NEI 06-14 [Revision 7]

Quality Assurance Program Description

July 2009

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Nuclear Energy Institute

Quality Assurance Program Description

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EXECUTIVE SUMMARY

NEI 06-14, "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 06-14 is structured as a template for use in developing the applicant-specific QAPD required as part of ESP and COL applications. The template consists of two documents: (1) a Policy Statement, and (2) a Quality Assurance Program Description that consists of four Parts. The applicant will format their specific QAPD in accordance with their process or program for developing such documents. The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for the ESP or COL application. NRC staff review of applicant-specific QAPDs based on NEI 06-14 is expected to focus on the specific information provided to replace the bracketed text in the generic template.

This is an update to NEI 06-14A, revision 4. The NRC approved NEI 06-14A, Revision 4, in an April 2007 Final Safety Evaluation for use on early site permit, combined license, construction, pre-operation and/or operation activities. Revision 4 included the original NRC Safety Evaluation. NEI 06-14, Revision 7, includes changes that address subsequent NRC Requests for Additional Information. An updated Safety Evaluation Report will be incorporated into NEI 06-14 following issuance by the NRC.

[Company Name]

POLICY STATEMENT

[Company Name] ([Company Abbreviation - CA]) shall design, procure, construct and operate the nuclear plant*[s]* 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 (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs 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]

TABLE OF CONTENTS

PART I INTRODUCTION

SECTION 1 GENERAL

[NOTE: The QAPD can be used for Early Site Permit (ESP)/Combined Operating License (COL)/ construction/pre-operation and/or operations. When developing a QAPD using this template, the bracketed text should be selected based on the intended application of the QAPD (e.g., ESP, COL, construction phase, operations, or all). Text that is defined as a NOTE is for information only, is not intended to be part of the QAPD, and should be removed.

NOTE: The QAPD template contains bracketed text that the applicants will select or modify with specific information as necessary for the application. When the bracketed text is NOT italicized, the text should be included if applicable to the scope without modification. This nonitalicized bracketed text is reviewed and approved as part of the standard template approval. See Part II, Section 2.7 for an example of the nonitalicized bracketed text. When the bracketed text IS italicized, the text is considered to be example text that the applicant/licensee will modify specific to their needs. This italicized text is subject to review by the NRC to determine the acceptability of the QAPD submitted by the applicant. See Part II, Section 1.1 for an example of the use of italicized bracketed text.]

[Company (CA)'s] [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 quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and recommendations of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I, II, and III, as specified in this document.

The QA Program (QAP) is defined by the NRC-approved regulatory document that describes the QA elements (i.e. the QAPD), 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 so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group 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

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

[ITAAC are those Inspections, Tests, Analyses and Acceptance Criteria the applicant must satisfy as determined by the commission in accordance with 10 CFR Part 52.]

Safety-related SSCs, 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 QA requirements for activities within their scope.

The policy of *[CA]* is to assure a high degree of availability and reliability of the nuclear plant*[s]* 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 1.4, 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 that perform 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 the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

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

[NOTE: The following information will be utility specific but should follow the SRP for the content. This also includes interface responsibilities for multiple organizations performing quality-related functions. This section should be developed to include the organization that is to implement the phase the QAPD is intended to cover e.g., ESP, COLA, Construction/Pre-operation/Test, and Operations. The description should include levels of authority, interfaces, and functional responsibilities for each position. In addition, for QAPDs that cover activities during both construction and operations, it should include enough detail to distinguish the organizational structure for construction and for operations. Include organization charts that describe the QA organization that is/will be in place for all positions responsible for establishing, maintaining, and implementing QA requirements from corporate positions through plant positions.]

[NOTE: Generic titles (e.g., Nuclear Development, Quality Assurance Manager) may be used in the QAPD. However, the generic titles established in the Organization Section must be used throughout the document.]

[NOTE: Provide a clear illustration of the organization's functional responsibilities, to include preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the audit function; and controlling records. Also, refer to the same organizational titles throughout the QAPD.]

[NOTE: Structure Section 1, Organization, of the QAPD such that it clearly delineates 1) how the QA program is implemented during all applicable phases such as the period of construction and testing and the operations phase. The transition process from one phase to another must be described. Position descriptions should clearly delineate these roles during each applicable phase such as the construction/preoperation phase, the operations phase, as well as the transition period between the phases. For example at the transition from construction to

operations, the following text may be appropriate: No later than six months prior to fuel load of the unit, those positions which are identified for Operations will be staffed and have the appropriate authority required to perform operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/preoperation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) are completed, control and authority (including oversight, configuration and operations) is transferred from the contractor to the cognizant owner departments in the operations phase. During the transition, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.]

[NOTE: The QAPD describes the functions and responsibilities associated with the quality assurance requirements of 10 CFR 50, Appendix B, Criteria I, Organization and Criteria II, Quality Assurance. All positions associated with the establishment, implementation, and verification of quality-related activities should be shown on the organization charts and described in the QAPD. For the operations phase, the level of detail to be included should include roles, responsibilities, and lines of authority for the positions necessary to implement the requirements of Appendix B. For example, this level of detail will identify where the independent review functions report within the organization. Comparable detail should be provided for the construction/preoperation phase.]

[NOTE: Sufficient detail must be included to fully describe how the organization will perform, manage, and/or oversee activities affecting the quality and performance of safety-related SSCs, including: testing, preoperational activities such as ITAAC, receiving, storing, repairing, decommissioning, refueling, and shipping.]

[NOTE: The applicant/licensee may provide the required organization description by incorporating by reference information from another section of the FSAR but by so doing, the regulatory change process established by 10 CFR 50.54(a) would be applicable to that incorporated section. If incorporation by reference is used, care must be taken to use the appropriate titles from that section in the QAPD in replacing bracketed text.]

[NOTE: Below is an example of a new plant organization, its independence, and its linking within an existing utility. The sample organization presented here is for illustration only. This is not representative of the level of detail sufficient to address all phases of potential applicability.]

[The [CA] [Nuclear Development (ND)] organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operations development activities. Several organizations within [CA] 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

NSSS 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 that furnish 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

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]

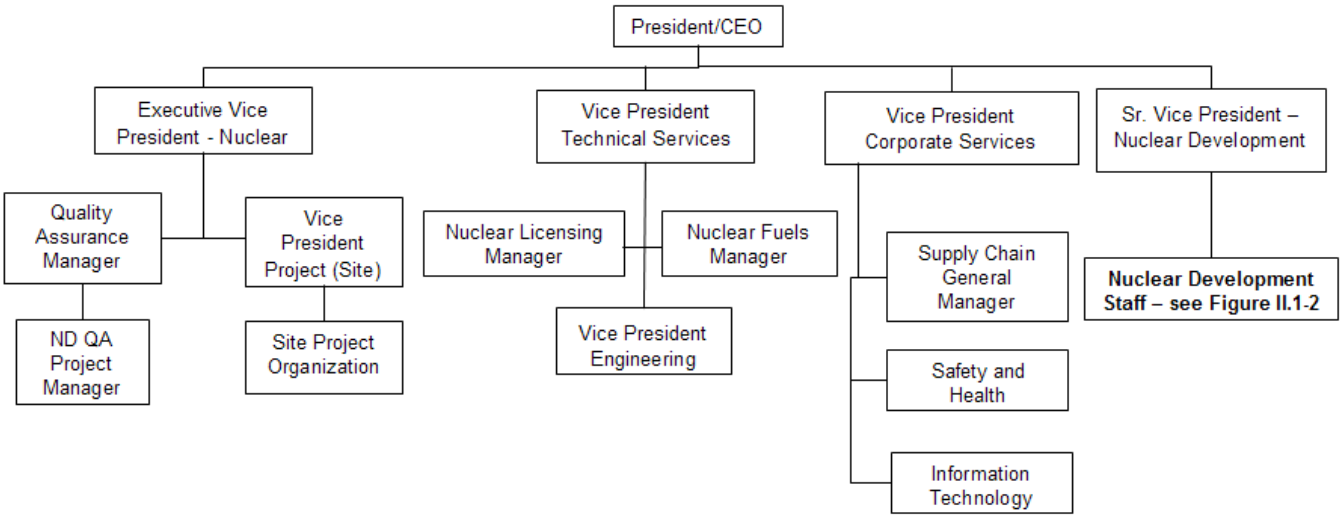
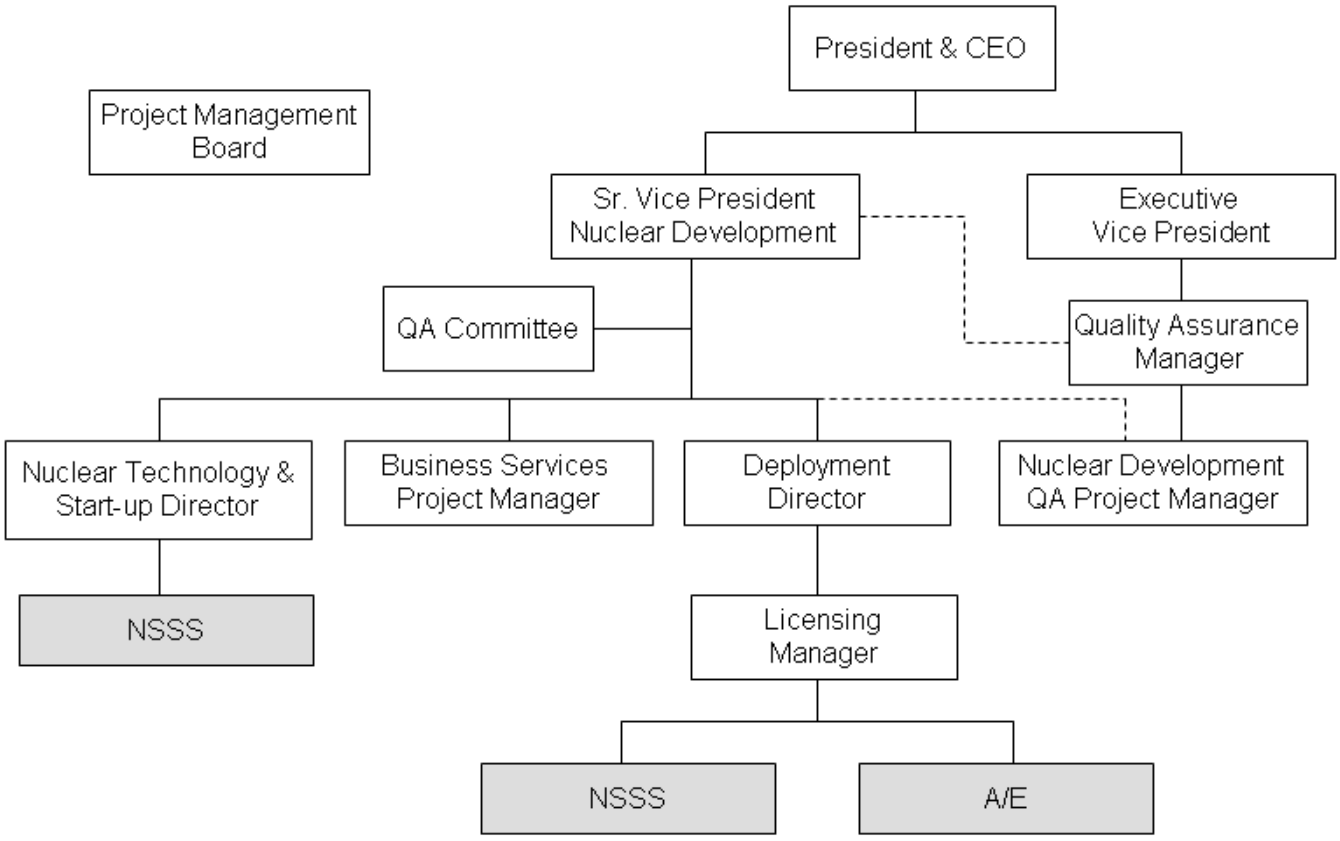


Figure II.1-2

[Nuclear Development] Organization

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]



SECTION 2 QUALITY ASSURANCE PROGRAM

[CA] has established the necessary measures and governing procedures to implement the QAP as described in the QAPD. *[CA]* is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plant*[s]* as described and to the extent delineated in the 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. Senior management is regularly apprised of the adequacy of implementation of the QAPD through the audit functions described in Part II, Section 18.

The objective of the QAPD is to assure that *[CA]*'s nuclear generating plant*[s are/is] [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 (excluding Design Certification activities), fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations]. [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 that identifies 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 the QAPD, specific program controls are applied to nonsafety-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. *[NOTE: The preceding sentences and Part III do not apply to an ESP-only QAP.]]*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, the 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, the 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 [a] new plant[s], the interface between nonsafety-related and

*safety-related SSCs and the placement of seismically-designed backfill. **[**NOTE: This does not apply to an ESP-only or an Operations-only QAP.**]]***

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 assurance 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 achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. *[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 QAP. Positions identified in Part II, Section 1, 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 Site-specific Safety-Related Design Basis Activities

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. Appropriate quality assurance measures are applied.*[NOTE: This does not apply to an Operations-only QAP]]*

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, whichever is shorter. [However, the period for assessing QA programs during the operations phase may be extended to once every two years.***[****NOTE: This does not apply to a non-Operations QAP****]***]

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)*[NOTE: Selection of regulation depends on the scope of the QAP. Select one or both references , 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 the QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD. ***[****NOTE: This does not apply to a non-Operations QAP.****]]***

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 the unit Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. ***[****NOTE: This does not apply to a non-Operations QAP.****]***] 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. ***[****NOTE: This does not apply to a non-Operations QAP.****]***] 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* that *[he/each]* holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in 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

[*NOTE: Section 2.7 This does not apply to a non-Operations QAP.****]***

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 events that are required to be reported to the NRC. 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,] [NOTE: the generic titles used here must match those established in Part II, Section 1 Organization]* 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.

[NOTE: Option I or Option II may be used. The generic terms Independent Review Body (IRB) and Independent Review Committee (IRC) may be substituted with the specific company terms.]

[NOTE: 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. The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the twelve areas listed below:
    (1) Nuclear power plant operations
    (2) Nuclear engineering
    (3) Chemistry and radiochemistry
    (4) Metallurgy
    (5) Nondestructive testing
    (6) Instrumentation and control
    (7) Radiological safety
    (8) Mechanical engineering
    (9) Electrical engineering

(10) Administrative control and quality assurance practices
(11) Training
(12) Emergency plans and related procedures and equipment).

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.]

[NOTE: Option II -]

[Independent Review Committee

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

2. The independent review committee reports to [CA is to identify a management level above the plant manager as described in the organization in Part II, Section 1].

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 *[NOTE: The applicant may either adopt non-mandatory Appendix 2A-1 as if it were part of the supplement by following option 1 below or take exception to 2A-1 following option 2.]*

  - *[NOTE: Option 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.] *[NOTE: When applying Option 1, either or both of 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 that perform 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.]*

- *[NOTE: Option 2 is based on SER ML050700416 and may only be applied during the Operations Phase. The post-TMI regulations at 10 CFR 50.34(f)(3)(iii) apply during construction phase.]*

  - [In lieu of Nonmandatory Appendix 2A-1, *[CA]* does not establish levels of qualification/ certification for inspection personnel. Instead, *[CA]* establishes initial qualification requirements and determines individual qualification through evaluation of education, training and experience, and through demonstration of capability in performing the type of inspections expected on the job.]

  - *[NOTE: When selecting option 2, the following alternative may be applied to the implementation of Supplement 2S-1.]* [Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b and c are not met, inspections, examinations or tests are carried out by individuals certified in accordance with Supplement 2S-1. Individuals performing visual inspections required by the ASME Boiler and Pressure Vessel Code are qualified and certified according to Code requirements.]

- 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 the 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 the 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 governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. *[CA]* and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures 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 is documented and approved by *[authorized personnel].* The QAPD is also 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 supplier, applicant for certification, or DC holder]*, 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.*[NOTE: This does not apply to an ESP-only QAP]]*

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 investigation

requirements in Subpart 2.20,*[NOTE: This does not apply to an Operations-only QAP]]* and the standards for computer software 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 *[CA]*'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. In addition, means are provided to disseminate to the staff 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]'s 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. 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 systems (including electronic systems used to make documents available) are documented and provide for the following:

(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 the 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 are reviewed for adequacy by qualified persons other than the preparer. [During the *[ESP or construction phase],* procedures for design, construction, and installation are also - reviewed by *[the organization responsible for quality verification]* to ensure quality assurance

measures have been appropriately applied. *[NOTE: This does not apply to an Operations-only QAP.]]* The documented review signifies concurrence.

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

To ensure effective and accurate procedures during the operational phase, applicable procedures are 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 Part II, Section 18.1.] [NOTE: This does not apply to a non-Operations QAP.]

Prior to issuance or use, documents including revisions thereto, are 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, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has 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.*[NOTE: This does not apply to a non-Operations QAP.]]* 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 provides 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 misuse.

- 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 *[the] [CA]* plant*[s]* 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 will be performed and will include a verification of the following:

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

        - National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology;

- American Association for Laboratory Accreditation (A2LA);
- ACLASS Accreditation Services (ACLASS);
- International Accreditation Service (IAS);
- Laboratory Accreditation Bureau (L-A-B);
- Other NRC-approved laboratory accrediting body.

▪ The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

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

- For Section 8.1, *[CA]* considers documents that may be stored in approved electronic media under *[CA]* or vendor control, not physically located on the plant site, but 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. *[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 are 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 Part II, Section 2. 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 following clarification. 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" from IEEE 603-1980. *[CA]* commits to the definition of Safety Systems 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 addressed in Part II, Section 12 of the QAPD.

- *[**[**NOTE: 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 the 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 to establish and adjust test schedules, and to maintain 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.*[NOTE: This does not apply to an ESP-only QAP]]*

Tests are performed and results documented in accordance with applicable technical and regulatory requirements, including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

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 are controlled as described in Part II, Section 7.

*[*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. *[NOTE: This does not apply to an ESP-only QAP.]]*

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, Subpart 2.4, 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 are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are 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 are 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.*[NOTE: This does not apply to a non-Operations QAP.]]* 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.*[NOTE: This does not apply to an ESP-only QAP.]]*

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 following clarifications and exceptions:

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 the nuclear power plant*[s]* during construction.

NQA-1-1994, Subpart 3.2

- Subpart 3.2, Appendix 2.1: Only Section 3 precautions are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.

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 the 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.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. 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, that 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 are 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 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during [ESP/COL design 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, *[CA]* may delegate specific responsibilities for corrective actions but *[CA]* maintains responsibility for the effectiveness of corrective action measures.

16.1 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ESP/COL design and construction, and 10 CFR 21 during operations]*.

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] has 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 established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for *[design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits]* and their retention times are defined in appropriate procedures. The records and retention times are *[based on Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, Revision 3 for design, construction, and initial start-up. Retention times for operations phase records are based on construction records that are similar in nature.] [NOTE: The applicant/licensee must address the records retention schedule for their plant by either referencing Table 1 of Regulatory Guide 1.28, Rev. 3, or including their specific table in the QAPD]* 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 the 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 Manager responsible for the day to day program as documented in Section 1]*

[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 Executive responsible for the Quality Assurance program at the Site/Plant/Company]*, 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.

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

18.2 Internal Audits

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.

*[*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. *[NOTE: This does not apply to a non-Operations QAP]]*

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the 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.

18.3 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 NONSAFETY-RELATED SSC QUALITY CONTROL

[NOTE: Part III does not apply to an ESP-only QAPs.]

SECTION 1 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to nonsafety-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 nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-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 nonsafety-related SSCs are established in the 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] has 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]* 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] provides 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 provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6 Document Control

[CA] controls 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] employs 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] employs 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] employs 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] uses 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 may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11 Test Control

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

1.13 Handling, Storage, and Shipping

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

1.17 Records

[CA] employs 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] employs 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 Nonsafety-Related SSCs Credited for Regulatory Events

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect 6 months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. Section 2 provides alternative approaches for satisfying the following NRC guidance:

- *Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."*

- *Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout."]*

[NOTE: The specific program controls identified in Part III, Section1 for nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, are commensurate with the NRC Guidance identified above.]

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]* implements 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" as identified in FSAR Chapter 1.] [NOTE: The applicant/licensee must address the conformance to Regulatory Guide 1.189. Part III Section 1 may not adequately address regulatory position 1.7 of RG1.189. In reviewing the Regulatory Positions the applicant should reference FSAR Section 9.5.]*

- *[CA]* implements the quality requirements for ATWS equipment in accordance with Part III, Section1.

- *[[CA*] implements quality requirements for SBO equipment in accordance with Part III, Section1.

[*NOTE: In addressing applicability of these Regulatory Guides care must be exercised to ensure conformance identified for the design is consistent with the technology specific design as documented in the applicable certified design.****]***

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

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

[NOTE: NEI 06-14A was prepared and reviewed to NUREG 0800 Standard Review Plan Section 17.5 March 2007; if there is a later version, an applicant would need to address conformance to the later revision in the FSAR.]

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. The section on Regulatory Guides below identifies where the template conforms with or provides alternative approaches for satisfying the identified NRC guidance.]

Regulatory Guides:

[See FSAR Chapter 1 for the [CA] evaluation of conformance with the guidance in NRC Regulatory Guides in effect six months prior to the submittal date of the application.]

[NOTE: The notes provide an applicant information to support addressing Regulatory Guide conformance in Chapter 1 of the FSAR consistent with RG 1.206, section C.I.1.9. The formatting of this section assumes the applicant will address conformance with RGs in a single location in Chapter 1 of the FSAR. If an applicant elects to provide the identification of conformance in this section for the identified RGs, conformance, exceptions, or alternatives for all regulatory positions of each RG should be included.]

[*NOTE: The information below identifies where this template conforms with or provides alternatives to the RGs and the indicated regulatory positions. Regulatory Positions determined to not be directly applicable to the QAPD include a pointer to the potentially applicable Chapter of the FSAR. The applicant is responsible to review this information and confirm its accuracy at the time of submittal of an application. In addressing conformance with the Regulatory Guides, the applicant must also consider the status of conformance for design and construction consistent with the referenced DCD. The revisions used below were in effect when this document was prepared. Use the appropriate revisions based on the time of application.****]***

Regulatory Guide 1.8, *[Rev. 3, May 2000]*, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses ANSI/ANS-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," with certain additions and exceptions that are listed in the Regulatory Position of this guide. Some of the exceptions are endorsements of certain sections of two other standards, ANSI N18.7-1976 (ANS-3.2), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," and ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants." Rather than to commit to those Standards in the QAPD, appropriate requirements have been directly incorporated into the text. These requirements are consistent with the identified acceptance criteria in SRP Section 17.5.]

[NOTE: Regulatory Positions C.1.1 through C.1.4 address definitions in ANSI/ANS-3.1-1993. Conformance with ANSI/ANS-3.1-1993 and those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.1 (2.1.1, 2.1.2, and 2.1.3) address alternatives and substitutions for education and experience for quality assurance personnel. Those alternatives and substitutions are reflected in Part II, Section 2.6 of the QAPD template.]

[NOTE: Regulatory Position C.2.2 through C.2.10 are not directly applicable to quality assurance personnel. Those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.11 addresses ANSI/ANS-3.1-1993 Section 4.5.5, Quality Control. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T.]

[NOTE: Regulatory Position C.2.12 addresses ANSI/ANS-3.1-1993 Section 4.5.6, Quality Assurance. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.S.]

[NOTE: Regulatory Position C.2.13 is not directly applicable to quality assurance personnel. Those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Positions C.2.14 and C.2.15 address ANSI/ANS-3.1-1993 Sections 4.7.1 and 4.7.2 relative to Independent Review qualifications. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.7. As documented in SER ML070510300, the QAPD template follows 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.]

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] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[*NOTE: This Regulatory Guide provides guidance on establishing quality group classifications for components of the nuclear plant and the appropriate industry standards to apply that ensure proper quality requirements. Regulatory Positions C.1 through C.3 provide guidance in establishing quality group classifications of components that correspond to ASME Section III, Class 2 and 3, and those that are not part of the reactor coolant system but may contain radioactive material. Table 1 of the RG identifies the industry standards that would be applied to establishing appropriate quality requirements. The classification of components would be addressed through the FSAR (and associated DCD) Section 3.2. The application of specific standards would be addressed in the FSAR/DCD sections that describe the identified components.****]***

Regulatory Guide 1.28, *[Rev. 3, August 1985]*, Quality Assurance Program Requirements (Design and Construction)

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses the basic and supplementary requirements in ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants" and the ANSI/ ASME NQA-1a-1983 Addenda along with the regulatory positions discussed below for the establishment and execution of quality assurance programs during the design and construction phases of nuclear power plants. The QAPD 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.]

[NOTE: Regulatory Position C.1 addresses the qualification of inspection and test personnel. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T. Note that SRP Section 17.5 paragraph II.T.5 and 6 represent alternatives to this regulatory position that were approved in SER ML050700416.]

[NOTE: Regulatory Position C.2 addresses quality assurance records. Guidance is included in the QAPD, Part II, Section 17.1 for the applicant to address this regulatory position.]

[NOTE: Regulatory Position C.3 addresses scheduling of audits. 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. It follows 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 scheduling of Internal Audits is addressed in QAPD Part II Section 18.2 and is consistent with position C.3.1 for the phase prior to placing the facility into operation. External Audits are addressed in QAPD Part II Section 7.1. The requirements are consistent with SRP paragraph II.R.11 and II.R.12. These requirements address regulatory position C.3.2.]

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] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide describes an acceptable method for identifying and classifying the features of nuclear power plants that must be designed to withstand the effects of the Safe Shutdown Earthquake(SSE). Regulatory Positions C.1 through C.3 provide guidance in establishing the SSCs, or portions thereof, classified as needing to meet seismic design requirements. The seismic design classification of SSCs would be addressed through the FSAR (and associated DCD) Section 3.2.]

[NOTE: Regulatory Position C.4 addresses the application of the QA requirements of Appendix B to 10 CFR Part 50 to all activities affecting the safety-related functions of those portions of the SSCs that are covered by Regulatory Positions 2 and 3. Those in Regulatory Position 1 are considered safety-related. The QAPD described in Section 17.5 of the FSAR addresses the QA program requirements applied to safety-related activities.]

[NOTE: Regulatory Position C.5 addresses the application of design requirements for portions of the fire protection SSCs as discussed in Regulatory Guide 1.189. The design and quality assurance requirements for fire protection SSCs is addressed in Section 9.5.1 of the FSAR (and associated DCD).]

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

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide endorses ANSI N18.7-1976/ANS-3.2 for complying with the quality assurance program requirements for the operation phase of nuclear power plants, subject to five regulatory positions. SER ML070510300 for NEI 06-14A concluded that the QAPD 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 identified in SRP

Section 17.5. This represents an approved alternative for Regulatory Positions C.2, C.3, C.4, and C.5.]

[NOTE: Regulatory Position C.1 addresses "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors." QAPD Part II, Sections 5 and 6 address requirements on review and approval of safety-related procedures consistent with requirements addressed in SRP 17.5 section II.F and ANSI N18.7-1976. However, FSAR Chapter 13, Conduct of Operations, which addresses plant procedures, should be used in addressing this regulatory position.]

[NOTE: Regulatory Position C.2 identifies additional standards referenced by ANSI N18.7-1976/ANS-3.2 and provides a cross reference for a regulatory Guide that addressed each of those standards. The QAPD identifies commitments to ASME NQA-1-1994 instead of the listed ANSI N45.2 series standards listed. Regulatory Guides 1.28, 1.37, 1.38, 1.39, 1.30, 1.94, 1.58, 1.116, 1.88, 1.74, 1.64, and 1.123 are listed for positions on the ANSI N45.2 series standards. RG 1.8, 1.17, and 1.54 are included as addressing other ANSI Standards. RG 1.8, 1.28, and 1.37 have been revised to reference newer standards and are discussed specifically in this section. RG 1.17, 1.58, 1.64, 1.74, 1.88, and 1.123 have been withdrawn. For RG 1.30, 1.38, 1.94 and 1.116 the QAPD provides an acceptable alternative using ASME NQA-1-1994 Subparts 2.2, 2.4, 2.5, and 2.8 as identified in Part II Sections 10.3 and 13.2 and SRP 17.5 Section II.U.2. For RG 1.39 the QAPD provides an acceptable alternative in Part II, Section 13.1, which is consistent with SRP Section 17.5, paragraph II.M. for operations; controls during design and construction should be addressed in the DCD. For applicability of RG 1.54, FSAR Chapter 6 should be consulted.]

[NOTE: Regulatory Position C.3 identifies a position related to Independent Review. The QAPD provides an alternative for this position by addressing Independent Review requirements specifically in Part II, Section 2.7 consistent with SRP 17.5 Section II.W rather than referencing ANSI N18.7. Item 2.7 c. specifically relates to the concern of this regulatory position.]

[NOTE: Regulatory Position C.4 relates to provisions of the audit program. In establishing the independent audit program, the QAPD provides an alternative for this position by committing the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1. It follows 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.]

[NOTE: Regulatory Position C.5 identifies concerns of the NRC with the usage of the verbs "should" and "shall" in ANSI N18.7-1976. QAPD provides an alternative to this position by providing 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 identified in SRP Section 17.5.]

[Regulatory Guide 1.37, *[Revision 1, March 2007]* – Quality Assurance 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] identifies conformance and exceptions for the applicable regulatory position guidance

provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.] [NOTE: Does not apply to ESP-only or Operations-only QAP]*]

[*NOTE: This Regulatory Guide finds that the provisions and recommendations included in ASME NQA-1-1994, Part II, Subpart 2.1 are generally acceptable for onsite cleaning of materials and components, cleanness control, and preoperational cleaning and layup of water-cooled nuclear power plant fluid systems with three regulatory positions. QAPD Part II, Section13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 2.1.]*

[*NOTE: Regulatory Position C.1 identifies that the applicability and acceptability of any of the codes, standards, and specifications referenced in the text are or will be addressed through other regulations or NRC guidance. FSAR Chapter 1 addresses the codes, standards, and other documents that are used in the COL and any exceptions or alternatives to those documents.]*

[*NOTE: Regulatory Position C.2 identifies the NRC position that the water quality for final flushes of fluid systems and associated components should be at least equivalent to the quality of the operating system water. The applicant will need to identify if there is a reason to deviate from this regulatory position.]*

[*NOTE: Regulatory Position C.3 recommends following Sections 8.2.2 and 8.2.3 of ASME NQA-1-1994, Part II, Subpart 2.1 precautions related to the use of alkaline cleaning solutions and chelating agents, respectively, by the use of the guidance in nonmandatory Appendix 2.1 to ASME NQA-1-1994, Part III, Subpart 3.2. In addition, this position recommends that a suitable chloride stress-cracking inhibitor be added to the fresh water used to flush systems containing austenitic stainless steels. QAPD Part II, Section13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 3.2. The applicant will need to identify if there is a reason to deviate from this regulatory position.****]***

Standards:

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

[CA] commits to NQA-1-1994, Parts I, II, and III, 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.

End of QAPD Template

Table of Changes from Revision 4 to Revision 7 Follows

Attachment A
Table of Changes from Revision 4 to Revision 7

Template Section	**Detailed Change Description**
General Corrections	Correction of punctuation, spelling, deletion of unnecessary use of the article "the" (e.g., prior to [CA]), changes to provide consistency in the use of verb tense (e.g., are, is, has, will), and insertion of hyphens for consistency of presentation (e.g., safety-related, quality-related) were made in the document but are not specifically identified in this table. In addition, there were some clarifications made to the *italicized* bracketed text that the applicants will modify, which is not discussed in this table.
Part I Section 1.1	Added paragraph referencing the definitions from ASME NQA-1-1994.
Part II, Section 1	Notes were added to Part II, Section 1, of the template prior to the sample organization section to provide additional guidance to the applicant. In addition, notes were added to the Organization Charts to better define the needed content. (Change to address RAI # 1 and Supplemental RAI # 1.)
Part II, Section 1	Clarified the note to provide consistency on the use of titles throughout the QAPD developed from the template. (Change to address RAI # 2 and Supplemental RAI # 2.)
Part II, Section 2	The first paragraph, fourth sentence was deleted. The removed information is now found in the third paragraph.
Part II, Section 2	Added brackets to part of the second paragraph, regarding the activities the QAPD applies to, based on the end users intended usage. Removed the FSAR as a reference for listing SSCs. (Change to address RAI # 6 and # 8.)
Part II, Section 2	Clarified third paragraph by adding reference to Part III. Enclosed the paragraph in brackets to allow the end user to choose the information based on the scope of the QAPD. (Change to address RAI # 8.)
Part II, Section 2	Clarified the interface in the fourth paragraph.
Part II, Section 2	Clarified sixth paragraph to remove reference to LWA-1 and LWA-2, leaving only reference to Limited Work Authorization (LWA) consistent with regulations. Enclosed this sentence in brackets and added a note indicating the text may be deleted if this is not within the scope of the applicant QAPD. (Change to address RAI # 8.)
Part II, Section 2.3	The paragraph was revised to remove wording that was specific to a single applicant. (Change to address RAI # 7.)
Part II, Section 2.4	Section 2.4 Replaced "and" with "to" between "responsible" and "assure" in the same sentence. Added brackets and italics to the operations only requirements to allow the choice based on the scope of the applicant QAPD.
Part II, Section 2.5	Section 2.5 Removed reference to 10 CFR 50.34(b)(6)(ii) in second paragraph. Depending on the scope of the QAPD, various regulations including 10 CFR 50.34(b)(6)(ii), 10 CFR Part 52.79(a)(25), 10 CFR Part 52.79(a)(27) require this content be addressed in the FSAR. Added brackets, italics, and a note since this paragraph would not apply to a QAPD for ESP or construction only.
Part II, Section 2.6	Corrected second paragraph, third line to "minimum of four years of related experience … ." Corrected second paragraph to clarify the required experience and make a complete sentence.

Attachment A
Table of Changes from Revision 4 to Revision 7

Template Section	**Detailed Change Description**
Part II, Section 2.7	Added brackets around IRB/IRC indicating that one of the options is to be selected. Changed "effect" to "affect" under review item a. Revised review item d. to remove reference to reports made to the NRC in 24-hours based on a change in the regulation for reporting. (Reference 10 CFR 50.72 and 50.73 for example)
Part II, Section 2.7	Option 1revised to clearly state the qualification requirements for the independent review staff consistent with the qualification criteria described in Section 4 of ANSI/ANS-3.1-1993 as endorsed by Regulatory Guide 1.8 Revision 3, including regulatory positions 2.14 and 2.15. Option 2 item 2 clarified for the reporting level of the IRC. (Change to address Supplemental RAI # 6)
Part II, Section 2.7	Under Option II, corrected item 3 to "…no less <u>than</u> 5 persons <u>and</u> no more than …" Removed the unnecessary word "be" from item 5.
Part II, Section 2.7	Under Option II, removed previous item 6 and renumbered the remaining items in the list. The removed item stated "The Independent Review committee is responsible for performing the following:" But the template included the functions the IRC performs as items a through g under section 2.7, rather than in this location.
Part II, Section 2.8	Added Notes to clarify the use of alternative exceptions for Supplement 2S-1 and Appendix 2A-1. Added an Option for the use of exceptions approved in SER ML050700416, which may only be applied during the Operations Phase. (Change resulted from supplemental RAI #5)
Part II, Section 3.4	Replaced "procedures" with "written instructions" in the second sentence under 3.4 Setpoint Control to be consistent with terminology in the first sentence of this paragraph. Bracketed "NSSS supplier" and added "Applicant for certification or DC holder" in item 1 under section 3.4 to reflect the usage of Certified Designs.
Part II, Section 4	Changed the term licensee in the second bullet to *[CA]* for consistency with Section 4.1. (Change to address RAI # 8.)
Part II, Section 4.1	Added "/ Exceptions" to the title of Section 4.1, since exceptions are identified.
Part II, Section 7.2	Added "/ Exceptions" to the title of Section 7.2, since exceptions are identified. Corrected the formatting of the final four paragraphs to clarify these exceptions to Supplement 7S-1.
Part II, Section 7.2	Bullet (3) of the exception for commercial-grade calibration services was updated to reflect additional acceptability approved by the NRC. (Change to address RAI # 3.)
Part II, Section 7.2	The last bullet under the exception to NQA-1-1994, Supplement 7S-1, Section 10 was revised to remove the reference to RIS 2002-22. (Change to address RAI # 4 and Supplemental RAI # 3.)
Part II, Section 10.	Identified headings as subsections 10.1 and 10.2. Renumbered 10.1 to be 10.3 following change above.
Part II, Section 10.3	Removed the word "Equipment" in two locations to align with terminology from IEEE 603 -1980.
Part II, Section 12	Identified "Installed Instrumentation and Control Devices to be subsection 12.1 and renumbered subsequent sub-sections.
Part II, Section 13.2	Added reference to Subpart 3.2, Appendix 2.1, consistent with Regulatory Guide 1.37, including identification of an exception to the content of this Subpart beyond the precautions.

Attachment A
Table of Changes from Revision 4 to Revision 7

Template Section	**Detailed Change Description**
Part II, Section 15.1	Revised the title, paragraph wording, and added brackets to clarify that the Reporting Program is non-QA and allow the user to select the appropriate text based on the scope of the QAPD. (Changed to be consistent with the change to Section 16.1 to address RAI # 8 and to clarify the relation of the QAP with the reporting requirements.)
Part II, Section 16	Revised the second paragraph to replace "licensee" with "*[CA]*" and clarified the responsibility for effectiveness of corrective actions. (Change to address RAI # 8.)
Part II, Section 16.1	Revised the title, paragraph wording, and added brackets to clarify that the Reporting Program is non-QA and allow the user to select the appropriate text based on the scope of the QAPD. (Change to address RAI # 8 and to clarify the relation of the QAP with the reporting requirements.)
Part II, Section 17.1	Revised section to provide guidance for addressing Regulatory Position C.2 of RG 1.28. (Change related to Supplemental RAI # 5.)
Part II, Section 18.1 Internal Audits	Added brackets and italics to allow the end user to select the appropriate text based on the scope of the QAPD. (Change to address RAI # 8.) Relocated sentence discussing supplier audits from the internal audit discussion to the Performance of Audits discussion.
Part II, Section 18.1 Internal Audits	Numbered the Internal Audit part of Section 18.1 as 18.2 and renumbered subsequent section. Formatted discussion of operational phase internal audits to be brackets and italics to allow the end user to choose the information based on the scope of the QAPD. Added “are conducted” in item (4) between “audit” and “utilizing” to complete the sentence.
Part III, Section 1.10	Replaced the final sentence with “These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.” Brackets were removed since this is not an optional element. (Change to address RAI # 5 and Supplemental RAI # 4.)
Part III, Section 2	Added Notes and revised this section to provide guidance to the applicant for addressing conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. The notes provide an applicant information to support addressing Regulatory Guide conformance in Chapter 1 of the FSAR consistent with RG 1.206, section C.I.1.9. (Change to address Supplemental RAI #5)
Part IV	Added Notes and revised this section to provide guidance to the applicant for addressing conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. The notes provide an applicant information to support addressing Regulatory Guide conformance in Chapter 1 of the FSAR consistent with RG 1.206, section C.I.1.9. The Notes in the section identify where the template conforms with or provides alternative approaches for satisfying the identified NRC guidance from RG 1.8 Rev. 3, RG 1.26, Rev. 4 RG 1.28, Rev. 3, RG 1.29 Rev. 4, RG 1.33, Rev. 2, and RG 1.37 Rev. 1. (Change to address Supplemental RAI #5)