

[Company Logo]

Quality Assurance Program Description

Title: *[Nuclear Development]* Quality Assurance Program Description

Process/Program Owner: ***[Senior Quality Assurance Manager]***

Version Number

Effective Date

Revision C

Revision Summary

Reviewed By/Date:

Approved By/Date:

_____/_____
[Senior Quality Assurance Manager]

_____/_____
[Senior Nuclear Development Officer]

[Company Name]

POLICY STATEMENT

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

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

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

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

[Date]

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PART I INTRODUCTION

SECTION 1 GENERAL

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

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

1.1 Scope / Applicability

This QAPD applies to activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing	Testing	Receiving	Decommissioning
Constructing	Licensing	Storing	Modifying
Procuring	Startup	Erecting	Inspecting
Fabricating	Siting	Installing	Refueling
Cleaning	Operating	Repairing	Shipping
Handling	Maintaining	Training	

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

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

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 and onsite functions for [Nuclear Development]. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

[The following information will be utility specific but should follow the SRP for the content. It should also include major suppliers of services – NSSS vendor, A/E, etc. Below is an example of level of detail which illustrates a new plant organization, its independence, and its linking within an existing utility.]

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

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

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

1.1 President and CEO

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

1.2 [Nuclear Development]

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

1.2.1 *[Senior Nuclear Development Officer]*

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

1.3 Technical Services

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

1.3.1 Vice President – Technical Services

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

1.4 Corporate Services

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

1.4.1 Vice President Corporate Services

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

1.5 Executive Vice President

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

1.5.1 Vice President – Project

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

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

1.5.1.1 Site Project Organization

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

1.5.2 Quality Assurance

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

1.5.2.1 Quality Assurance Manager

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

1.5.2.1.1 [Nuclear Development] Quality Assurance Project Manager

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

1.6 NSSS

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 furnishing safety-related materials and services to [CA].

1.9 NQA-1-1994 Commitment

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

Figure II.1-1

***[CA]* Organization**

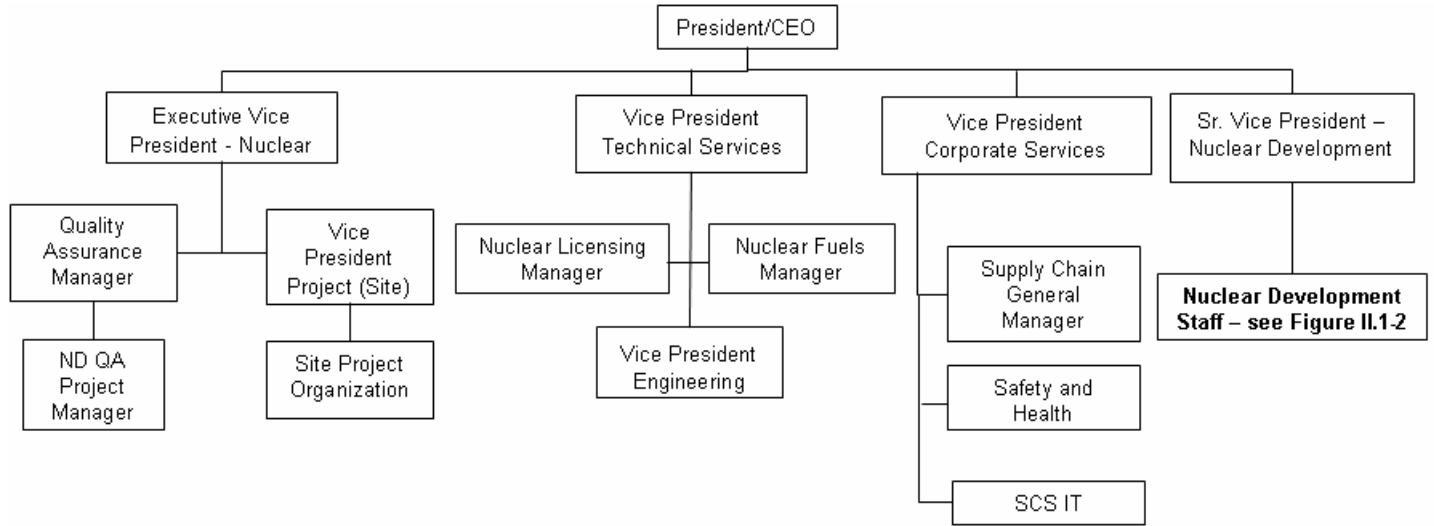
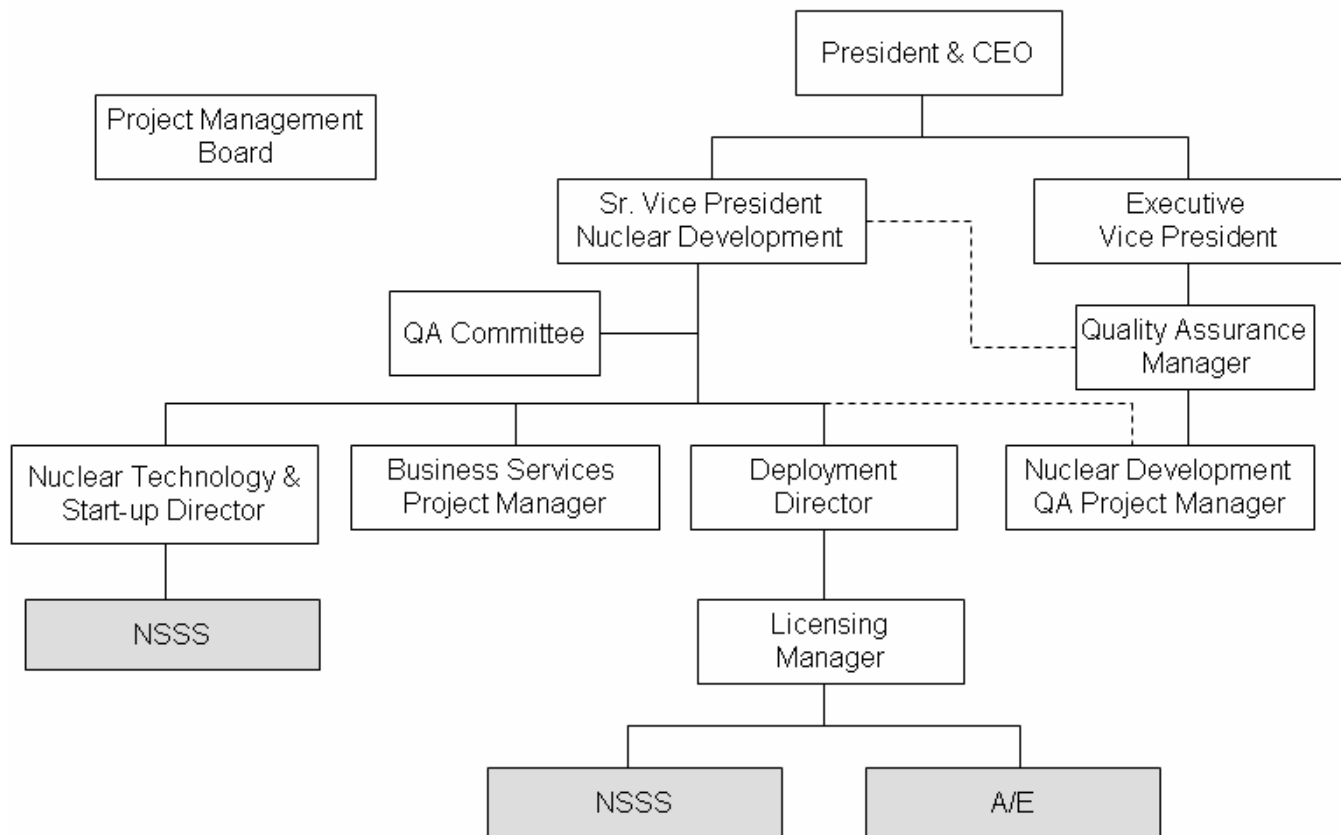


Figure II.1-2

***[Nuclear Development]* Organization**



SECTION 2 QUALITY ASSURANCE PROGRAM

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

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

Delegated responsibilities may be performed under a supplier's or principal contractor's QAPD that has been approved by the *[CA]* Quality Assurance organization. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the approved program and implementing procedures. In addition, routine interfaces with project personnel assure that quality expectations are met.

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

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) 1 and LWA 2 activities that could impact safety-related SSCs would include impacts of construction to existing facilities and for construction of new plants, the design interface between non safety-related and safety-related SSCs and the placement of seismically designed backfill.

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

A grace period of 25% may be applied to the 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 25% grace period will be applied.

2.1 Responsibilities

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

2.2 Delegation of Work

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

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

ESP site specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that will be used to determine the bounding physical parameters of the site. The development of the *[CA]* ESP and COL applications will involve site testing, data collection and calculations that may create or bound safety-related design basis data. Site testing and data collection of information pertaining to the physical characteristics of the site that have the potential to affect safety-related design will be considered safety related. In addition, calculations and other engineering data that bounds or characterizes the site will be classified as safety related. The *[ND]* organization will develop an ESP application Quality Criteria Document (QCD) identifying the sections of the application that include safety-related design basis activities. In addition the QCD will identify those sections of the application and supporting analysis that will be treated with appropriate quality requirements. The *[ND]* organization will develop annotated outlines for the COL application that will identify the sections safety classification and the regulatory requirements applicable to the section content.

2.4 Periodic Review of the Quality Assurance Program

Reviews of the status and adequacy of the *[Nuclear Development]* QAP and its implementation will be conducted on an ongoing basis via senior management review of quality assurance audit reports.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a), as appropriate. Changes to the QAPD are evaluated by the *[ND Quality Assurance Project Engineer]* 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]*.

2.6 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end *[CA]* establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. Plant and support staff minimum qualification requirements are as delineated in each site's Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable *[CA]* procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. Records of personnel training and qualification are maintained.

The minimum qualifications of the *[Quality Assurance Manager]* and the *[Nuclear Development Quality Assurance Project Manager]* are that each holds an engineering or related science degree and has a minimum of four year or related experience (3 of the 4 years must include 2 years of nuclear power plant experience and 1 year of supervisory or management experience. One year of experience performing quality verification activities. 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 cases-by-case basis and approved and documented by senior management.

- Check for exceptions to N45.2.6 for inspector qualifications – post-TMI requirements may require a separate organization for review. Sections S & T of the SRP.

2.7 Independent Review

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

- a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). Changes to the facility as described in the SAR that **do** effect safety or require a technical specification change must be reviewed by the IRB prior to implementation.
- 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 prior to implementation.
- c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously approved change.
- d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- e. Reviews any matter related to nuclear safety that is requested by the Site Vice President, Site Director, Plant Manager, or any IRB member,
- f. Reviews corrective actions for significant conditions adverse to quality.
- g. Reviews the adequacy of the audit program every 24 months.

Option I or Option II may be used.

[Option I - Independent Review Body

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

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

- c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.
2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.
 - a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities.
 - b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.
 - c. Results of the review are documented and reported to responsible management.
 - d. Management periodically consider issues that they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.
 - e. Management determines the scheduling and scope of review and the composition of the team performing the review.]

[Option II - Independent Review Committee]

1. An independent review committee is assigned independent review responsibilities.
2. The independent review committee reports to a management level above the plant manager.
3. The independent review committee is composed of no less than 5 persons, no more than a minority of members are from the onsite operating organization.

For example, at least 3 of the 5 members must be from offsite 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 conducted no less than twice a year.
5. Results of the meeting are documented and be recorded.
6. The Independent Review committee is responsible for performing the following:
7. Consultants and contractors are used for the review of complex problems beyond the expertise of the offsite/onsite independent review committee.

8. 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
 - [CA] Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement. The following two alternatives may be applied to the implementation of this Supplement and Appendix:
 - (1) In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel performing independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be

responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.

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

- NQA-1-1994, Supplement 2S-2
 - In lieu of Supplement 2S-2, for qualification of nondestructive examination personnel, *[CA]* will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at *[CA]* sites.

- NQA-1-1994, Supplement 2S-3
 - The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, “The prospective lead auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by *[CA]*, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.”

SECTION 3 DESIGN CONTROL

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

3.1 Design Verification

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

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

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

[CA] normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture or construction. When such timing cannot be achieved, the design

verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

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

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

3.3 Computer Application and Digital Equipment Software

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

3.4 Setpoint Control

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

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

3.5 NQA-1-1994 Commitment

In establishing its program for design control and verification, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1 and the standards for computer software contained in Subpart 2.7.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

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

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a QAPD consistent with the applicable requirements of this QAPD.

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

In establishing controls for procurement, [CA] commits to compliance with NQA-1-1994, Basic Requirements 4 and Supplements 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 documents for Commercial Grade Items that will be dedicated by [CA] as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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

5.1 Procedure Adherence

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

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

5.2 Procedure Content

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

5.3 NQA-1-1994 Commitment

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

SECTION 6 DOCUMENT CONTROL

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

- (a) identification of documents to be controlled and their specified distribution;
- (b) a method to identify the correct document (including revision) to be used and control of superseded documents;
- (c) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
- (d) review of documents for adequacy, completeness, and correctness prior to approval and issuance.
- (e) a method for providing feedback from users to continually improve procedures and work instructions.

The types of documents to be controlled include:

- (a) drawings such as design, construction, installation, and as-built drawings;
- (b) engineering calculations
- (c) design specifications
- (d) purchase orders and related documents
- (e) vendor-supplied documents
- (f) audit, surveillance, and quality verification/inspection procedures
- (g) inspection and test reports
- (h) instructions and procedures for activities covered by this QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing
- (i) technical specifications and safety analysis reports
- (j) nonconformance reports and corrective action reports

Personnel from the QA organization review and concur with quality-related procedures associated with design, construction and installation. During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1 Review and Approval of Documents

Documents shall be reviewed for adequacy by qualified persons other than the preparer. During the construction phase, procedures for design, construction, and installation shall also be reviewed by *[the organization responsible for quality verification]* to ensure quality assurance measures have been appropriately applied.

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

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

- (a) following any modification to a system;
- (b) following an unusual incident, such as an accident, significant operator error, or equipment malfunction;
- (c) when procedure discrepancies are found;
- (d) prior to use if not used in the previous two years;

Prior to issuance or use, documents including revisions thereto, shall be approved by the designated authority.

6.2 Changes to Documents

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

6.3 NQA-1-1994 Commitment

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

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

7.1 Acceptance of Item or Service

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

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

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

7.2 NQA-1-1994 Commitment

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

- NQA-1-1994, Supplement 7S-1
 - *[CA]* considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to *[CA]* plants are not required to be evaluated or audited.
 - When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:
 - (1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the *[CA]* QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.
 - (2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
 - (3) A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:
 - The calibration laboratory holds an accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through a Mutual Recognition Arrangement (MRA).
 - The accreditation is based on ANSI/ISO/IEC 17025.
 - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
 - For Section 8.1, *[CA]* considers documents that may be stored in approved electronic media under *[CA]* control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site.
 - In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in *[CA]* documents using the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05. *[CA]* will also use other appropriate approved regulatory

means and controls to support [CA] commercial grade dedication activities. One example of this is NRC Regulatory Issue Summary 2002-22.

- [CA] will assume 10 CFR 21 reporting responsibility for all items that [CA] dedicates as safety-related. 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.

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. 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 and installation activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results shall be documented.

Inspection Program

The inspection program establishes inspections (including surveillance of processes), as applicable: (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, inservice, operating and decommissioning activities. The post-maintenance testing program ensures that a functional test can be performed as additional assurance demonstrating the quality of work where inspections for breach of a pressure boundary are performed by an individual within the same functional group (e.g., Maintenance).

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 include 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: reject, acceptance, and reinspection results; and the person(s) performing the inspection.

Inspector Qualification

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

10.1 NQA-1-1994 Commitment / Exceptions

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

the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.

- Subpart 2.4 commits *[CA]* to IEEE 336-1985. IEEE 336-1985 refers to IEEE 498-1985. Both IEEE 336 -1985 and IEEE 498-1985 use the definition of "Safety Systems Equipment" from IEEE 603- 1980. *[CA]* commits to the definition of Safety Systems Equipment in IEEE 603-1980, but does not commit to the balance of that standard.
- An additional exception to Subpart 2.4 is contained in Section 12 of this QAPD.
- An exception to NQA-1 (1994), 10 S.1, section 3.1 (operational phase only) to allow use of peer inspections and alternate reporting relationships.

SECTION 11 TEST CONTROL

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

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

11.1 NQA-1-1994 Commitment

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

11.2 NQA-1-1994 Commitment for Computer Program Testing

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

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

[CA] has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment and 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 provisions of this QAPD Section are intended to assure that:

- Measuring and test equipment is calibrated at specified intervals on the basis of the item's required accuracy, intended use, frequency of use, and stability characteristics or other conditions affecting its performance. Alternatively, equipment may be calibrated immediately before and after use if a defined interval is not appropriate.
- Measuring and test equipment is labeled, tagged or otherwise controlled to indicate its calibration status and provide traceability to calibration test data or records.
- Calibrations are performed against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated. When this is not possible, the standards have an accuracy that ensures the equipment being calibrated will be within the required tolerance.
- Where possible, calibration standards are traceable to appropriate national standards. Calibration standards have greater accuracy than the standards being calibrated, except where the same accuracy as the instruments being calibrated can be shown to be adequate for the service requirements.
- Measuring and Test Equipment (M&TE) found out of calibration is tagged or segregated and not used until it is successfully re-calibrated. An evaluation is performed to determine the acceptability of any items measured, inspected or tested with an out-of-calibration device from the time of the previous calibration.
- M&TE that will be exempt from the requirements of this section include: measuring equipment used for preliminary checks or troubleshooting where accuracy is not required; rulers, tape measures, levels and other basic tools where normal commercial practices provide adequate accuracy.

Installed Instrument and Control Devices

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

12.1 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.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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

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

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

Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

13.1 Housekeeping

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

13.2 NQA-1-1994 Commitment / Exceptions

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

In addition, [CA] commits, during the construction and pre-operational phase of the plant, to compliance with the requirements of NQA-1-1994, Subpart 2.1, to establish appropriate provisions for the cleaning of fluid systems and associated components with the following clarifications and exceptions

- NQA-1-1994, Subpart 2.1

- Subpart 2.1, sections 3.1 and 3.2, establish criteria for classifying items into cleanliness classes and requirements for each class. Instead of using the cleanliness level system of Subpart 2.1, *[CA]* plants may establish cleanliness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. *[CA]* establishes appropriate cleanliness controls for work on safety related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign materials prior to system closure.
- NQA -1-1994, Subpart 2.2
 - Subpart 2.2, sections 3.2 and 3.5: For items in storage, as determined by facility management, the packaging requirements described under section 3, Packaging, may include alternate methods of affording required protection such as maintaining a storage atmosphere free from harmful contaminants in concentrations that could produce damage to the stored items, or utilizing storage practices that obviate the need for capping all openings.
 - Subpart 2.2, section 6.6, “Storage Records:” This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, *[CA]* documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.
 - Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for nuclear power plants during construction. During the operational phase, *[CA]* establishes and implements controls over hoisting, rigging and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, *[CA]* complies with applicable hoisting, rigging and transportation regulations and codes.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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

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

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

14.1 NQA-1-1994 Commitment

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

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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

15.1 10 CFR 50.55(e) Reporting Program

[CA] will establish the necessary measures and governing procedures that implement a reporting program which conforms to the requirements of 10 CFR 50.55(e). Such a reporting program will be in-place when [CA] applies for a COL. Such a reporting program will be in-place when [CA] applies for a COL.

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, conduct cause analysis 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. 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.

The licensee may delegate specific responsibilities of the Corrective Action program but the licensee maintains responsibility for the program's effectiveness.

16.1 10 CFR Part 21 Reporting Program

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

16.2 NQA-1-1994 Commitment

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

SECTION 17 QUALITY ASSURANCE RECORDS

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

17.1 Record Retention

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

17.2 Electronic Records

When using electronic records storage and retrieval systems, *[CA]* complies with NRC guidance in RIS 2000-18, October 2000, "Guidance on Managing Quality Assurance Records in Electronic Media" and Generic Letter 88-18, "Plant Record Storage on Optical Disks."

- Add Operational Phase information from SRP

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.
- NIRMA guidelines exceptions need to be added.; TG 11-1998, TG15-1998, TG16-1998, and TG21-1998. *[CA]* will also meet the NRC Regulatory Position C.2 of Regulatory Guide 1.28, Revision 3, August 1985 except that the reference to ASME NQA-1 will be to the 1994 edition.

SECTION 18 AUDITS

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

18.1 Performance of Audits

18.1.1 General

The *[CA]* is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures, 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 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 the *[QA Manager]*.

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

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

18.1.2 Pre-Operations

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.

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.

18.1.3 Operations audits/assessments

Functional areas of an organization's QA program for auditing/assessing 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.

Internal *[audit/assessment]* 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

During the operations phase *[audits/assessments]* are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure *[audits/assessments]* of all applicable QA program elements are completed within a period of two years. These *[audits/assessments]* 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 utilizing either a qualified offsite licensed fire protection engineer or an outside qualified fire protection consultant.
- (5) Other activities and documents considered appropriate by the Executive Management Position Responsible for Nuclear Operations, or the CNO

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

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

18.2 NQA-1-1994 Commitment

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

PART III REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

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

Regulatory Guides:

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

Regulatory Guide 1.26 defines classification of systems and components.

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

Regulatory Guide 1.29, Revision 3, September 1978 – Seismic Design Classification

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

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

Regulatory Guide 1.54, Revision 1, July 2000- Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants

Regulatory Guide 1.54 defines requirements and guidelines for protective coatings applied to various materials.

[CA] commits to the applicable regulatory position guidance provided in this regulatory guide for [ND] with the exception of Criteria C.1 and C.2. Refer to the Westinghouse AP1000 Design Control Document, Appendix 1A for a detailed discussion of these exceptions.

Regulatory Guide 1.97, Revision 3, May 1983 – Instrumentation for Light-Water Nuclear Power Plants to Assess Plant and Environs Condition During and Following an Accident

Regulatory Guide 1.97 describes an acceptable method to provide instrumentation to monitor plant variables and systems during and following an accident.

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

Regulatory Guide 1.143, Revision 2, November 2001 – Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants

Regulatory Guide 1.143 furnishes design guidance acceptable to the NRC regarding seismic and quality group classification and quality assurance provisions for radioactive waste management SSCs.

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

Regulatory Guide 1.152, Revision 2, January 2006 - Criteria for Digital Computers in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.152 describes a method acceptable to the NRC regarding use of digital computers in safety systems.

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

Regulatory Guide 1.168, Revision 1, February 2004 - Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.168 describes acceptable methods regarding verification and validation; reviews; and audits of digital computer software used in safety systems.

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

Regulatory Guide 1.169, Revision 0, September 1997 - Configuration Management Plans for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.169 describes acceptable methods regarding configuration management plans for digital computer software used in safety systems.

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

Regulatory Guide 1.170, Revision 0, September 1997 - Software Test Documentation for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.170 describes acceptable methods regarding software test documentation for digital computer software used in safety systems.

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

Regulatory Guide 1.171, Revision 0, September 1997 - Software Unit Testing for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.171 describes acceptable methods regarding software unit testing for digital computer software used in safety systems.

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

Regulatory Guide 1.172, Revision 0, September 1997 - Software Requirements Specifications for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.172 describes acceptable software requirements specifications for digital computer software used in safety systems.

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

Regulatory Guide 1.173, Revision 0, September 1997 - Developing Software Life Cycle Processes for Digital Computer Software Used in Safety Systems of Nuclear Power Plants

Regulatory Guide 1.173 describes acceptable methods regarding development of software life cycle processes for digital computer software used in safety systems.

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

Standards:

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

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

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

[CA] commits to NIRMA TGs as described in section 17 of this document.