD. *[CA]* is committed to implementing the Quality Assurance Program in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in this QAPD. Further, *[CA]* ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. This QAPD also applies to certain non-safety-related structures, systems, components and activities to a degree consistent with their importance to safety. Senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAPD through the audit functions described in the Audit Section of this QAPD.

The objective of the QAPD is to assure that [CA] nuclear generating plants are designed constructed and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAPD applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the design, licensing, construction and operation of new nuclear power plants as described in the *[ESP Site Safety Analysis Report and COL Final Safety Analysis Report.] [Examples of ESP/COL program safety-related activities include, but are not limited to, site specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis.]* A list or system identifying SSCs and activities to which this program applies is maintained at the appropriate facility. The Design Certification Document is used as the basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAPD.

As described in Part III of this QAPD, specific program controls are applied to non-safety-related SSCs that are significant contributors to plant safety. 10CFR50, Appendix B is not applicable to these SSCs. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAPD, provided that the supplier or principle contractor has been approved as a supplier in accordance with the QAPD. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principle contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier’s personnel provide added assurance that quality expectations are met.

For the *[ESP and/or COL]* applications, this QAPD applies to those [Nuclear Development] and [CA] activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In addition, this QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of *[CA]'s [Nuclear Development]* organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD and *[NSSS]* QA programs prior to commencement of *[preconstruction*

(ESP) and/or construction (COL)] activities. *[Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and for construction of new plants, the interface between non-safety-related and safety-related SSCs and the placement of seismically designed backfill.]*

In general, the program requirements specified herein are detailed in implementing procedures that are either *[CA]* implementing procedures, or supplier implementing procedures governed by a supplier quality program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audits schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for *[CA]* are responsible for the achievement of acceptable quality in the work covered by this QAPD. This includes those activities delineated in Part I, Section 1.1 of this QAPD. *[CA]* personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The *[Quality Assurance Project Manager]* is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

[CA] retains and exercises the responsibility for the scope and implementation of an effective QAPD. Positions identified in the Organization Section of this QAPD may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

[2.3 ESP and COL Identification of Site Specific Safety-Related Design Basis Activities

ESP site specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that will be used to determine the bounding physical parameters of the site. The development of the [CA] ESP and COL applications will involve site testing, data collection and calculations that may create or bound safety-related design basis data. Site testing and data collection of information

pertaining to the physical characteristics of the site that have the potential to affect safety-related design will be considered safety-related. In addition, calculations and other engineering data that bounds or characterizes the site will be classified as safety-related. The [ND] organization will develop an ESP application Quality Criteria Document (QCD) identifying the sections of the application that include safety-related design basis activities. In addition the QCD will identify those sections of the application and supporting analysis that will be treated with appropriate quality requirements. The [ND] organization will develop annotated outlines for the COL application that will identify the sections safety classification and the regulatory requirements applicable to the section content.]

2.4 Periodic Review of the Quality Assurance Program

Management, of those organizations implementing the QA program or portions thereof, assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, which ever is shorter. However, the period for assessing QA programs during the operations phase may be extended to once every two years.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a), as appropriate. Changes to the QAPD are evaluated by the *[ND Quality Assurance Project Manager]* to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the *[ESP and COL]* application development process. New revisions to the document will be reviewed, at a minimum, by the *[CA] [Quality Assurance Manager]* and approved by the *[Senior Vice President - Nuclear Development].*

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of Appendix B will be satisfied. In order to comply with this requirement, the FSAR references this QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD.

2.6 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end *[CA]* establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. Plant and support staff minimum qualification requirements are as delineated in each site's Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable *[CA]* procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed.

Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. Records of personnel training and qualification are maintained.

The minimum qualifications of the *[[Quality Assurance Manager] and the [Nuclear Development Quality Assurance Project Manager] are]* an engineering or related science degree and a minimum of four years of related experience with at least two years of nuclear power plant experience. During the four years, the individual shall have at least one year of supervisory or management experience, and one year of experience performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7 Independent Review

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). The [*Independent Review Body (IRB)/Independent Review Committee (IRC)]* also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.

b. Reviews proposed tests and experiments not described in the SAR. Changes to proposed tests and experiments not described in the SAR that do require a technical specification change must be reviewed by the *[IRB/IRC]* prior to NRC submittal and implementation.

c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.

d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

e. Reviews any matter related to nuclear safety that is requested by the Site Vice President, Site Director, Plant Manager, or any *[IRB/IRC]* member.

f. Reviews corrective actions for significant conditions adverse to quality.

g. Reviews the adequacy of the audit program every 24 months.

[Option I or Option II may be used.]

[Option I - Independent Review Body

A group may function as an independent review body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

1. IRB reviews are supplemented as follows:

   a. A qualified person, independent of the preparer, reviews proposed changes in the
   procedures as described in the SAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.

   b. Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.

   c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.

2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

   a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities.

   b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.

   c. Results of the review are documented and reported to responsible management.

   d. Management periodically consider issues they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.

e. Management determines the scheduling and scope of review and the composition of the team performing the review.]

[Option II - Independent Review Committee

1. An independent review committee is assigned independent review responsibilities.

2. The independent review committee reports to a management level above the plant manager.

3. The independent review committee is composed of no less than 5 persons and no more than a minority of members are from the on-site operating organization.

   For example, at least 3 of the 5 members must be from off-site if there are 5 members on the committee. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.

4. During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards meetings are conduced no less than twice a year.

5. Results of the meeting are documented and recorded.

6. Consultants and contractors are used for the review of complex problems beyond the expertise of the off site/on site independent review committee.

7. Persons on the independent review committee are qualified as follows:

   a. Supervisor or Chairman of the Independent Review Committee
      - Education: baccalaureate in engineering or related science
      - Minimum experience: 6 years combined managerial and technical support

   b. Independent Review Committee members

   Education: Baccalaureate in engineering or related science for those Independent review personnel who are required to review problems in
      - nuclear power plant operations,
      - nuclear engineering,
      - chemistry and radiochemistry,
      - metallurgy,
      - nondestructive testing,
      - instrumentation and control,
      - radiological safety,
      - mechanical engineering, and electrical engineering.

   High school diploma for those independent review personnel who are required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.

Minimum experience: 5 years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment)]

2.8 NQA-1-1994 Commitment / Exceptions

• In establishing qualification and training programs, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 2S-1

  - *[Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement. The following two alternatives may be applied to the implementation of this Supplement and Appendix:*

    - *(1) In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel performing independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.*

    - *(2) A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.]*

- NQA-1-1994, Supplement 2S-2

- In lieu of Supplement 2S-2, for qualification of nondestructive examination personnel, *[CA] will* follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at *[CA]* sites.

NQA-1-1994, Supplement 2S-3

- The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, "The prospective lead auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by *[CA],* to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification."

SECTION 3 DESIGN CONTROL

[CA] has established and implements a process to control the design, design changes and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of this QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records and organizational interfaces within *[CA]* and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in *[CA]* and supplier procedures. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the *[CA]* design organization or by other organizations so authorized by *[CA].*

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1 Design Verification

[CA] design processes provide for design verification to ensure that items and activities subject to the provisions of this QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for item's intended use.

[CA] normally completes design verification activities before the 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 such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

[CA] maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3 Computer Application and Digital Equipment Software

The QAPD shall govern the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non-safety-related applications. *[CA]* and suppliers shall be responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto shall be documented and approved by *[authorized personnel].* This QAPD shall also be applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4 Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

(1) Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes originally supplied by the *[NSSS, Applicant for certification or DC Holder]* supplier, the A/E, and the plant's technical staff.
(2) Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.
(3) Provide for documentation of setpoints, including those determined operationally.
(4) Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate or maintain plant equipment, develop or revise design documents, or develop or revise accident analyses.

3.5 NQA-1-1994 Commitment

In establishing its program for design control and verification, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1, the subsurface investigations requirements contained in Subpart 2.20 and the standards for computer software contained in

Subpart 2.7.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

[CA] has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under the licensee's approved QA program).

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1 NQA-1-1994 Commitment / Exceptions

In establishing controls for procurement, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 4S-1

  - Section 2.3 of this Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, *[CA]* may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement.

  - With regard to service performed by a supplier, *[CA]* procurement documents may allow the supplier to work under the *[CA]* QAP, including implementing procedures, in lieu of the supplier having its own QAP.

  - Section 3 of this supplement 4S-1 requires procurement documents to be

reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.

- Procurement documents for Commercial Grade Items that will be procured by [CA] for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

[CA] has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAPD as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6 of this QAPD. In addition, means are provided for dissemination to the staff of instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

[CA] policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6 of this QAPD. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the introduction to Part II of NQA-1-1994. In addition, procedures governing tests, inspections, operational activities and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1-1994 Commitment

In establishing procedural controls, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 5.

SECTION 6 DOCUMENT CONTROL

[CA] has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control system (including electronic systems used to make documents available) shall be documented and shall provide for (a) through (f) below:

(a) identification of documents to be controlled and their specified distribution;

(b) a method to identify the correct document (including revision) to be used and control of superseded documents;

(c) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;

(d) review of documents for adequacy, completeness, and correctness prior to approval and issuance;

(e) a method for providing feedback from users to continually improve procedures and work instructions; and

(f) coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

[(a) drawings such as design, construction, installation, and as-built drawings;

(b) engineering calculations;

(c) design specifications;

(d) purchase orders and related documents;

(e) vendor-supplied documents;

(f) audit, surveillance, and quality verification/inspection procedures;

(g) inspection and test reports;

(h) instructions and procedures for activities covered by this QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing;

(i) technical specifications; and

(j) nonconformance reports and corrective action reports.]

[During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.]

6.1 Review and Approval of Documents

Documents shall be reviewed for adequacy by qualified persons other than the preparer. During the *[ESP or construction phase],* procedures for design, construction, and installation shall also

be reviewed by *[the organization responsible for quality verification]* to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

[During the operations phase, documents affecting the configuration or operation of the station as described in the SAR shall be screened to identify those that require review by the [IRB/IRC] prior to implementation as described in Section 2 of this QAPD.

To ensure effective and accurate procedures during the operational phase, applicable procedures shall be reviewed, and updated as necessary, based on the following conditions:

(a) following any modification to a system;

(b) following an unusual incident, such as an accident, significant operator error, or equipment malfunction;

(c) when procedure discrepancies are found;

(d) prior to use if not used in the previous two years; or

(e) results of QA audits conducted in accordance with Section 18.1 of this QAPD.]

Prior to issuance or use, documents including revisions thereto, shall be approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval. Where temporary procedure changes are necessary during the operations phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3 NQA-1-1994 Commitment

In establishing provisions for document control, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

[CA] has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.1 Acceptance of Item or Service

[CA] establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or isuse.

- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. *[CA]* may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet *[CA]* requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the

Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1-1994 Commitment / Exceptions

In establishing procurement verification controls, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

• NQA-1-1994, Supplement 7S-1

- *[CA]* considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to *[CA]* plants are not required to be evaluated or audited.

- When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

  (1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the *[CA]* QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

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

  (3) A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:

  ■ The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

- The accreditation is based on ANS/ISO/IEC 17025.
- The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

- For Section 8.1, *[CA]* considers documents that may be stored in approved electronic media under *[CA]* or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to *[CA]* to support operations. The *[CA]* records management system will provide for timely retrieval of necessary records.

- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in *[CA]* documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.

    - For commercial grade items, special quality verification requirements are established and described in *[CA]* documents to provide the necessary assurance an item will perform satisfactorily in service. The *[CA]* documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

    - *[CA]* will also use other appropriate approved regulatory means and controls to support *[CA]* commercial grade dedication activities. One example of this is NRC Regulatory Issue Summary 2002-22. *[CA]* will assume 10 CFR 21 reporting responsibility for all items that *[CA]* dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

[CA] has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, erection, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1 NQA-1-1994 Commitment

In establishing provisions for identification and control of items, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

SECTION 9 CONTROL OF SPECIAL PROCESSES

[CA] has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1 NQA-1-1994 Commitment

In establishing measures for the control of special processes, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

SECTION 10 INSPECTION

[CA] has established the necessary measures and governing procedures to implement inspections that assure items, services and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, and operations activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results shall be documented.

10.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a Supplier's facility or at a Company facility, (3) for final acceptance of fabricated and/or installed items during construction, (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as: rejection, acceptance, and re-inspection results; and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2 Inspector Qualification

[CA] has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Section 2 of this QAPD. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3 NQA-1-1994 Commitment / Exceptions

In establishing inspection requirements, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 10, Supplement 10S-1 and Subpart 2.4, with the clarification that follows below. In addition, *[CA]* commits to compliance with the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.

- Subpart 2.4 commits *[CA]* to IEEE 336-1985. IEEE 336-1985 refers to IEEE 498-1985. Both IEEE 336 -1985 and IEEE 498-1985 use the definition of "Safety Systems Equipment" from IEEE 603-1980. *[CA]* commits to the definition of Safety Systems Equipment in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.

- An additional exception to Subpart 2.4 is contained in Section 12 of this QAPD.

- *[This in an optional alternative for those sites where the reporting independence of NQA-1-1994, Supplement 10S-1, Section 3.1 may not be met. Refer to accession number ML052490337. Where inspections at the operating facility are performed by persons within the same organization (e.g. Maintenance group), [CA] takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to the [quality control management] while performing those inspections.]*

SECTION 11 TEST CONTROL

[CA] has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of this QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. These programs include criteria for determining when testing is required, such as *[proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by Plant Technical Specifications)],* to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions for establishing and adjusting test schedules and maintaining status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety, (1) instructions and prerequisites to perform the test, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

The tests are performed and results documented in accordance with applicable technical and regulatory requirements including those described in the Technical Specifications and SAR. The test programs ensure appropriate retention of test data in accordance with the records requirements of this QAPD. The personnel performing or evaluating tests are qualified in accordance with the requirements established in Section 2 of this QAPD.

11.1 NQA-1-1994 Commitment

In establishing provisions for testing, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

11.2 NQA-1-1994 Commitment for Computer Program Testing

[CA] establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end *[CA]* commits to compliance with the requirements of NQA-1-1994, Supplement 11S-2 and Subpart 2.7 to establish the appropriate provisions.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

[CA] has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services shall be controlled as described in Section 7 of this QAPD.

12.1 Installed Instrument and Control Devices

For the operations phase of the facilities, *[CA]* has established and implements procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device.

12.2 NQA-1-1994 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 12 and Supplement 12S-1 with the following clarification and exception:

- The out of calibration conditions described in paragraph 3.2 of Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration.

- Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-1994, Subpart2.4, Section 7.2.1 (ANSI/IEEE Std. 336-1985).

SECTION 13 HANDLING, STORAGE, AND SHIPPING

[CA] has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment. During the operational phase, *[CA]* establishes and implements controls over hoisting, rigging and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, *[CA]* complies with applicable hoisting, rigging and transportation regulations and codes.

13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems and components within the plant. This includes control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste. Housekeeping practices help assure that only proper materials, equipment, processes and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination are developed and used.

13.2 NQA-1-1994 Commitment / Exceptions

In establishing provisions for handling, storage and shipping, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. *[CA]* also commits, during the construction and pre-operational phase of the plant, to compliance with the requirements of NQA-1-1994, Subpart 2.1, Subpart 2.2, and Subpart 3.2 Appendix 2.1 with the clarifications and

exceptions shown below:

NQA-1-1994, Subpart 2.2

- Subpart 2.2, section 6.6, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, *[CA]* documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

- Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for nuclear power plants during construction.

NQA-1-1994, Subpart 3.2

- Subpart 3.2, Appendix 2.1: Only section 3 precautions, which address the use of alkaline cleaning compounds and chelating agents that will be used in conjunction with the cleaning activities under Subpart 2.1, sections 8.2.2 and 8.2.3, are committed to in accordance with RG 1.37.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

[CA] has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of this QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications and status tracking.

The administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. The review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1 NQA-1-1994 Commitment

In establishing measures for control of inspection, test and operating status, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

[CA] has established the necessary measures and governing procedures to control items, including services, which do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is, shall be subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with *[CA]* procedures, regulatory requirements, and industry standards.

15.1 Reporting Program

[CA] will establish the necessary measures and governing procedures that implement a reporting program which conforms to the requirements of 10 CFR 52, 10 CFR 50.55(e) and/or 10 CFR 21 during *[ESP/COL and construction]* and 10 CFR 21 during operations.

15.2 NQA-1-1994 Commitment

In establishing measures for nonconforming materials, parts, or components, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

SECTION 16 CORRECTIVE ACTION

[CA] has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. *[CA]* procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. *[CA]* procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, *[CA]* documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, the licensee may delegate specific responsibilities of the Corrective Action program but the licensee maintains responsibility for the program's effectiveness.

16.1 Reporting Program

[CA] has in-place the necessary measures and governing procedures that implement a program to identify, evaluate and report defects and non-compliances in accordance with 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable. Such a reporting program applies to safety-related activities and services performed by *[CA]* and/or *[CA]* suppliers / sub-suppliers providing input to the ESP and COL application development.

16.2 NQA-1-1994 Commitment

In establishing provisions for corrective action, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

[CA] shall establish the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program *for [CA] and* include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Such records and their retention times are defined in appropriate procedures. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

When using electronic records storage and retrieval systems, *[CA]* complies with NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks." *[CA]* will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

17.3 NQA-1-1994 Commitment / Exceptions

In establishing provisions for records, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 17S-1

  - Supplement 17S-1, section 4.2(b) requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard-copy records maintained by *[CA],* the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage.

SECTION 18 AUDITS

[CA] has established the necessary measures and governing procedures to implement audits to verify that activities covered by this QAPD are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of licensing, design, construction phase and operating activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of *[Nuclear Development]* activities, audits will focus on areas including, but not limited to, *[site investigation],* procurement, and corrective action. Functional areas of an organization's QA program for auditing include at a minimum verification of compliance and effectiveness of implementation of internal rules, procedures *[(e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping].*

The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the *[Quality Assurance Project Manager]*

The *[CA]* is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD. External audits determine the adequacy of supplier and contractor quality assurance program.

The results of each audit are reported in writing to the responsible *[Senior Nuclear Development Officer]*, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Internal Audits

a. Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

b. Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

   During the operations phase audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

   (1) The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.

   (2) The performance, training, and qualifications of the facility staff.

   (3) The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B.

   (4) The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified off-site licensed fire protection engineer or an outside qualified fire protection consultant.

   (5) Other activities and documents considered appropriate by the *[Vice President of Nuclear Operations, or the CNO].*

   Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code.

   Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of this QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by this QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of construction, fabrication, operating, refueling, maintenance and modification activities including associated record

keeping.

c. Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.1.

18.2 NQA-1-1994 Commitment

In establishing the independent audit program, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

PART III NON-SAFETY-RELATED SSC QUALITY CONTROL

(NOTE: Part III does not apply to ESP-only QA programs.)

SECTION 1 Non-safety-Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to non-safety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the non-safety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for non-safety-related SSCs.

1.1 Organization

The verification activities described in this part may be performed by the *[CA]* line organization. The QA organization described in Part II is not required to perform these functions.

1.2 QA Program

[CA] QA requirements for non-safety-related SSCs are contained in this QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3 Design Control

[CA] shall establish design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4 Procurement Document Control

Procurement documents for items and services obtained by or for *[CA]* shall include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5 Instructions, Procedures, and Drawings

[CA] shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6 Document Control

[CA] shall establish controls for the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7 Control of Purchased Items and Services

[CA] shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8 Identification and Control of Purchased Items

[CA] shall establish measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

1.9 Control of Special Processes

[CA] shall establish process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

[CA] shall establish documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. *[These inspections are performed by knowledgeable personnel who may be in the same line organization as those performing the activity in question, and are, at a minimum, as qualified as the person who performed the activity.]*

1.11 Test Control

[CA] shall establish measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12 Control of Measuring and Test Equipment (M&TE)

[CA] shall establish measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13 Handling, Storage, and Shipping

[CA] shall establish measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14 Inspection, Test, and Operating Status

[CA] shall establish measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15 Control of Nonconforming Items

[CA] shall establish measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16 Corrective Action

[CA] shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17 Records

[CA] shall establish measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18 Audits

[CA] shall establish measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line

management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2 Non-safety-Related SSCs Credited for Regulatory Events

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related;

- *[CA]* shall implement quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants."

- *[CA]* shall implement the quality requirements for ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."

- *[CA]* shall implement quality requirements for SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout."

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides and the other quality assurance standards which have been selected to supplement and support the *[CA]* QAPD. *[CA]* commits to compliance with these standards to the extent described herein. Commitment to a particular Regulatory Guide or other QA standard does not constitute a commitment to the Regulatory Guides or QA standards that may be referenced therein.

Regulatory Guides:

Regulatory Guide 1.26, Revision 4, March 2007 - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

[CA] commits to the applicable regulatory position guidance provided in this regulatory guide for *[ND] [with the exception of Criteria C.1, C.1.a, C.1.b, and C.3. Refer to the Westinghouse AP1000 Design Control Document, Appendix 1A for a detailed discussion of these exceptions]*.

Regulatory Guide 1.29, Revision 4, March 2007 - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

[CA] commits to the applicable regulatory position guidance provided in this regulatory guide for *[ND] [with the exception of Criteria C.1.d, C.1.g, and C.1.n. Refer to the Westinghouse AP1000 Design Control Document, Appendix 1A, for a detailed discussion of these exceptions]*.

Regulatory Guide 1.37, Revision 1, March 2007 - Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

[CA] commits to the applicable regulatory position guidance provided in this regulatory guide for *[ND].*

Standards:

ASME NQA-1-1994 Edition - Quality Assurance Requirements for Nuclear Facility Applications

[CA] commits to NQA-1-1994, Parts I and II, as described in the foregoing sections of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

[CA] commits to NIRMA TGs as described in Part II, Section 17 of this document.

Appendix 1 – Final Safety Evaluation

April 25, 2007

Adrian P. Heymer, Senior Director
New Plant Deployment Nuclear
Generation Division Nuclear Energy
Institute 1776 I Street, NW, Suite
400 Washington, DC 20006-3708

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 06-14, "QUALITY ASSURANCE PROGRAM DESCRIPTION" (PROJECT NO. 689; TAC NO. MD3406)

Dear Mr. Heymer:

By letter dated October 19, 2006, the Nuclear Energy Institute (NEI) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review, its proposed Quality Assurance Program Description (QAPD), Revision 0. By letter dated October 27, 2006, NEI designated this program as NEI 06-14.

Enclosed is the staff's safety evaluation (SE) which defines the basis for acceptance of NEI 06-14. On the basis of its review, the NRC staff finds that the NEI template for a QAPD complies with the applicable NRC regulations and industry standards and can be used for early site permits, combined licenses, construction, pre-operation and/or operation activities.

Our acceptance applies only to material provided in NEI 06-14. We do not intend to repeat our review of the acceptable material described in the NEI 06-14. When the NEI 06-14 appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from NEI 06-14 will be subject to a plant- or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that NEI publish the accepted version of NEI 06-14 within three months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information and your responses. The accepted versions shall include a "-A" (designating accepted) following the report identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of NEI 06-14, NEI will be expected to revise NEI 06-14 appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Joelle Starefos at (301) 415-8488, or JLS1@nrc.gov.

Sincerely,

/RA/

Stephanie M. Coffin, Chief AP1000
Projects Branch Division of New
Reactor Licensing Office of New
Reactors

Project No. 689

Enclosure: Safety
Evaluation

cc w/encl: See next page

If you have any questions, please contact Joelle Starefos at (301) 415-8488, or JLS1@nrc.gov.

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FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

TECHNICAL REPORT NEI-06-14

"TEMPLATE FOR A QUALITY ASSURANCE PROGRAM DESCRIPTION"

NUCLEAR ENERGY INSTITUTE (NEI)

PROJECT NO. 689

1. INTRODUCTION

By letter dated October 19, 2006 (Ref. 1), the Nuclear Energy Institute (NEI), submitted a technical report on an industry quality assurance program description (QAPD) template for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff. The NEI New Plant Quality Assurance Task Force developed the technical report for use by early site permit (ESP) applicants and combined license (COL) applicants and holders for new plant construction and operation. Letters dated January 4, 2007 (Ref. 2), and February 13, 2007 (Ref. 3), provided additional information in support of and revisions to the original QAPD template submitted on October 19, 2006.

The quality assurance program described in the QAPD template commits to the guidance in American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications." NEI used the guidance of the draft Standard Review Plan (NUREG-0800, referred to as the SRP), Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," to determine the appropriate regulatory guidance that applies to the proposed QAPD template.

The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for the ESP or COL application. The staff will review and approve the bracketed text included in the QAPD template with the ESP and COL application to determine the acceptability of the QAPD submitted by the applicant.

2. REGULATORY EVALUATION

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," sets forth the Commission's regulatory requirements related to quality assurance programs.

Appendix B establishes quality assurance requirements for the design, fabrication, construction, and testing of the structures, systems and components (SSCs) of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

3. EVALUATION

In evaluating the adequacy of the format and level of detail of the QAPD template, the staff followed draft SRP Section 17.5 for guidance (Ref.4). Draft SRP Section 17.5 outlines a quality assurance program for design certification, ESP, COL, construction permit, and operating license applicants. The staff developed draft SRP Section 17.5 using ASME NQA Standard NQA-1-1994, as supplemented by additional regulatory and industry guidance for nuclear operating facilities.

3.1 Quality Assurance Program Description Template Overview

The QAPD template provides guidance for establishing a top-level policy document that defines the quality policy and assigns major functional responsibilities. This QAPD template can be used for ESP, COL, construction, preparation and/or operation activities, as applicable, affecting the quality and performance of safety-related SSCs. In addition, the QAPD template applies selected elements of the QAPD to non-safety-related SSCs that are significant contributors to plant safety. It will be incumbent upon the applicant to identify the specific quality assurance requirements that need to be met for its specific scope of activities.

3.2 QAPD Template Details

3.2.1 Organization

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.A, for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The QAPD template establishes independence between the organization responsible for checking a function and the organization that performs the function. In addition, the QAPD template allows management to size the quality assurance organization commensurate with the duties and responsibilities assigned. The information in this section will be specific to the applicant and will require additional review and approval by the staff.

The template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

3.2.2 Quality Assurance Program

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.B for establishing the necessary measures to implement a quality assurance program to ensure that the design, construction, and operation of nuclear power plants are in accordance with governing regulations and license requirements. The quality assurance program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, including certain non-safety-related SSCs and activities that are significant contributors to plant safety, as described in the ESP site safety analysis report or COL final safety analysis report, as applicable. A list or system identifying SSCs and activities to which the QAPD applies is maintained at the appropriate facility.

The QAPD template provides measures to assess the adequacy of the QAPD and to ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. The period for assessing the QAPD during the operations phase may be extended to once every 2 years. In addition, consistent with draft SRP Section 17.5, paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early.

The QAPD template follows the guidance of draft SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure that they achieve and maintain suitable proficiency. The plant technical specifications delineate the minimum qualifications for plant and support staff. Personnel complete the training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Plant Personnel," according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD template also provides the minimum training requirements for managers responsible for QAPD implementation, in addition to the minimum training requirements for the individual responsible for planning, implementing, and maintaining the QAPD.

The QAPD template follows draft SRP Section 17.5, paragraph II.W for providing guidance to the applicant to establish an independent review program for activities occurring during the operational phase.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, with the following clarifications and exceptions:

NQA-1-1994, Supplement 2S-1, includes use of the guidance provided in Appendix 2A-1 to NQA-1-1994 . The following alternatives may be applied to the implementation of this supplement and appendix:

- As an alternative to the requirement in Appendix 2A-1 to be certified as Level I, II, or III; personnel performing independent quality verification inspections, examinations, measurements, or tests will be required to possess qualifications equal to or better than those required for performing the task being verified. In addition, the verification performed must be within the skills of these personnel and/or addressed by procedures. These personnel will not be responsible for planning quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspection), evaluating inspection training programs, or certifying inspection personnel. This alternative is consistent with draft SRP Section 17.5, paragraph II.T.5.

- A qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purposes of these functions, a qualified engineer is one who has a baccalaureate degree in engineering in a discipline related to the inspection activity (such as electrical, mechanical, or civil engineering) and has at least 5 years of engineering work experience, with at least 2 years of this experience related to nuclear facilities. In accordance with Supplement 2S-1 to

NQA-1-1994, the organization must designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. The NRC staff determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is acceptable. The staff's review determined that there is no conflict with regulatory guidance, NQA-1-1994, or other industry guidance in this subject area.

- As an alternative to NQA-1-1994, Supplement 2S-2, for the qualification requirements of nondestructive examination personnel, the QAPD template provides guidance to follow the applicable standard cited in the version(s) of Sections III and XI of the ASME Boiler and Pressure Vessel Code. The regulation in 10 CFR 50.55a, "Codes and Standards," requires use of the latest edition and addenda of Sections III and XI. Therefore, the staff finds the use of Sections III and XI of the ASME Boiler and Pressure Vessel Code for qualification of nondestructive examination personnel acceptable.

- As an alternative to the requirement of NQA-1-1994, Supplement 2S-3, that prospective lead auditors must have participated in a minimum of five audits in the previous 3 years, the QAPD template follows the guidance provided in draft SRP Section 17.5, paragraph II.S.4.c:

  The prospective Lead Auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by the company, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.

3.2.3 Design Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The QAPD template design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the QAPD template provides for individuals knowledgeable in quality assurance principles to review design documents to ensure that they contain the necessary quality assurance requirements.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, for establishing the program for design control and verification, Subpart 2.20 for the subsurface investigation requirements and Subpart 2.7 for the standards for computer software quality assurance controls.

3.2.4 Procurement Document Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that procurement

documents include or reference applicable regulatory, technical, and quality assurance program requirements. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and the regulation at 10 CFR Part 21, "Reporting of Defects and Noncompliance") are invoked for procurement of items and services.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 2.3, which states that procurement documents must require suppliers to have a documented quality assurance program that implements NQA-1-1994, Part I, the QAPD proposes that suppliers have a documented quality assurance program that meets Appendix B to 10 CFR Part 50, as applicable to the circumstances of the procurement. Criterion IV, "Procurement Document Control," of Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the staff determined that this clarification is acceptable, as delineated in draft SRP Section 17.5, paragraph II.D.2.d.

- The QAPD proposes that procurement documents allow the supplier to work under the applicant's QAPD, including implementing procedures, in lieu of the supplier having its own quality assurance program. Criterion IV of Appendix B requires suppliers to have a quality assurance program consistent with Appendix B. Therefore, the staff determined this clarification to be acceptable, as delineated in draft SRP Section 17.5, paragraph II.D.2.d.

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 3, which requires procurement documents to be reviewed before award of the contract, the QAPD proposes to conduct the quality assurance review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, before contract award. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive quality assurance review. The staff evaluated this proposed alternative and determined that it provides adequate quality assurance review of procurement documents before awarding the contract and after any change. Therefore, the staff concluded that this alternative is acceptable.

  Procurement documents for commercial-grade items that the applicant or holder will procure as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated. This alternative is consistent with staff guidance in Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in draft SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

3.2.5 Instructions, Procedures, and Drawings

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings.

The QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 5, for establishing procedural controls.

3.2.6 Document Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The template provides measures to ensure that the same organization that performed the original review and approval also reviews and approves revisions or changes to documents, unless other organizations are specifically designated. A listing of all controlled documents identifying the current approved revision or date is maintained so personnel can readily determine the appropriate document for use.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary, consistent with staff guidance provided in draft SRP Section 17.5, paragraph II.F.8. If temporary procedure changes are necessary during the operational phase, changes that clearly do not alter the intent of the approved procedure may be implemented provided that two members of the staff knowledgeable in the areas affected by the procedure approve the changes. During the operational phase, temporary changes include a designation of the period of time during which it is acceptable to use the changed procedure.

In establishing provisions for document control, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

3.2.7 Control of Purchased Material, Equipment, and Services

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, the program provides for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, pre- and post-installation tests, and review of documentation, such as certificates of conformance, to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment or by properly reviewed and approved revisions to ensure that the items are suitable for the intended service and are of acceptable quality, consistent with their effect on safety.

In establishing procurement verification control, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- The QAPD template proposes that other 10 CFR Part 50 licensees (i.e., other than the applicant or holder), authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to the applicant or holder are not required to be evaluated or audited.

  The staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the NIST, and other State and Federal agencies perform work under acceptable quality programs, and no additional audit or evaluation is required. The staff determined that this exception is acceptable as documented in a previous safety evaluation (Ref. ADAMS Accession No. ML003693241). The applicant or holder is still responsible for ensuring that the items or services conform with its Appendix B program, applicable ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. The applicant or holder is also responsible for ensuring that the items or services are suitable for the intended application and for documenting this evaluation. The proposed exception is acceptable on the basis that it provides an appropriate level of quality and safety.

- The QAPD template includes provisions consistent with the regulatory guidance provided in draft SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications. The QAPD template proposes not to require procurement source evaluation and selection measures provided each of the following conditions are met:

  - Purchase documents impose additional technical and administrative requirements to satisfy QAPD and technical requirements.

  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.

  - A documented review of the supplier's accreditation will be performed and will include a verification of the following:

    - The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association for Laboratory Accreditation, as recognized by NVLAP through the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.

    - The accreditation is based on ANS/ISO/IEC 17025.

    - The published scope of the accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

- As an alternative to NQA-1-1994, Supplement 7S-1, Section 8.1, in terms of the requirement for documents to be available at the site, the QAPD template proposes that documents may be stored in approved electronic media under the applicant's, holder's or

supplier's control and not physically located at the plant site, as long as they are accessible from the respective nuclear facility. Following completion of the construction period, sufficient as-built documentation will be turned over to the licensee to support operations. The staff determined that this alternative meets Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services." Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, this provision, which would allow for accessing and reviewing the necessary procurement documents at the site before installation and use, would meet this requirement.

- As an alternative to NQA-1-1994, Supplement 7S-1, Section 10, requirements for the control of commercial-grade items and services, the QAPD template commits the applicant to follow NRC guidance discussed in Generic Letter 89-02 and Generic Letter 91-05 as delineated in draft SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

  Consistent with the guidance mentioned above for commercial-grade items and services, the commercial-grade program provides for special quality verification requirements to be established and described in applicable documents to provide the necessary assurance that the item will perform satisfactorily in service. In addition, the documents provide for determining critical characteristics to ensure that an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

3.2.8 Identification and Control of Materials, Parts, and Components

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.H, for establishing the necessary measures for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation, consistent with the item's effect on safety.

In establishing provisions for identification and control of items, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

3.2.9 Control of Special Processes

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph I I. I, for establishing and implementing programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations, are controlled in accordance with the applicable codes, specifications, and standards of the specific work.

In establishing measures for the control of special processes, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

3.2.10 Inspection

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.J, for establishing the necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the frequency of inspection, and identifying special tools needed to perform the inspection. Properly qualified personnel who are independent of those who performed or directly supervised the work perform the inspections.

In establishing inspection requirements, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5 and 2.8, with the following clarifications and exceptions:

NQA-1-1994, Subpart 2.4, commits the applicant or licensee, as applicable, to Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE 336-1985 refers to IEEE 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities." Both of these standards use the definition of "safety systems equipment" from IEEE 603-1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." The QAPD template commits the applicant or licensee, as applicable, to the definition of safety systems equipment from IEEE 603-1980 but does not commit the applicant or holder to the balance of IEEE 603-1980. This definition applies only to equipment in the context of Subpart 2.4.

The following is the definition of safety system in IEEE 603-1980:

> Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

The QAPD needs to commit to the definition of safety systems equipment from IEEE 603-1980 in order to appropriately implement Subpart 2.4 of NQA-1-1994. The clarification is to reinforce the fact that the QAPD is not committing to the entirety of IEEE 603-1980. The staff determined that the use of the definition of safety systems equipment in the context of Subpart 2.4 is acceptable because it clarifies the definition.

- As an alternative for sites that may not meet the requirement of NQA-1-1994, Supplement 10S-1, Section 3.1, for independent reporting, the QAPD proposes that the inspector must report to quality control management while performing the inspection. This alternative is consistent with staff guidance provided in draft SRP 17.5, paragraph II.J.1.

3.2.11 Test Control

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.K, for establishing the necessary measures and governing provisions to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant, as a whole, is satisfactory.

In establishing provisions for testing, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

In establishing provisions to ensure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Supplements 11S-2 and Subpart2.7.

3.2.12 Control of Measuring and Test Equipment

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.L, for establishing the necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provides information important to safe plant operation.

In establishing provisions for control of measuring and test equipment, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, with the following clarifications and exceptions:

- The QAPD template clarifies that the out-of-calibration conditions, described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994, refer to cases where the measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The staff determined that the clarification for the out-of-calibration conditions is acceptable, on the basis that it clarifies a definition.

- As an alternative to the NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the QAPD template proposes that the required calibration information be maintained in suitable documentation traceable to the device for measuring and test equipment which is impossible or impractical to mark because of equipment size or configuration. This alternative is consistent with the staff guidance provided in draft SRP 17.5, paragraph II.L.3.

3.2.13 Handling, Storage, and Shipping

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.M, for establishing the necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In establishing provisions for handling, storage, and shipping, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. The QAPD template also commits the applicant, during the

construction and preoperations phase of the plant, as applicable, to comply with the requirements of NQA-1-1994, Subparts 2.1, 2.2, and 2.15, with the following clarification and exception:

- As an alternative to the NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," requirement for the preparation of records containing information on personnel access to quality assurance records, the QAPD template provides for documents to establish control of storage areas that describe those authorized to access the area and the requirements for recording access of personnel. The QAPD template proposes not to consider these records as quality records. The plants will retain these records in accordance with the plants' administrative controls. The staff determined that the proposed alternative is acceptable, on the basis that these records do not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7.

3.2.14 Inspection, Test, and Operating Status

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.N, for establishing the necessary measures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety and avoid inadvertent operation of equipment.

In establishing procurement verification control, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 14.

3.2.15 Nonconforming Materials, Parts, or Components

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.O, for establishing the necessary measures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Nonconformances are evaluated for their impact on operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the QAPD template provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," 10 CFR 50.55(e), and/or 10 CFR Part 21, as applicable.

In establishing measures for nonconforming material, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1.

3.2.16 Corrective Action

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.P, for establishing the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD template requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify

trends. Significant conditions adverse to quality are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant or holder, as applicable, may delegate specific responsibility for the corrective action program, but the applicant or holder maintains responsibility for the program's effectiveness.

In addition, the QAPD template provides for establishing the necessary measures to implement a program to identify, evaluate, and report defects and noncompliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

In establishing a corrective action program, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 16.

3.2.17 Quality Assurance Records

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

Concerning the use of electronic records storage and retrieval systems, the QAPD template provides for compliance with NRC guidance given in Generic Letter 88-18, "Proposed Final NRC Generic Letter 88-18, Supplement 1, 'Guidance on Managing Quality Assurance Records in Electronic Media,'" dated September 13, 1999; Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000; and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, TG 15-1998, and TG 21-1998.

In establishing provisions for records, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarification and exception:

- As an alternative to the NQA-1-1994, Supplement 17S-1, Section 4.2(b), requirements for records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers, the QAPD template proposes that hard records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage. In a previous safety evaluation (Ref.6 ADAMS Accession No. ML052360625), the staff determined that this proposed alternative is acceptable.

3.2.18 Quality Assurance Audits

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The audit program is also reviewed for effectiveness as part of the overall audit process. The QAPD provides for the applicant or holder, as applicable, to conduct periodic internal and external audits. Internal audits are conducted to determine the adequacy of the program and its procedures and to determine if they are meaningful and comply with the overall QAPD. Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to

ensure that an audit of all applicable quality assurance program elements is completed for each functional area within a period of 2 years after the determination that the program is well established. External audits determine the adequacy of a supplier's or contractor's quality assurance program. The responsible management documents and reviews audit results. Management responds to all audit findings and initiates corrective action where indicated. In addition, where corrective actions are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

In establishing the independent audit program, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

3.3 Non-safety-Related SSC Quality Assurance Control

3.3.1 Non-safety-Related SSCs—Significant Contributors to Plant Safety

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to non-safety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD template applies specific controls to those items in a selected manner, targeting those characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

3.3.2 Non-safety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafey-related SSCs credited for regulatory events, the QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.V.2, and commits the applicant to comply with the following regulatory guidance:

- The applicant or holder shall implement quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants," issued April 2001.

- The applicant or holder shall implement quality requirements for anticipated transient without scram (ATWS) equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued January 1985.

- The applicant or holder shall implement quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout," issued August 1988.

3.4 Regulatory Commitments

The QAPD template follows the guidance of draft SRP Section 17.5, paragraph II.U, for establishing quality assurance program commitments. The QAPD template commits the applicant to comply with the following NRC regulatory guides and other quality assurance

standards to supplement and support the QAPD:

Regulatory Guide 1.26, Revision 3, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued February 1976.

The QAPD template commits the applicant to comply with the regulatory positions of this guidance with the exception of Criteria C.1, C.1.a, C.1.b, and C.3. As documented in the staff's "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design" (NUREG-1793), issued September 2000, and Supplement 1 to NUREG-1793, issued December 2005, the staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

Regulatory Guide 1.29, Revision 3, "Seismic Design Classification," issued September 1978.

The QAPD template commits the applicant to comply with the regulatory positions of this guidance with the exception of Criteria C.1.d, C.1.g, andC.1.n. As documented in NUREG-1793 and Supplement 1 to NUREG-1793, the staff determined that the proposed exceptions are acceptable for use with the AP1000 design.

- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described in Sections 3.2.1 through 3.2.18 of this safety evaluation report (SER).

NIRMA technical guides, as described in Section 3.2.17 of this SER. 4. ALTERNATIVES

AND EXCEPTIONS NOT PREVIOUSLY REVIEWED AND APPROVED

During the QAPD template review, the staff needed to evaluate the following areas where the QAPD template takes exceptions or offers alternatives to the guidance of draft SRP Section 17.5 or NQA-1-1994:

- As an alternative to Appendix 2A-1 to NQA-1-1994, a qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. As described in Section 3.2.2 of this SER, for purposes of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, or civil engineering) and has a minimum of 5 years of engineering work experience, with at least 2 years of this experience related to nuclear facilities. Supplement 2S-1 of NQA-1-1994 requires the organization to designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these personnel. The staff determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is acceptable.

- As an alternative to the NQA-1-1994, Supplement 4S-1, Section 3, requirements that procurement documents be reviewed before bid award of the contract, the QAPD provides for quality assurance review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements,

before bid award of the contract. As described in Section 3.2.4 of this SER, procurement document changes (e.g., changes in scope, technical, or quality requirements) will also receive quality assurance review. The staff evaluated this proposed alternative and determined that it provides adequate quality assurance review of procurement documents before bid award of the contract and after any change. Therefore, the staff concluded that this alternative is acceptable.

- As an alternative to the NQA-1-1994, Supplement 7S-1, Section 8.1, requirement for documents to be available at the site, the QAPD template considers documents that may be stored in approved electronic media under the applicant's, holder's, or supplier's control and that are not physically located at the plant site but are accessible from the facility, as meeting the requirement. As described in Section 3.2.7 of this SER, following completion of the construction period, sufficient as-built documentation will be turned over to the licensee to support operations. The staff determined that this alternative meets Appendix B, Criterion VII. Criterion VII requires documentary evidence that items conform to procurement documents to be available at the nuclear facility before installation or use. Therefore, accessing and reviewing the necessary procurement documents at the site before installation and use would meet the requirement.

- As an alternative to the NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," requirement for the preparation of records containing information on personnel access, the QAPD template provides for documents to establish control of storage areas that describe those authorized to access the area and the requirements for recording access of personnel. As described in Section 3.2.13 of this SER, the QAPD template does not consider these records to be quality records. The plants will retain these records in accordance with the plants' administrative controls. The staff determined that the proposed alternative is acceptable, on the basis that these records did not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7.

5. CONCLUSION

The staff used the provisions of Appendix B to 10 CFR Part 50 and the guidance of Draft SRP Section 17.5 as the basis for evaluating the acceptability of the QAPD template. On the basis of the staff's review of the QAPD template, the staff concludes that:

- The QAPD template provides adequate guidance for an applicant to describe the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

- The QAPD template provides adequate guidance for an applicant to provide for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The QAPD template provides adequate guidance for an applicant to apply a QAPD to activities and items that are important to safety.

- The QAPD template provides adequate guidance for an applicant to establish controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, Appendix B

to 10CFR Part 50, 10CFR Part 21, and 10 CFR 50.55(e), with the criteria contained in draft SRP Section 17.5, and with the commitments to regulatory guidance.

On the basis of its review, the staff concludes that the QAPD template provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance. Accordingly, the staff concludes that the QAPD template can be used by an applicant or holder for ESP, COL, construction, preoperation and/or operation activities, as applicable.

6. REFERENCES

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4. NUREG-0800, "Standard Review Plan," Draft Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," January 2006.

5. U.S. NRC, Office of Nuclear Reactor Regulation, "Edwin I. Hatch Nuclear Power Station, Units 1 and 2, Approval of Relief Request RR-27, Third-Year Interval Inservice Inspection Program (TAC Nos. MA6163 and MA6164)" (ADAMS Accession No. ML003693241), March 20, 2000.

6. U.S. NRC, Office of Nuclear Reactor Regulation, Safety Evaluation of the Proposed Change to the Quality Assurance Program, "Approval of Nuclear Management Company Quality Assurance Topical Report" (ADAMS Accession No. ML052360625), August 26, 2005.

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Appendix 2 – Requests for Additional Information

Request for Additional Information
Regarding the Nuclear Energy Institute
Quality Assurance Program Description
Topical Report No. NEI-06-14, Revision 0

Part I INTRODUCTION

1. 10 CFR 52.17 (a)(1)(xii) requires the applicant of an early site permit (ESP) to include a quality assurance program description (QAPD) that satisfies applicable portions of Appendix B to 10 CFR Part 50. 10 CFR 52.79 (a)(25) requires that the applicant of a combined license (COL) includes a QAPD to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility that satisfies applicable portions of Appendix B to 10 CFR Part 50. Part I, Section 1.1 of the template provides information on activities to which the QAPD template applies.

   a. For consistency with the above regulations, the staff needs clarification of the overall scope (e.g., ESP, COL) that applies or could apply to the QAPD, in addition to the list of activities already mentioned.

   b. The staff recommends that the list of activities be included as bracketed text in order that the applicant using the template determine the extent of the applicability/scope of the QAPD. Additionally, the staff recommends the addition of pre-operational activities to the list.

   c. The template states that "the QAPD may be applied to certain activities where regulations other than 10 CFR [Part] 50 establish QAPD requirements for activities within their scope." Since application of this QAPD will mainly be under the regulations of 10 CFR Part 52, and by reference to 10 CFR Part 50, the staff determined that it would be appropriate that the QAPD template include 10 CFR Part 52 in the statement.

PART II QAPD DETAILS

SECTION I ORGANIZATION

2. Draft Standard Review Plan (SRP) Section 17.5, paragraph II.A.3, states that, for multiple organizations, the QA program organizational description should clearly define the interface responsibilities. Clarify how the QAPD template will provide guidance for the applicant or holder to describe the interface of multiple organizations.

3. Draft SRP Section 17.5, paragraph I I.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how the QAPD template will provide guidance for the applicant or holder to implement measures to control the independence of organizations consistent with Section 17.5 of the draft SRP.

4. Draft SRP Section 17.5, paragraph I I.A.7, states that management should ensure that the size of the QA organization is commensurate with its duties and responsibilities. In order to satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how the QAPD template will provide guidance for the applicant or holder to ensure

that the size of the QA organization is commensurate with its duties and responsibilities.

SECTION II QUALITY ASSURANCE PROGRAM

5. Draft SRP Section 17.5, paragraph II.B.1, states that management implementing portions of the QAPD should assess the part of the program for which they are responsible and assure is effective implementation at least once each year or at least once during the life of the activity, which ever is shorter, or may extend it to once every two years. Section II of the QAPD template states that reviews of the status and adequacy of the program and its implementation will be conducted on an ongoing basis via senior management review of quality assurance audit reports. In addition, Section 18.1 of the QAPD template provides measures to assess the effective implementation of the program at least once a year or at least once during the life of the activity, which ever is shorter. Clarify how the QAPD template will provide for these requirements consistently throughout the QAPD template and consistent with Section 17.5 of the draft SRP.

6. Draft SRP Section 17.5, paragraph II.B.8, states that "a general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early." Section II of the QAPD template incorporates a grace period of 25% to be applied to provisions that are required to be performed on a periodic basis. In addition, the statement in the QAPD template does not discuss the "clock" portion of this provision. The entire provision as stated in draft SRP Section 17.5, paragraph II.B.8 should be addressed in the QAPD template.

7. Draft SRP Section 17.5, paragraph II.S.2 states the qualification requirements for individuals responsible for managing the implementation of the QA plan. Section 2.6 of the QAPD template provides the minimum qualification of the quality assurance manager and the nuclear development quality assurance project manager. However, these qualifications do not provide for requirements for management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Clarify how the QAPD template will provide for these requirements consistent with Section 17.5 of the draft SRP.

8. Draft SRP Section 17.5, paragraph II.S.3, states the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan. Clarify how the QAPD template will provide for these requirements consistent with Section 17.5 of the draft SRP.

SECTION IV PROCUREMENT DOCUMENT CONTROL

9. Draft SRP Section 17.5, paragraph II.D.1, states, in part, that changes made as a result of bid evaluations or pre-contract negotiations are incorporated into the procurement documents, and the review of such changes and their effects are completed prior to contract award. Section 4.1 of the QAPD template establishes a commitment to NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, and includes clarifications and exceptions to these requirements. As an exception, the template proposes that "the

quality assurance review of procurement documents is satisfied through review of the applicable procurement specifications, including the technical and quality procurement requirements, prior to bid or award of contract." This exception does not specify if procurement documents as well as changes to procurement documents will be part of the proposed quality assurance review. Clarify how the proposed quality assurance review of procurement documents includes the considerations delineated in Section 17.5 of the draft SRP.

SECTION VI DOCUMENT CONTROL

10. Draft SRP Section 17.5, paragraph II.C.1.q, states that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction, and installation. This paragraph applies to ESP and construction QA programs. The inclusion of these criteria satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(C). Section 6.1 of the QAPD template provides for the review of design, construction and installation procedures by the organization responsible for quality verification during the construction phase. Clarify how the QAPD template will implement measures to control the documented review and concurrence of quality-related procedures during ESP phase consistent with Section 17.5 of the draft SRP.

11. Draft SRP Section 17.5, paragraph II.F.9.b, states that there should be coordination and control of interface documents. The QAPD template does not provide measures for coordinating and controlling interface documents. Clarify how the QAPD template addresses coordination and control of interface documents consistent with Section 17.5 of the draft SRP.

SECTION VII CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

12. Draft SRP Section 17.5, paragraph II.L.8, states that, for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation (A2LA) are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. One of the conditions states that the use of the alternative method is limited to the National Voluntary Accreditation Program (NVLAP) and A2LA, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC). Section 7.2 of the QAPD template proposes to use this alternative method with a calibration laboratory accredited by NVLAP or A2LA as recognized by NVLAP through a Mutual Recognition Arrangement (MRA). An MRA is a generic term referring to a conformity assessment process. For assessment of calibration laboratories, the NRC has found the ILAC MRA to be an acceptable alternative. The alternative does not include MRAs administered under other programs. Clarify which MRA the QAPD template proposes to use.

13. Draft SRP Section 17.5, paragraph II.L.8, states that, for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the A2LA are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. Paragraph II.L.8.h states that the proposed alternative is limited to the domestic calibration service suppliers. Clarify how the QAPD template will implement the procurement of commercial-grade calibration

services consistent with Section 17.5 of the draft SRP.

14. In lieu of Section 8.1 of NQA-1-1994, Supplement 7S-1, regarding documents to be available at the site, the QAPD template proposed to consider documents that may be stored in approved electronic media under the company or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Clarify if measures are in place to ensure that documents store in approved electronic media under company or supplier control and not physically located on site will be reviewed for acceptance. In addition, clarify if measures are in place for timely retrieval of these documents consistent with Section 17.5 of the draft SRP.

SECTION X INSPECTION

15. Section 10.1 of the QAPD template provides an alternative to Subpart 2.4, regarding the use of the definition of "Safety Systems Equipment" from IEEE 603-1980. Clarify how the proposed definition is consistent with Section 17.5 of the draft SRP.

16. Draft SRP Section 17.5, paragraph II.J.5, states that inspections are performed by individuals other than those who performed the activity being inspected and that do not report directly to the supervisor responsible for the work being inspected. Section 10 of the QAPD template states that "inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work." In addition, Section 10.1 proposes an alternative to those sites where the reporting independence may not be met, and where inspections are performed by persons within the same organization.

    The proposed alternative states that this is an exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1. Supplement 10S-1, Section 3.1 requires that inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected, which are the same requirements of Draft SRP Section 17.5, Paragraph II.J.5. Paragraph II.J.1 states, in part, that the inspection program may be implemented by or for the organization performing the activity being inspected. However, inspection personnel still cannot report directly to same immediate supervisor who is responsible for the work being inspected as required by NQA-1-1994, Supplement 10S-1, Section 3.1, and Paragraph II.J.5 of draft SRP Section 17.5. Clarify how the QAPD template will provide measure for an inspection program consistent with Section 17.5 of the draft SRP.

SECTION XI TEST CONTROL

17. Draft SRP Section 17.5, paragraph II.K. 1, states that a test control program is required to be established to demonstrate that items will perform satisfactorily in service. Section 11 of the QAPD template provides measures for a test control program during construction and the operations phase. Clarify if test control measures are applicable for tests performed during the ESP phase.

SECTION XIII HANDLING, STORAGE, AND SHIPPING

18. Draft SRP Section 17.5, paragraph II.M.8, states that during operation, cleanliness controls for work on safety related and risk-significant non-safety related equipment are required to be established to the extent necessary to minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. During the construction phase, draft SRP Section 17.5 references the use of Subpart 2.1 of NQA-1-1994. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.1, and includes a clarification and exception to these requirements. Clarify how the proposed alternative is acceptable during construction phase and is consistent with Section 17.5 of the draft SRP.

19. During construction phase, draft SRP Section 17.5 references the use of Subpart 2.2 of NQA-1-1994. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.2. Section 13.2 of the QAPD template provides an alternative to Subpart 2.2, sections 3.2 and 3.5 regarding alternate methods for packaging. Clarify how the proposed alternative is acceptable during construction phase and is consistent with Section 17.5 of the draft SRP.

20. Draft SRP Section 17.5, paragraph II.M.7, states that during operational phase controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. During construction phase, draft SRP Section 17.5 references the use of Subpart 2.15. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.2. Subpart 2.2, section 7.1 refers to Subpart 2.15 for the requirements related to handling of items. Section 13.2 of the QAPD template provides an alternative to Subpart 2.15 during operational phase. Since the QAPD is not committing to use Subpart 2.15 during operation phase, the staff recommends taking the measures established for the controls over hoisting, rigging and transport during operational phase outside the commitment and exceptions to Subpart 2.2.

SECTION XV NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

21. Section 15.1 of the QAPD template provides for measures "that implement a reporting program which conforms to the requirements of 10 CFR 50.55(e) and/or 10 CFR [Part] 21 during construction and 10 CFR Part 21 during operations." Clarify how the QAPD template will provide measures for reporting of nonconforming materials, parts, or components during ESP phase consistent with 10 CFR Part 52 requirements.

SECTION XVII QUALITY ASSURANCE RECORDS

22. Draft SRP Section 17.5, paragraph II.Q.4, states that document access controls, user privileges, and other appropriate security controls must be established. The QAPD template does not provide measures for security control of records. Clarify how the QAPD template will implement measures to provide document access and security consistent with Section 17.5 of the draft SRP.

23. Draft SRP Section 17.5, paragraph II.Q.5, states, in part, that design documentation and records include not only the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the

important steps, including sources of design inputs that support the final design. The QAPD template does not provide measures for incorporation of documentation of design input sources that support the final design as part of the record retention program. Clarify how the QAPD template will implement measures to control records consistent with Section 17.5 of the draft SRP.

24. Draft SRP Section 17.5, includes a reference to Regulatory Issue Summary 2000-18. Regulatory Issue Summary 2000-18 provides guidance on storing and maintaining QA records in electronic media. Section 17 of the QAPD template includes the commitment to Regulatory Issue Summary 2000-18 as bracketed text. Clarify how an applicant or holder using the QAPD template will provide alternate measures consistent with the above guidelines if the applicant or holder chooses not to follow Regulatory Issue Summary 2000-18.

SECTION XVIII AUDITS

25. Draft SRP Section 17.5, paragraph II.R.10, states that when any work carried out under the requirements of the QA program is delegated to others, the work is to be audited by the QA audit program. Clarify how the QAPD template will provide measures to address the audit of QA program requirements delegated to others, consistent with Section 17.5 of the draft SRP.

26. Draft SRP Section 17.5, paragraph II.R.11, provides guidance to conduct procurement audits of suppliers. The guidance states, in part that: (1) the supplier's QA program is audited on a triennial basis, (2) the triennial period starts when the first audit is performed, and, (3) an audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. Section 18.1 of the QAPD template makes reference to Section 7.1 of the QAPD template for the description of measures established for audits of safety-related component suppliers. Section 7.1 of the QAPD template states that qualified suppliers are audited on a triennial basis. Clarify how the QAPD template will implement the full supplier audit controls consistent with Section 17.5 of the draft SRP.

PART III REGULATORY TREATMENT OF NON-SAFETY SYSTEMS (RTNSS)

27. Draft SRP Section 17.5, paragraph II.V.1.b, provides the quality assurance program controls required for non-safety related structures, systems, and components (SSCs) that are identified as being significant contributors to plant safety. Paragraph II.V.1 .b states that the supplier's procedures describe the quality controls applied to the subject equipment. Part III, Section 2 of the QAPD template states that "suppliers of these SSCs or related services may describe the quality controls applied in appropriate procedures, [and] a new or separate QA program is not required." Clarify how the proposed quality assurance program controls are consistent with Section 17.5 of the draft SRP.

28. Draft SRP Section 17.5, paragraph II.V.2 provides guidance for measures that applies to non-safety related SSCs credited for regulated events, including fire protection (10 CFR 50.48), anticipated transient without scram (10 CFR 50.62), and station blackout (10 CFR 50.63). Clarify how the QAPD template will implement measures for non-safety

related SCCs credited for regulated events consistent with Section 17.5 of the draft SRP

GENERAL

29. The staff recommends that the QAPD template include these additional statements as bracketed text in order that the applicant or holder using the template make the final determination of the applicability of these text to their application (e.g., ESP, COL, construction, pre-operation, operation). The template should allow the applicant or holder to determine the specific information applicable for the type of application for which they will be using the QAPD template.

a. Page 4 first paragraph: "for plants designed and constructed by or for [CA]."

b. Page 4, second paragraph, states the types of procedures that will be used along with the QAPD. The template should allow the applicant and holder to determine the types of procedures they will use along with the QAPD.

c. Page 11, second paragraph, provides examples of ESP/COL program safety-related activities.

d. Page 11, fifth and sixth paragraphs provides measures that can be used during ESP and/or COL application/activities.

e. All of Section 2.3 on page 12 should be bracketed. In addition, the note at the beginning of the section should have been included since the beginning of the template.

f. Page 13, first paragraph of Section 2.5 provides option for ESP or COL.

g. Page 23, second paragraph provides types of documents to be controlled.

h. Page 23, third and last paragraphs provide measure during operational phase.

i. Page 24, first paragraph provides measures applicable to operational phase procedures.

j. Page 32, first paragraph provides types of tests requiring test controls.

k. Page 37, Section 15.1 provides measures for reporting nonconforming material, parts and components during construction and operation.

l. Page 40, first paragraph provides different types of activities and focus areas of internal audits.

m. Page 40, first paragraph provides examples of procedures to be audited.

n. All of Part III on page 42 should be bracketed.

30. Consistent with your letter dated October 26, 2006, from Adrian P. Heymer, place the NEI document number, NEI-06-14, with the revision number on the cover page of the QAPD document.

**Request for Additional Information
Regarding the Nuclear Energy Institute
Quality Assurance Program Description
Topical Report No. NEI 06-14, Revision 0**

Part I INTRODUCTION

1. 10 CFR 52.17 (a)(1)(xii) requires the applicant of an early site permit (ESP) to include a quality assurance program description (QAPD) that satisfies applicable portions of Appendix B to 10 CFR Part 50. 10 CFR 52.79 (a)(25) requires that the applicant of a combined license (COL) includes a QAPD to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility that satisfies applicable portions of Appendix B to 10 CFR Part 50. Part I, Section 1.1 of the template provides information on activities to which the QAPD template applies.

    a. For consistency with the above regulations, the staff needs clarification of the overall scope (e.g., ESP, COL) that applies or could apply to the QAPD, in addition to the list of activities already mentioned.

NEI Response: This QAPD is a full scope document and could be used for any or all portions of nuclear development. Revision 0 stated that: "For the ESP and COL applications, this QAPD applies to those *[Nuclear Development]* and *[CA]* activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In addition, this QAPD applies to engineering activities that are used to characterize the site or analyze that characterization." For clarification, an additional reference to ESP, COL, Construction and or Operation was added in Part I, Section 1.1.

While "designing" is listed in Part 1, Section 1.1, the intent is design activities performed by the licensee for initial construction or modifications to the plant during its operational phase. The "designing" did not intend to imply "Design Certification." The expected use of NEI 06-14 is by licensees; however, it could be used for Design Certification provided that differences in the document and the vendor's actual programs are acceptably justified.

    b. The staff recommends that the list of activities be included as bracketed text in order that the applicant using the template determine the extent of the applicability/scope of the QAPD. Additionally, the staff recommends the addition of pre-operational activities to the list.

NEI Response: Added "Pre-operational Activities (including ITAAC)" and bracketed listing in QAPD template.

    c. The template states that "the QAPD may be applied to certain activities where regulations other than 10 CFR [Part] 50 establish QAPD requirements for activities within their scope." Since application of this QAPD will mainly be under the regulations of 10 CFR Part 52, and by reference to 10 CFR Part 50, the staff determined that it would be appropriate that the QAPD template include 10 CFR Part 52 in the statement.

NEI Response: Added reference is 10 CFR 52 in Part I, Section 1 and Section 1.1 to the QAPD template.

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

2. Draft Standard Review Plan (SRP) Section 17.5, paragraph II.A.3, states that, for multiple organizations, the QA program organizational description should clearly define the interface responsibilities. Clarify how the QAPD template will provide guidance for the applicant or holder to describe the interface of multiple organizations.

NEI Response: Added text to Part II, Section 1 of the QAPD template.

3. Draft SRP Section 17.5, paragraph I I.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how the QAPD template will provide guidance for the applicant or holder to implement measures to control the independence of organizations consistent with Section 17.5 of the draft SRP.

NEI Response: Added new Part II, Section 1.9 of the QAPD template.

4. Draft SRP Section 17.5, paragraph I I.A.7, states that management should ensure that the size of the QA organization is commensurate with its duties and responsibilities. In order to satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how the QAPD template will provide guidance for the applicant or holder to ensure that the size of the QA organization is commensurate with its duties and responsibilities.

NEI Response: Added additional paragraph to Part II, Section 1 in the QAPD template.

SECTION II QUALITY ASSURANCE PROGRAM

5. Draft SRP Section 17.5, paragraph II.B.1, states that management implementing portions of the QAPD should assess the part of the program for which they are responsible and assure is effective implementation at least once each year or at least once during the life of the activity, which ever is shorter, or may extend it to once every two years. Section II of the QAPD template states that reviews of the status and adequacy of the program and its implementation will be conducted on an ongoing basis via senior management review of quality assurance audit reports. In addition, Section 18.1 of the QAPD template provides measures to assess the effective implementation of the program at least once a year or at least once during the life of the activity, which ever is shorter. Clarify how the QAPD template will provide for these requirements consistently throughout the QAPD template and consistent with Section 17.5 of the draft SRP.

NEI Response: Agree to remove the current word in favor of similar words from the SRP. The term "activity" applies as described in Part I, Section 1.1 and does not apply to a specific/discrete task (e.g., a specific weld or pump overhaul).

6. Draft SRP Section 17.5, paragraph II.B.8, states that "a general grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied.

The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early." Section II of the QAPD template incorporates a grace period of 25% to be applied to provisions that are required to be performed on a periodic basis. In addition, the statement in the QAPD template does not discuss the "clock" portion of this provision. The entire provision as stated in draft SRP Section 17.5, paragraph II.B.8 should be addressed in the QAPD template.

NEI Response: Agree to remove the 25 percent grace in favor of similar words from the SRP. Based on verbiage from the NRC SER dated June 17, 2005 (ML051570349) the audits schedules are based on the month in which the audit starts.

7. Draft SRP Section 17.5, paragraph II.S.2 states the qualification requirements for individuals responsible for managing the implementation of the QA plan. Section 2.6 of the QAPD template provides the minimum qualification of the quality assurance manager and the nuclear development quality assurance project manager. However, these qualifications do not provide for requirements for management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Clarify how the QAPD template will provide for these requirements consistent with Section 17.5 of the draft SRP.

NEI Response: Added text to Part II, Section 2.6 of the QAPD template.

8. Draft SRP Section 17.5, paragraph II.S.3, states the qualification requirements for individuals responsible for planning, implementing, and maintaining the QA plan. Clarify how the QAPD template will provide for these requirements consistent with Section 17.5 of the draft SRP.

NEI Response: Added text to Part II, Section 2.6 of the QAPD template.

SECTION IV PROCUREMENT DOCUMENT CONTROL

9. Draft SRP Section 17.5, paragraph II.D.1, states, in part, that changes made as a result of bid evaluations or pre-contract negotiations are incorporated into the procurement documents, and the review of such changes and their effects are completed prior to contract award. Section 4.1 of the QAPD template establishes a commitment to NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, and includes clarifications and exceptions to these requirements. As an exception, the template proposes that "the quality assurance review of procurement documents is satisfied through review of the applicable procurement specifications, including the technical and quality procurement requirements, prior to bid or award of contract." This exception does not specify if procurement documents as well as changes to procurement documents will be part of the proposed quality assurance review. Clarify how the proposed quality assurance review of procurement documents includes the considerations delineated in Section 17.5 of the draft SRP.

NEI Response: Added text to Part II, Section 4.1 of the QAPD template. Added the requirements that procurement document changes (e.g., scope, technical or quality requirements) will be part of the quality assurance review. The original requirements remain in the clarifications and exceptions sub-bullet because they clarify how the QA review of technical and quality requirements occur.

SECTION VI DOCUMENT CONTROL

10. Draft SRP Section 17.5, paragraph II.C.1.q, states that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction, and installation. This paragraph applies to ESP and construction QA programs. The inclusion of these criteria satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(C). Section 6.1 of the QAPD template provides for the review of design, construction and installation procedures by the organization responsible for quality verification during the construction phase. Clarify how the QAPD template will implement measures to control the documented review and concurrence of quality-related procedures during ESP phase consistent with Section 17.5 of the draft SRP.

NEI Response: Added text to Part II, Section 6.1 of the QAPD template.

11. Draft SRP Section 17.5, paragraph II.F.9.b, states that there should be coordination and control of interface documents. The QAPD template does not provide measures for coordinating and controlling interface documents. Clarify how the QAPD template addresses coordination and control of interface documents consistent with Section 17.5 of the draft SRP.

NEI Response: Part II, Section 6 of the QAPD template was revised to reflect a requirement to coordinate and control interface documents and procedures.

SECTION VII CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

12. Draft SRP Section 17.5, paragraph II.L.8, states that, for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation (A2LA) are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. One of the conditions states that the use of the alternative method is limited to the National Voluntary Accreditation Program (NVLAP) and A2LA, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC). Section 7.2 of the QAPD template proposes to use this alternative method with a calibration laboratory accredited by NVLAP or A2LA as recognized by NVLAP through a Mutual Recognition Arrangement (MRA). An MRA is a generic term referring to a conformity assessment process. For assessment of calibration laboratories, the NRC has found the ILAC MRA to be an acceptable alternative. The alternative does not include MRAs administered under other programs. Clarify which MRA the QAPD template proposes to use.

NEI Response: Part II, Section 7.2, 3 of the QAPD template was revised to reflect a requirement to only reflect International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

13. Draft SRP Section 17.5, paragraph II.L.8, states that, for procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation

programs administered by the National Institute of Standards and Technology and by the A2LA are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance, provided that certain conditions are met. Paragraph II.L.8.h states that the proposed alternative is limited to the domestic calibration service suppliers. Clarify how the QAPD template will implement the procurement of commercial-grade calibration services consistent with Section 17.5 of the draft SRP.

NEI Response: Part II, Section 7.2 of the QAPD template was clarified to be limited to calibration laboratories that hold a domestic accreditation by NAVLAP or A2LA as recognized through the ILAC MRA.

14. In lieu of Section 8.1 of NQA-1-1994, Supplement 7S-1, regarding documents to be available at the site, the QAPD template proposed to consider documents that may be stored in approved electronic media under the company or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Clarify if measures are in place to ensure that documents store in approved electronic media under company or supplier control and not physically located on site will be reviewed for acceptance. In addition, clarify if measures are in place for timely retrieval of these documents consistent with Section 17.5 of the draft SRP.

NEI Response: The specification and the procurement contract for vendor services will include the document review for acceptance. If a vendor is performing the design work then their responsibilities for design review and records retention must be part of the vendor's QA program that is audited. Part of the objectives for the audit of the vendor will be verification of timely retrieval of the documents. Following completion of the construction period, sufficient as-built documentation will be turned over to the licensee to support operation. The records management system will provide for timely retrieval of necessary records.

SECTION X INSPECTION

15. Section 10.1 of the QAPD template provides an alternative to Subpart 2.4, regarding the use of the definition of "Safety Systems Equipment" from IEEE 603-1980. Clarify how the proposed definition is consistent with Section 17.5 of the draft SRP.

NEI Response: Because IEEE 336-1985 references the definition of "Safety Systems Equipment" from IEEE 603-1980, the definition must be committed to in order to appropriately implement Subpart 2.4 of NQA-1-1994. This clarification is simply to reinforce the fact that the entirety of IEEE 603-1980 was not referenced or committed to in Subpart 2.4. The definition of safety systems in IEEE 603-1980 is: "Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary features) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function." This definition is consistent with Section 17.5 of the draft SRP and is only applicable to equipment in the context of Subpart 2.4.

16. Draft SRP Section 17.5, paragraph II.J.5, states that inspections are performed by individuals other than those who performed the activity being inspected and that do not report directly to the supervisor responsible for the work being inspected. Section 10 of the QAPD template states that "inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work." In addition,

Section 10.1 proposes an alternative to those sites where the reporting independence may not be met, and where inspections are performed by persons within the same organization.

The proposed alternative states that this is an exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1. Supplement 10S-1, Section 3.1 requires that inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected, which are the same requirements of Draft SRP Section 17.5, Paragraph II.J.5. Paragraph II.J.1 states, in part, that the inspection program may be implemented by or for the organization performing the activity being inspected. However, inspection personnel still cannot report directly to same immediate supervisor who is responsible for the work being inspected as required by NQA-1-1994, Supplement 10S-1, Section 3.1, and Paragraph II.J.5 of draft SRP Section 17.5. Clarify how the QAPD template will provide measure for an inspection program consistent with Section 17.5 of the draft SRP.

NEI Response: This proposed alterative has been revised to reflect the Dominion QAPD which was accepted by SER dated September 9, 2005 (ML052490337).

SECTION XI TEST CONTROL

17. Draft SRP Section 17.5, paragraph II.K. 1, states that a test control program is required to be established to demonstrate that items will perform satisfactorily in service. Section 11 of the QAPD template provides measures for a test control program during construction and the operations phase. Clarify if test control measures are applicable for tests performed during the ESP phase.

NEI Response: Part II, Section 2.3 of the QAPD template was intended to cover all ESP activities unless a licensee went directly to a COL.

SECTION XIII HANDLING, STORAGE, AND SHIPPING

18. Draft SRP Section 17.5, paragraph II.M.8, states that during operation, cleanliness controls for work on safety related and risk-significant non-safety related equipment are required to be established to the extent necessary to minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. During the construction phase, draft SRP Section 17.5 references the use of Subpart 2.1 of NQA-1-1994. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.1, and includes a clarification and exception to these requirements. Clarify how the proposed alternative is acceptable during construction phase and is consistent with Section 17.5 of the draft SRP.

NEI Response: During the construction phase, Subpart 2.1 of NQA-1-1994 will be followed. The referenced exception has been deleted from NEI 06-14.

19. During construction phase, draft SRP Section 17.5 references the use of Subpart 2.2 of NQA-1-1994. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.2. Section 13.2 of the QAPD template provides an alternative to Subpart 2.2, sections 3.2 and 3.5 regarding

alternate methods for packaging. Clarify how the proposed alternative is acceptable during construction phase and is consistent with Section 17.5 of the draft SRP.

NEI Response: During the construction phase, NQA-1-1994, Subpart2.2, Sections 3.2 and 3.5 will be followed. The referenced exception has been deleted from NEI 06-14. .

20. Draft SRP Section 17.5, paragraph II.M.7, states that during operational phase controls for hoisting, rigging, and transport activities are required to be established that protect the integrity of the item involved as well as potentially affected nearby structures and components. During construction phase, draft SRP Section 17.5 references the use of Subpart2.15. Section 13.2 of the QAPD template establishes the commitment during construction and pre-operational phase to NQA-1-1994, Subpart 2.2. Subpart 2.2, section 7.1 refers to Subpart 2.15 for the requirements related to handling of items. Section 13.2 of the QAPD template provides an alternative to Subpart 2.15 during operational phase. Since the QAPD is not committing to use Subpart 2.15 during operation phase, the staff recommends taking the measures established for the controls over hoisting, rigging and transport during operational phase outside the commitment and exceptions to Subpart 2.2.

NEI Response: Agreed with the comment. The discussion regarding operational phase was moved outside the commitment and exceptions to Subpart 2.2.

SECTION XV NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

21. Section 15.1 of the QAPD template provides for measures "that implement a reporting program which conforms to the requirements of 10 CFR 50.55(e) and/or 10 CFR [Part] 21 during construction and 10 CFR Part 21 during operations." Clarify how the QAPD template will provide measures for reporting of nonconforming materials, parts, or components during ESP phase consistent with 10 CFR Part 52 requirements.

NEI Response: Agreed with comment. Revised Part II, Section 15.1 accordingly.

SECTION XVII QUALITY ASSURANCE RECORDS

22. Draft SRP Section 17.5, paragraph II.Q.4, states that document access controls, user privileges, and other appropriate security controls must be established. The QAPD template does not provide measures for security control of records. Clarify how the QAPD template will implement measures to provide document access and security consistent with Section 17.5 of the draft SRP.

NEI Response: Agreed with comment. Revised Part II, Section 17 introduction accordingly.

23. Draft SRP Section 17.5, paragraph II.Q.5, states, in part, that design documentation and records include not only the final design documents, such as drawings and specifications, and revisions thereto, but also documentation which identifies the important steps, including sources of design inputs that support the final design. The QAPD template does not provide measures for incorporation of documentation of design input sources that support the final design as part of the record retention program. Clarify how the QAPD template will implement measures to control records consistent with Section 17.5 of the draft SRP.

NEI Response: The clarification is addressed in NQA-1, Supplement 3S-1, Section 7. Since this is stated explicitly in the standard which the template commits to, there is no need for redundancy.

24. Draft SRP Section 17.5, includes a reference to Regulatory Issue Summary 2000-18. Regulatory Issue Summary 2000-18 provides guidance on storing and maintaining QA records in electronic media. Section 17 of the QAPD template includes the commitment to Regulatory Issue Summary 2000-18 as bracketed text. Clarify how an applicant or holder using the QAPD template will provide alternate measures consistent with the above guidelines if the applicant or holder chooses not to follow Regulatory Issue Summary 2000-18.

NEI Response: Agreed with the comment. Brackets were removed from text.

SECTION XVIII AUDITS

25. Draft SRP Section 17.5, paragraph II.R.10, states that when any work carried out under the requirements of the QA program is delegated to others, the work is to be audited by the QA audit program. Clarify how the QAPD template will provide measures to address the audit of QA program requirements delegated to others, consistent with Section 17.5 of the draft SRP.

NEI Response: Work delegated to others would be controlled either under the licensee's QA program (internal audits) or under a contract (supplier audits) for those specific services. Internal and supplier audits would cover the auditing of work delegated to others.

26. Draft SRP Section 17.5, paragraph II.R.11, provides guidance to conduct procurement audits of suppliers. The guidance states, in part that: (1) the supplier's QA program is audited on a triennial basis, (2) the triennial period starts when the first audit is performed, and, (3) an audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. Section 18.1 of the QAPD template makes reference to Section 7.1 of the QAPD template for the description of measures established for audits of safety-related component suppliers. Section 7.1 of the QAPD template states that qualified suppliers are audited on a triennial basis. Clarify how the QAPD template will implement the full supplier audit controls consistent with Section 17.5 of the draft SRP.

NEI Response: Agreed with the comment. Revised Part II, Section18.1.c and added additional information in Part II, Section 7.1 regarding scope changes and also regarding initial audits of suppliers following sufficient work to demonstrate compliance with a QA program.

PART III REGULATORY TREATMENT OF NON-SAFETY SYSTEMS (RTNSS)

27. Draft SRP Section 17.5, paragraph II.V.1.b, provides the quality assurance program controls required for non-safety related structures, systems, and components (SSCs) that are identified as being significant contributors to plant safety. Paragraph II.V.1.b states that the supplier's procedures describe the quality controls applied to the subject equipment. Part III, Section 2 of the QAPD template states that "suppliers of these SSCs or related services may describe the quality controls applied in appropriate procedures, [and] a new or separate QA program is not required." Clarify how the proposed quality assurance program controls are consistent with Section 17.5 of the draft SRP.

NEI Response: Agreed with comment. Removed "may." Also, revised RTNSS to reflect Draft SRP language - "non-safety-related SSC Quality Control."

28. Draft SRP Section 17.5, paragraph II.V.2 provides guidance for measures that applies to non-safety related SSCs credited for regulated events, including fire protection (10 CFR 50.48), anticipated transient without scram (10 CFR 50.62), and station blackout (10 CFR 50.63). Clarify how the QAPD template will implement measures for non-safety related SCCs credited for regulated events consistent with Section 17.5 of the draft SRP

NEI Response: Part III, Section 2 has been added to the QAPD template to address this issue.

GENERAL

29. The staff recommends that the QAPD template include these additional statements as bracketed text in order that the applicant or holder using the template make the final determination of the applicability of these text to their application (e.g., ESP, COL, construction, pre-operation, operation). The template should allow the applicant or holder to determine the specific information applicable for the type of application for which they will be using the QAPD template.

    a. Page 4 first paragraph: "for plants designed and constructed by or for [CA]."

NEI Response: Agreed - text revised

    b. Page 4, second paragraph, states the types of procedures that will be used along with the QAPD. The template should allow the applicant and holder to determine the types of procedures they will use along with the QAPD.

NEI Response: Agreed - text revised

    c. Page 11, second paragraph, provides examples of ESP/COL program safety-related activities.

NEI Response: Agreed - text revised

    d. Page 11, fifth and sixth paragraphs provides measures that can be used during ESP and/or COL application/activities.

NEI Response: Agreed - text revised

e. All of Section 2.3 on page 12 should be bracketed. In addition, the note at the beginning of the section should have been included since the beginning of the template.

NEI Response: Agreed - text revised

f. Page 13, first paragraph of Section 2.5 provides option for ESP or COL.

NEI Response: Agreed - text revised

g. Page 23, second paragraph provides types of documents to be controlled.

NEI Response: Agreed - text revised

h. Page 23, third and last paragraphs provide measure during operational phase. NEI

Response: Agreed - text revised

i. Page 24, first paragraph provides measures applicable to operational phase procedures.

NEI Response: Agreed - text revised

j. Page 32, first paragraph provides types of tests requiring test controls.

NEI Response: Agreed - text revised

k. Page 37, Section 15.1 provides measures for reporting nonconforming material, parts and components during construction and operation.

NEI Response: Agreed - text revised

l. Page 40, first paragraph provides different types of activities and focus areas of internal audits.

NEI Response: Agreed - text revised

m. Page 40, first paragraph provides examples of procedures to be audited. NEI

Response: Agreed - text revised

n. All of Part III on page 42 should be bracketed.

NEI Response: Agreed - Note was placed at the beginning of Section III stating that it was not applicable to ESP-only QA programs.

30. Consistent with your letter dated October 26, 2006, from Adrian P. Heymer, place the NEI document number, NEI-06-14, with the revision number on the cover page of the QAPD document.

NEI Response: Agreed - text revised