Part 11A — New Nuclear Plant Development Quality Assurance Program Description Topical Report



## NGG PROGRAM MANUAL

## NGGM-PM-0033

## **Revision 4**

Title: New Nuclear Plant Development Quality Assurance Program

Description Topical Report

**Lead Department: Nuclear Oversight** 

### **Revision Summary:**

Revision 4 incorporate the following changes in support of DRR: 391918

The changes made in this revision were editorial in nature and made to reflect changes in organizational position titles, organizational structure, and reporting relationships for organizations responsible for the development and deployment of new nuclear generating plants.

Changes were made throughout the document to: incorporate a new position within the company for the Executive Vice President Energy Supply; to change the name of the Nuclear Plant Development organization to New Generation Programs and Projects; to change the title of position responsible for New Generation Programs and Projects to Senior Vice President Corporate Development and Improvement Group. Changed positions reporting to the Vice President Nuclear Engineering to reflect organizational alignment changes.

These changes included:

- Revision number changed throughout document.
- Changed title on approval list from Executive Vice President Corporate Development Group to Senior Vice President Corporate Development and Improvement Group.
- Table of contents revised to reflect renumbering of pages and changes in titles.
- Part II, Section 1 Organization, added the word proposed in first sentence.
- Part II, Section 1 Organization, changed titles of Nuclear Plant Development to New Generation Programs and Projects, and Executive Vice President Corporate Development Group to Senior Vice President Corporate Development and Improvement Group
- Part II, Section 1.1, Added new position of Executive Vice President Energy Supply as a
  position reporting to Chairman, President and CEO, and title change for New Generation

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Programs and Projects.

- Part II, Section 1.2, Revised title to Senior Vice President Corporate Development and Improvement Group, and changed NPD to New Generation Programs and Projects.
- Part II, Section 1.2.1, Revised title to be Vice President New Generation Programs and Projects and reflect title change to report to Senior Vice President CDIG.
- Part II, Section 1.2.1.1, Changed Vice President NDP to NGPP.
- Part II, Section1.2.1.1.4, Changed title from Director to Manager Program Coordination and Performance Improvement and replaced NPD with NGPP.
- Part II, Section 1.2.1.2, Changed NPD to NGPP.
- Part II, Section 1.2.2, Changed Executive Vice President to Senior Vice President and changed CDG to CDIG.
- Part II, Section 1.2.3, Changed General Manager CDG to CDIG and Executive Vice President CDG to Senior Vice President CDIG.
- Part II, Section 1.3, Added new position of Executive Vice President Energy Supply and described roles, responsibilities and reporting relationships.
- Part II, Section 1.3.1, Renumbered based on addition of new position, described new reporting relationship, and changed CDG to CDIG.
- Part II, Section 1.3.1.3.1, Added QA Program Leader New Plant Development in a support role for the Director Corporate Nuclear Oversight.
- Part II, Section 1.3.2, Renumbered based on addition of new position and changed description to match organization changes.
- Part II, Section 1.3.3, Renumbered
- Part II, Section 1.3.3.1, Renumbered, and changed CDG to CDIG
- Part II, Section 1.3.4, Renumbered, changed Executive Vice President to Senior Vice President, Corporate Development Group to Corporate Development and Improvement Group, and CDG to CDIG.
- Part II, Sections 1.3.4.1.1, 1.3.4.1.2, 1.3.4.1.3, Renumbered
- Part II, Section 1.3.4.1.4, Renumbered, removed Nuclear Plant Development from position title, changed CDG to CDIG, and changed Nuclear Plant development to NGPP.
- Part II, Section 1.4, Changed reporting relationship for VP CIO to Senior Vice President Corporate Development and Improvement Group, changed NPD to NGPP.
- Part II, Section 1.5, Changed reporting relationship to Senior Vice President Corporate Development and Improvement Group, removed services from Nuclear Engineering.
- Part II, Section 1.7, Changed CDG to CDIG.
- Figures II.1-1, II.1-2, II.1-3, and II.1-4 revised to reflect above noted changes in titles and reporting relationships.
- Part II, Section 2, Changed Nuclear Plant Development to New Generation Programs and Projects.
- Part II, Section 2.5, Revised positions responsible for review and approval of changes to the QAPD, reviewed at a minimum by Director Corporate Nuclear Oversight and approved by the Vice President NOS and the Vice President NGPP.
- Part II, Section 18.1, Changed Nuclear Plant Development to the new nuclear plant development activities and Executive Vice President Corporate Development Group to Senior Vice President Corporate Development and Improvement Group.

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# **Quality Assurance Program Description**

**Title:** Progress Energy New Nuclear Plant Quality Assurance Program
Description Topical Report

Process/Program Owner: Vice President Nuclear Oversight Department

Harris Nuclear Power Plants Units 2 and 3 Docket Nos. 52-022 and 50-023	<b>Version Number</b> Revision 4	Effective Date:
Levy Nuclear Power Plants Units 1 and 2 Docket Nos. 52-029 and 52-030		

#### **Revision Summary:**

The changes made in this revision were editorial in nature and made to reflect changes in organizational position titles, organizational structure, and reporting relationships for organizations responsible for the development and deployment of new nuclear generating plants.

Changes were made throughout the document to incorporate: a new position within the company for the Executive Vice President Energy Supply; to change the name of the Nuclear Plant Development organization to New Generation Programs and Projects; to change the title of position responsible for New Generation Programs and Projects to Senior Vice President Corporate Development and Improvement Group. Changed organization structure and titles of personnel reporting to the Vice President Nuclear Engineering.

Changed organization structure and titles of personnel reporting to the Vice President Nuclear Engineering.		
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### Progress Energy, Inc.

#### **POLICY STATEMENT**

Progress Energy, Inc. (PGN) shall design, procure, construct and operate the 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 Progress Energy New Nuclear Plant 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 PGN activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents PGN'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 PGN QAP.

W. D. Johnson

Progress Energy, Inc.

Chairman, President, and Chief Executive Officer

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### PART I INTRODUCTION

#### **SECTION 1 GENERAL**

Progress Energy (PGN) New Nuclear Plant Quality Assurance Program Description (QAPD) Topical Report is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for procurement, construction, pre-operations and operations activities conducted by or for PGN. The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and recommendations of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I, II, and III, as specified in this document.

The QA Program (QAP) is defined by the NRC approved regulatory document that describes the QA elements (i.e. the QAPD), along with the associated implementing documents. Procedures and instructions that control new nuclear plant 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 PGN organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to a site, organization, or group establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

### 1.1 Scope/Applicability

The QAPD applies to procurement, construction, pre-operations and operations activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

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

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

This QAPD was developed to address COL activities associated with Harris Nuclear Power Plant Units 2 and 3, Levy Nuclear Power Plant Units 1 and 2, and any future nuclear power units pursued by PGN in accordance with 10 CFR Part 52. This QAPD does not apply to the existing PGN nuclear power plants – Brunswick Units 1 and 2, Crystal River Unit 3, Harris Unit 1, and Robinson Unit 1.

Safety-related SSCs under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability,

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including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QAPD requirements for activities within their scope.

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

The definitions provided in ASME NQA-1-1994, Part 1, Section 1.4, apply to select terms as used in this document.

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## PART II QAPD DETAILS

### **SECTION 1 ORGANIZATION**

This section describes the proposed PGN organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate/support/off-site and on-site functions for the development and construction of new nuclear plants including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

PGN senior management is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

The PGN New Generation Programs and Projects Department is responsible for new nuclear generating plant licensing, engineering, procurement, construction, startup and operations development activities. Several organizations within PGN implement and support the QAPD. These organizations include, but are not limited to Corporate Development and Improvement, New Generation Programs and Projects, Nuclear Engineering, Nuclear Operations, Nuclear Oversight, Nuclear Information Technology, and Material Services.

Engineering, Procurement and Construction (EPC) services are provided to PGN in support of the development of new nuclear plants by the primary contractors in accordance with their respective Quality Assurance Programs. The primary contractors for these functions are Westinghouse and Shaw Stone and Webster for the development of the Westinghouse AP-1000 new nuclear generating plants. This contract will extend the applicable quality assurance requirements described in this document to the applicable contractors and subcontractors.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the New Nuclear Plant QA Program. The PGN organization and the New Generation Programs and Projects organizations are shown in Figures II.1-1 and II.1-2 II.1-3 respectively. Figure II.1-4 shows a typical operating plant structure within PGN. The detailed roles, responsibilities and organizational structure and reporting relationships for the operations phase organization is detailed in Chapter 13 of the respective plant's FSAR.

#### Responsibilities, Structure, Functions, and Interfaces

The Senior Vice President, Nuclear Generation Group/Chief Nuclear Officer (CNO) has overall responsibility for establishing the quality policy and implementation of the quality program for the Nuclear Generation Group activities. The Senior Vice President Corporate Development and Improvement Group – Progress Energy, Inc., is responsible for establishing and implementing the quality policy and program for the activities associated with the licensing, development and construction of new nuclear generation plants by the New Generation Programs and Projects

Department. The authority to accomplish quality assurance functions is delegated to the staff as necessary to fulfill the identified responsibilities.

PGN has established a quality policy and commitment to facilitate an organization to implement it as detailed in this QAPD. Additionally, management shall ensure that the role of QA in design and analysis activities is defined and the size of the QA organization is commensurate with its duties and responsibilities.

Individual managers are to ensure that personnel working under their management are qualified in accordance with written procedures and that personnel only perform those activities for which they are qualified. Personnel performing work activities such as, but not limited to, design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, and modification shall also be responsible for achieving acceptable quality. Independence between the organization performing checking functions and the organization performing the functions shall be maintained.

When PGN delegates responsibility for planning, establishing or implementing any part of its overall QA program, sufficient authority to accomplish the assigned responsibility shall also be delegated. Additionally, when PGN delegates a major portion of its work to participant(s) outside the PGN organization, the delegation shall be identified and described such that:

- The organizational elements responsible for the work are identified.
- Management controls and lines of communication are established.
- Responsibility for an appropriate QAP and extent of PGN management oversight is established.
- Performance of delegated work is formally evaluated by PGN.

PGN assigns responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items (such as Systems, Structures Components (SSCs), parts, materials, equipment, consumable materials, and software) such that cost and schedule considerations do not override safety considerations.

The organizational structure defines onsite functions and details off-site reporting relationships at the construction site. 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.

The organizations responsible for the implementation of the requirements of this Quality Assurance Program Description Topical Report for new nuclear generating plants are described below. There are two primary organizations responsible for implementation within the corporate structure based on the activity being performed. The responsibility for the licensing, development and construction of new nuclear generating plants for Progress Energy, Inc. in the Carolinas or Florida is assigned to the Senior Vice President Corporate Development and Improvement Group (CDIG). The responsibility for the operation of the new nuclear generating plants is assigned to the Senior Vice President Nuclear Generation Group / Chief Nuclear Officer. Each of these individuals reports directly to the Chairman, President, and Chief Executive Officer Progress

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Energy, Inc. Figure II.1-1 displays the relationships of the Progress Energy, Inc. organizations described in and responsible for implementing the requirements of this QAPD. This division of responsibilities was made to allow the Chief Nuclear Officer and the NGG to remain focused on improving the performance of the operating fleet and minimize the distractions associated with the construction of new nuclear generating plants. Organizational control and responsibility for the newly constructed nuclear generating plants transfers from CDIG to NGG following the completion of construction activities and prior to loading of fuel. This transition point allows for the continued support by the CDIG organization, while the Operational Readiness (OR) organization transitions to the final structure typical of the operating fleet.

### 1.1 Chairman, President, and Chief Executive Officer

The Progress Energy, Inc. Chairman, President, and Chief Executive Officer (CEO) has the ultimate responsibility for the safe and reliable operation of each nuclear station owned and/or operated by the utility. The Chairman, President, and CEO is responsible for the overall direction and management of the corporation, and the execution of the company policies, activities, and affairs. The Chairman, President, and CEO is responsible for directing Progress Energy, Inc. core operational businesses including Progress Energy Florida, Progress Energy Carolinas, Nuclear Generation, Corporate Development and Improvement, and Power Operations Groups. The Chairman, President and CEO is assisted in these activities by the Executive Vice President - Energy Supply who is responsible for the management of the Nuclear Generation Group and the Power Generation Groups of both Progress Energy Carolinas and Progress Energy Florida. The Chairman, President, and CEO is assisted in the direction of the Nuclear Generation Group and nuclear operations by the Senior Vice President Nuclear Generation Group (NGG) / Chief Nuclear Officer (CNO) and other executive staff in the nuclear division of the corporation. The Progress Energy, Inc. CEO is assisted in the direction of new nuclear plant development activities by the Senior Vice President CDIG and other executive staff in the New Generation Programs and Projects organization; Operational Readiness; and CDIG Business Services Sections.

#### 1.2 Senior Vice President – Corporate Development and Improvement Group

The Senior Vice President – Corporate Development and Improvement Group (CDIG) reports directly to the Chairman, President, and CEO – Progress Energy, Inc. The Senior Vice President - CDIG has overall responsibility for the licensing, development and construction of new nuclear generation plants in Florida and the Carolinas. The Senior Vice President - CDIG maintains oversight responsibility for the activities at each new nuclear generation plant under construction. The Senior Vice President - CDIG delegates the authority and responsibility for the licensing, development and construction of the new nuclear generating plants to the Vice President – New Generation Programs and Projects. The Senior Vice President – CDIG delegates the responsibility for the start-up; operational testing; and preparation and integration of the new nuclear plants into the Nuclear Generation Group to the Vice President Operational Readiness. The Senior Vice President – CDIG delegates the responsibility for the safety related contract management and procurement activities to the General Manager CDIG Business Services. This organizational alignment with all new plant development and construction activities assigned to the Senior Vice President – CDIG allows the Senior Vice President Nuclear Generation Group and Chief Nuclear Officer to focus on the performance of the operating fleet until such time as a unit under construction is turned over to the operating fleet.

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#### 1.2.1 Vice President – New Generation Programs and Projects

The Vice President – New Generation Programs and Projects (NGPP) reports through the Senior Vice President – CDIG to the Chairman, President, and CEO Progress Energy, Inc. This position is responsible for the licensing, development and construction of new nuclear generating plants in Florida and the Carolinas. This position will be responsible for: the construction of the new nuclear generation facilities; construction scheduling and cost control; all on-site manufacturing control of construction and testing activities; and performance of maintenance. This position is supported in this role by the General Manager Engineering and Licensing; Director Program Coordination and Performance Improvement; and Director Construction Management. This position serves as the Owner's Project Director interfacing with the EPC contractor Project Director.

### 1.2.1.1 General Manager Engineering and Licensing

The General Manager Engineering and Licensing reports directly to the Vice President NGPP. This position is responsible for both the overall design, engineering and licensing activities associated with the deployment of the new nuclear generating plants in both the Carolinas and Florida. This position is responsible for: directing the design and engineering of site specific structures and facilities; supporting AP1000 design finalization activities; overseeing and managing the design products developed by contractors such as the EPC contractors; providing all Regulatory Interface activities for the project; directing the development of the Combined Operating License applications; directing the development of the Site Certification Applications; obtaining and maintaining all permits, approvals and authorizations necessary to construct and operate the new nuclear generation plants; coordinating the completion, documentation and closure of Inspection, Test, Analysis and Acceptance Criteria (ITAAC) results for submittal to the NRC; and establishment of appropriate controls and process associated with the management of the project document control and records management programs. This position is supported in performing these responsibilities by the Manager Nuclear Engineering; the Manager Nuclear Licensing and Regulatory Affairs; and the Manager Document Control and Records Management.

#### 1.2.1.1.1 Manager - Nuclear Engineering

The Manager Nuclear Plant Engineering reports to the General Manager Engineering and Licensing. This position is responsible for: development of the Final Safety Analysis Report (FSAR) for each proposed new nuclear plant based on the design-certified advanced reactor technology; engineering aspects of the advanced reactor technology systems; design interface with the reactor technology provider and other Builders Group companies on the engineering design finalization of the standardized nuclear plant island; and engineering oversight of design development of site specific structures that are outside of the scope of the standard advanced reactor technology nuclear plant island.

#### 1.2.1.1.2 Manager – Nuclear Plant Licensing and Regulatory Affairs

The Manager Nuclear Plant Licensing and Regulatory Affairs reports to the General Manager Engineering and Licensing. This position is responsible for the development and implementation of COLAs for new nuclear plants in the Progress Energy fleet; review and oversight of licensing products developed by NuStart, the Joint Venture Team and vendors supporting licensing activities; the development of manuals, programs, procedures and reports required to fully implement license requirements; the preparation and implementation of required environmental

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permits; and the development of training program requirements to support plant construction, startup and operation.

### 1.2.1.1.3 Manager Document Control and Records Management

The Manager Document Control and Records Management reports to the General Manager Engineering and Licensing. This position is responsible for the development and implementation of appropriate programs to manage the document control process and records management processes for the CDIG activities associated with the development and deployment of new nuclear generation plants.

### 1.2.1.2 Manager Program Coordination and Performance Improvement

The Manager Program Coordination and Performance Improvement reports directly to the Vice President NGPP. This position is responsible for implementation of the Progress Energy self evaluation; corrective action; and performance monitoring programs for new nuclear projects in both the Carolinas and Florida. This includes implementation of the corrective action program in accordance with the requirements of this QAPD. This position is supported in performing these responsibilities by the Supervisor Self Evaluation and Corrective Action Program; and the Supervisor Performance Improvement.

#### 1.2.1.3 Director Construction Management

The Director Construction reports directly to the Vice President NGPP. This position is responsible for the construction planning and execution of new nuclear generating plants in both the Carolinas and Florida. This position manages and provides the technical and managerial oversight of the EPC contractor's construction planning, execution and supply chain activities. This position is responsible for facility management as buildings and structures are turned over to the Owner from the contractors. This position is responsible for the performance of construction performance monitoring audits. This position is responsible for the implementation of environment compliance and Health and Industrial Safety programs for the NGPP projects. This position is supported in performing these responsibilities by the Manager Construction Planning and the Supervisor Environmental Health and Safety.

#### 1.2.2 Vice President Operational Readiness

The Vice President Operational Readiness reports directly to the Senior Vice President - CDIG through the completion of construction activities on site. This reporting relationship transitions to the Senior Vice President – NGG /CNO following the completion of construction activities on the new unit and prior to loading fuel. Figures II.1-2 and II.1-3 show the construction phase and prior to fuel load organizational relationships of the Vice President Operational Readiness. This management transition precedes and supports the transition and integration of the new plant into the NGG fleet. This position is responsible for the overall operational readiness of the new nuclear generating plants in both the Carolinas and Florida. This responsibility includes the recruiting, hiring, and training of the permanent plant operating staffs for the new nuclear generating plants. This position is responsible for the development and implementation of all technical programs, policies, procedures and other needed infra structure necessary to start-up,

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operate and maintain the new nuclear generating plants. This position is directly supported in performing these responsibilities by the: Plant General Manager; Manager Operations; the Manager Training; the Manager Maintenance; the Manager Plant Test and Operations; the management of the Document Control and Records Management; the management of the Environmental, Chemistry and Radiation Control organizations; and the management of the Emergency Preparedness organization. This position is also supported by additional management positions that report outside of the Operational Readiness Organization. Additional matrixed support includes: the Manager Site Nuclear Security who reports through the Director Nuclear Protective Services through the Vice President Nuclear Operations to the CNO; and the Manager Site Nuclear Engineering who reports through the Vice President Nuclear Engineering to the CNO. This outside support is addressed in an interface agreement between the CDIG and NGG, as well as corporate organizational alignments.

#### 1.2.3 General Manager - CDIG Business Services

The General Manager – CDIG Business Services reports directly to the Senior Vice President – CDIG. This position is responsible for the financial and contract management activities associated with the procurement and deployment of new nuclear generating plants in both the Carolinas and Florida. This position is supported in performing these responsibilities by the Manager Engineering, Procurement, Construction (EPC) contract; and the Manager Other Contract Management.

#### 1.3 Executive Vice President – Energy Supply

The Executive Vice President – Energy Supply reports directly to the Chairman, President, and CEO Progress Energy, Inc. The Executive Vice President – Energy Supply is responsible for the management of the Nuclear Generation Group and the Power Generation Groups of both Progress Energy Carolinas and Progress Energy Florida. This position is supported in development, transition and deployment of new nuclear generating facilities by the Senior Vice President – Nuclear Generation Group / Chief Nuclear Officer and other executive staff in the Nuclear Generation Group.

#### 1.3.1 Senior Vice President – Nuclear Generation Group / Chief Nuclear Officer

The Senior Vice President – Nuclear Generation Group (NGG) / Chief Nuclear Officer (CNO) reports through the Executive Vice President – Energy Supply to the Chairman, President, and CEO Progress Energy, Inc. The CNO is responsible for overall plant nuclear safety and takes the measures needed to provide acceptable performance of the staff in operating, maintaining, and providing technical support to operating the nuclear plants. An interface agreement between the CDIG and NGG provides for additional NGG support of the CDIG activities associated with the development and deployment of new nuclear generating plants. The CNO is responsible for oversight of operations at each of the operating nuclear units in the NGG Fleet, and newly constructed nuclear units turned over to the NGG prior to fuel load. The CNO delegates authority and responsibility for the operation and support of the NGG Fleet through: the respective Site Vice Presidents; the Vice President Nuclear Engineering; the Vice President – Nuclear Operations; and the Vice President – Nuclear Oversight. The CNO has no ancillary responsibilities that might detract attention from nuclear safety matters.

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#### 1.3.1.1 Vice President – Nuclear Engineering

The Vice President – Nuclear Engineering reports to the CNO and is responsible for providing integrated technical, design control and configuration management functions. This position is responsible for engineering, procurement, outsourcing engineering services, fabrication of nuclear fuel, and probabilistic safety assessment (PSA) activities. This position provides direction on matters relating to operational analysis, design, systems, engineering programs, and nuclear fuels. The Vice President Nuclear Engineering is supported in the performance of these responsibilities by the General Manager – Nuclear Design Engineering; the General Manager Nuclear System Engineering and Technical Programs; and Director Nuclear Fuel Management and Safety Analysis and the Site Directors of Nuclear Engineering.

#### 1.3.1.2 Vice President – Nuclear Operations

The Vice President – Nuclear Operations Department reports to the Senior Vice President NGG /CNO. This position is responsible for establishing NGG fleet operating standards; assessing site and fleet operating performance; standardizing and implementing operational performance indicators; developing fleet positions for industry operational issues; providing governance over fleet peer group functions; implementing nuclear security, access authorization, and Fitness for Duty programs; and serving as the company's key nuclear industry interface. The Vice President – Nuclear Operations is assisted in performing these functions for the operating fleet of nuclear plants by the Director – Nuclear Protective Services; Director - Nuclear Work Management; Director – Nuclear Fleet Training; Director – Nuclear Fleet Support Services; Director – Nuclear Fleet Operations; Director Nuclear Upgrades; and Manager Material Services.

#### 1.3.1.2.1 Manager – Materials Services

The Manager – Material Services reports to the Director, Nuclear Fleet Operations, who reports to the Vice President – Nuclear Operations. This position is responsible for material acquisition and administrative services for the NGG and CDIG, providing analytical, chemistry, and metallurgy services; environmental monitoring program support; and dosimetry and strategic radiological support existing and new nuclear generation facilities. This responsibility also includes the preparation, review, approval, and issuance of procurement requisitions; and receipt and storage of materials, parts and components, including receipt inspections.

#### 1.3.1.3 Vice President – Nuclear Oversight

The Vice President – Nuclear Oversight (NOS) is responsible for and reports to the Senior Vice President NGG / CNO on all matters related to the independent monitoring and assessing of activities that are performed by the line organizations for, or in support of the NGG. The Vice President – NOS is responsible for all and reports to the Senior Vice President Corporate Development and Improvement Group (CDIG) on all matters related to the independent monitoring and assessing of activities performed by or in support of the development and deployment of new nuclear generating plants. This responsibility is established and implemented through an interface agreement between the NGG and CDIG for the quality assurance oversight of CDIG new nuclear plant development activities. The Vice President – NOS shall have access to corporate management including the Senior Vice President Corporate Development and Improvement Group to resolve any quality or nuclear safety related concerns that cannot be resolved satisfactorily at a lower management level. Nuclear Oversight reports the results of their

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activities directly to the Senior Vice President NGG /CNO for NGG activities and to the Senior Vice President CDIG for CDIG activities. The Vice President Nuclear Oversight is responsible to ensure that quality assurance and oversight has the independence to conduct quality-related activities without undue pressure for cost and schedule. This position will establish the goals and objectives of the quality assurance policies, including oversight and maintenance of this QAPD in accordance with regulatory requirements. This position is responsible for the maintenance and updating of this Quality Assurance Program Description Topical Report in accordance with applicable commitments and regulations. This position is responsible for the administration of the Nuclear Employee Concerns Program. The Vice President – NOS is supported in the performance of these responsibilities by the Director – Corporate Nuclear Oversight; a Manager Nuclear Oversight at each operating site; and a Director Nuclear Plant Development Quality Assurance.

#### 1.3.1.3.1 Director Corporate Nuclear Oversight

The Director Corporate Nuclear Oversight reports directly to the Vice President NOS and is responsible for the overall management of oversight and assessment activities of the corporate NGG organizations and implementation of the NGG Employee Concerns Program. These responsibilities include the development periodic oversight analysis reports and ensuring the independent assessment of the Nuclear Oversight program as required. This position is supported in the performance of these responsibilities by the Manager Corporate NOS; the Supervisor Vendor and Equipment Quality; Supervisor Employee Concerns and the QA Program Leader New Plant Development.

#### 1.3.1.3.1.1 Supervisor Vendor and Equipment Quality

The Supervisor Vendor and Equipment Quality is responsible for the overall supervision of the vendor qualification, surveillance and audit/survey process and oversight of supplier improvement initiatives of poor performing suppliers. This includes the establishment and maintenance of the Progress Energy Approved Suppliers List (ASL); performance of audits/surveys of suppliers to ensure proper QA and Commercial Grade Dedication program implementation; Access Authorization/Fitness for Duty audits; performance of source surveillances at vendor facilities for safety related, critical non-safety, and nuclear fuel facilities. These activities extend to the vendors and suppliers being used to support the development and construction of new nuclear plants by the CDIG.

#### 1.3.1.3.2 Manager Site Nuclear Oversight

The Manager Site Nuclear Oversight reports directly to the Vice President NOS. This manager is responsible for the development and implementation of quality assurance plans and oversight functions for an operational new nuclear generating plant. This position is responsible for the performance of independent oversight activities, including assessments, evaluations, and monitoring the performance of the onsite organizations responsible for implementing the requirements of the Quality Assurance Program. This position is also responsible for the implementation of the Independent Review activities described in Section 2.7 and the Quality Control activities at the operational new nuclear generating plant.

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#### 1.3.1.3.3 Director Quality Assurance

The Director Quality Assurance reports directly to the Vice President NOS. This director is responsible for the development and implementation of quality assurance plans and oversight functions associated with the new nuclear plant development activities performed by or in support of the CDIG. This position is responsible for the performance of independent oversight activities, including audits, independent assessments, evaluations, surveillances, and performance monitoring of NGPP; Operational Readiness; and CDIG Business Services activities. This position is responsible for the identification of quality-related problems; initiation, recommendation, or provision of solutions to quality related problems; and verification of the implementation and effectiveness of solutions.

#### 1.4 Director – Nuclear Information Technology

The Director – Nuclear Information Technology provides Information Technology services, safety related software services, and design, maintenance, and configuration control for NGG, NGPP, and Operational Readiness plant computing systems, structures and components. The Director Nuclear Information technology reports through the Vice President and Chief Information Officer of Information Technology and Telecommunications to the Senior Vice President Corporate Development and Improvement to the Chairman, President, and Chief Executive Officer of Progress Energy, Inc. This support is provided through an Interface Agreement with Nuclear Engineering.

#### 1.5 Vice President – Supply Chain and Chief Procurement Officer

The Vice President – Supply Chain and Chief Procurement Officer provides procurement and contract support for NGG and Corporate Development and Improvement Group activities in accordance with applicable quality assurance requirements for activities affecting quality. This position reports through the Senior Vice President Corporate Development and Improvement to the Chairman, President, and CEO Progress Energy Inc. This support is provided through an interface agreement with Nuclear Engineering.

#### 1.6 Plant Operations

Following completion of construction activities, the new nuclear generating plant will transition to the operations phase. The typical operations phase site organizational structure is shown in Figure II.1-4, with the Site Vice President reporting to the Senior Vice President – NGG/CNO. Nuclear Oversight for the plant operations phase is performed by the Manager Site NOS who reports to the Vice President NOS. The detailed roles, responsibilities and organizational structure and reporting relationships for the operations phase organization is detailed in Chapter 13 of the respective plant's FSAR. This description is incorporated by reference and establishes the organization responsible for implementing the operational requirements of this QAPD. Changes to the information contained within the respective plant's FSAR Chapter 13 is controlled and changes are reviewed under the provisions of 10 CFR 50.54(a) to ensure that any reduction in commitments in this QAPD (as accepted by the NRC) are submitted to and approved by the NRC, prior to implementation.

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#### 1.7 Agents and Contractors

Progress Energy contracts the Engineering, Procurement and Construction activities for the construction of new nuclear plants. These contracts include the flow down of applicable quality program requirements described in the document to applicable contractors and subcontractors. CDIG personnel are responsible for the implementation of the QAPD requirements in this document assigned to the Engineering, Construction and Procurement contractors and subcontractors.

#### 1.7.1 Design Certification Holder

Westinghouse has been selected as the Design Certification Holder/NSSS vendor and provides engineering services for plant design and licensing. In accordance with the requirements of the Engineering, Procurement, and Construction contract, Westinghouse will provide the engineering services for plant design, including site specific engineering and design necessary to support initial procurement, construction, pre-operations and operational activities for the new nuclear generating plants. This work will be performed in accordance with Westinghouse's Quality Assurance Program.

#### 1.7.2 A/E

Shaw Stone and Webster has been selected as the A/E firm, and in accordance with the requirements of the Engineering Procurement and Construction contract will provide engineering services including planning and support for initial procurement, construction, pre-operations, and operational activities for the new nuclear plants. This work will be performed in accordance with Shaw Stone and Webster's Quality Assurance Program.

Westinghouse and Shaw Stone and Webster have formed a consortium to support the requirements of the Engineering, Procurement, and Construction contract for the delivery of new AP-1000 nuclear plants.

#### 1.8 Authority

The program and procedures require that the authority and duties of persons and organizations performing activities affecting quality functions be clearly established and delineated in writing and these individuals and organizations have sufficient authority and organizational freedom to:

- 1. Identify quality, nuclear safety, and performance problems.
- 2. Order unsatisfactory work to be stopped and control further processing, delivery, or installation of nonconforming material.
- 3. Initiate, recommend, or provide solutions for conditions adverse to quality.
- 4. Verify implementation of solutions.

### 1.9 Authority to Stop Work

Quality Assurance and inspection personnel have the authority, and the responsibility, to stop

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work in progress which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers that furnish safety-related materials and services to PGN.

#### 1.10 Quality Assurance Organizational Independence

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

#### 1.11 NQA-1-1994 Commitment

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

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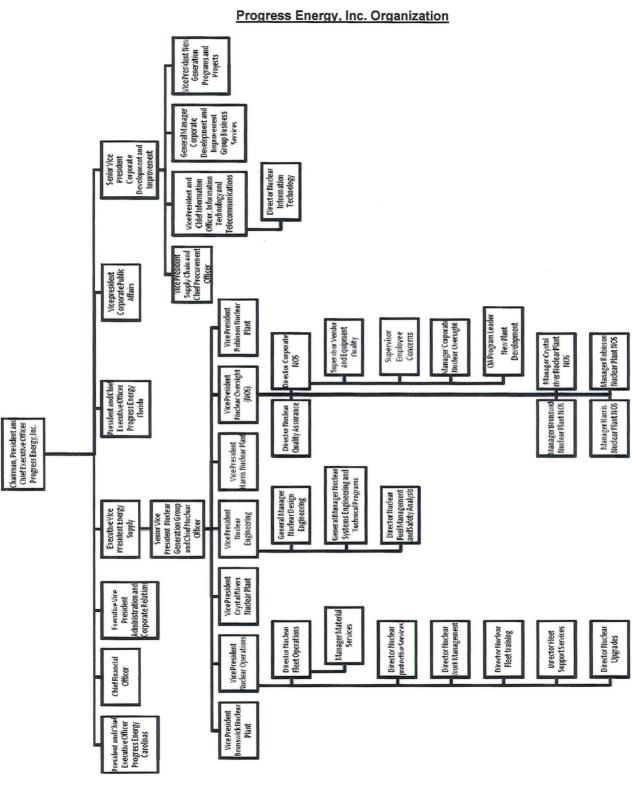


Figure II.1-1

Figure II.1-2

Nuclear Plant Development Organization Construction Phase

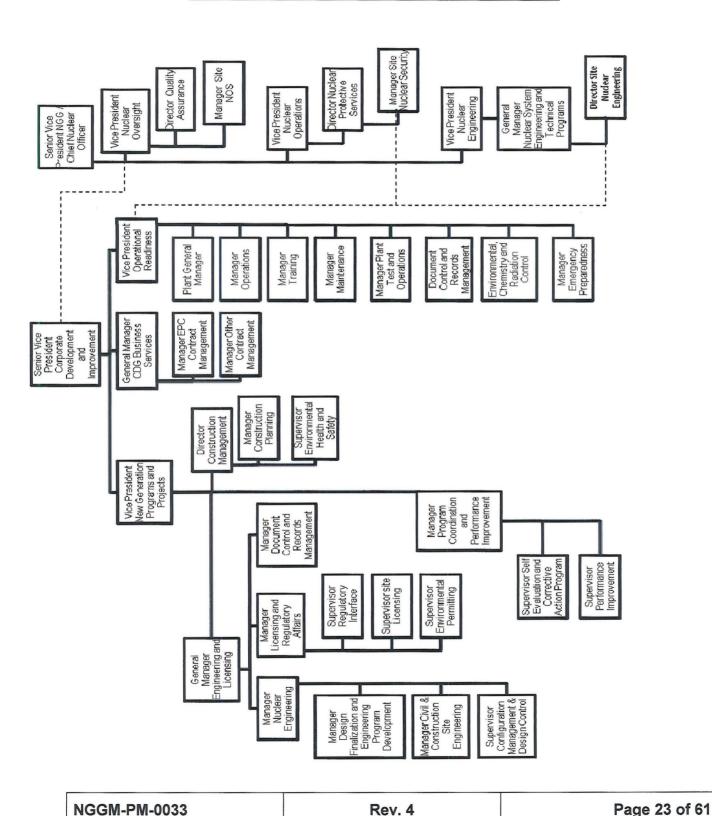


Figure II.1-3

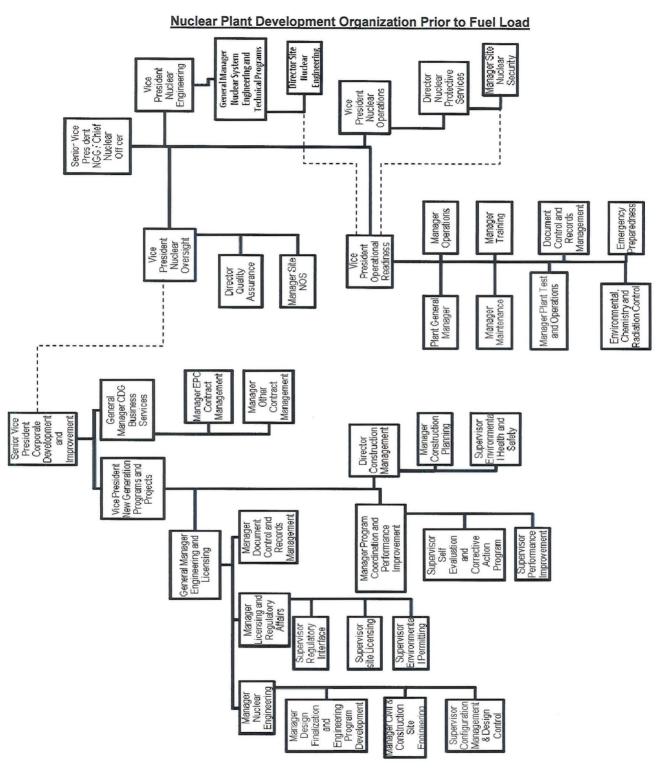
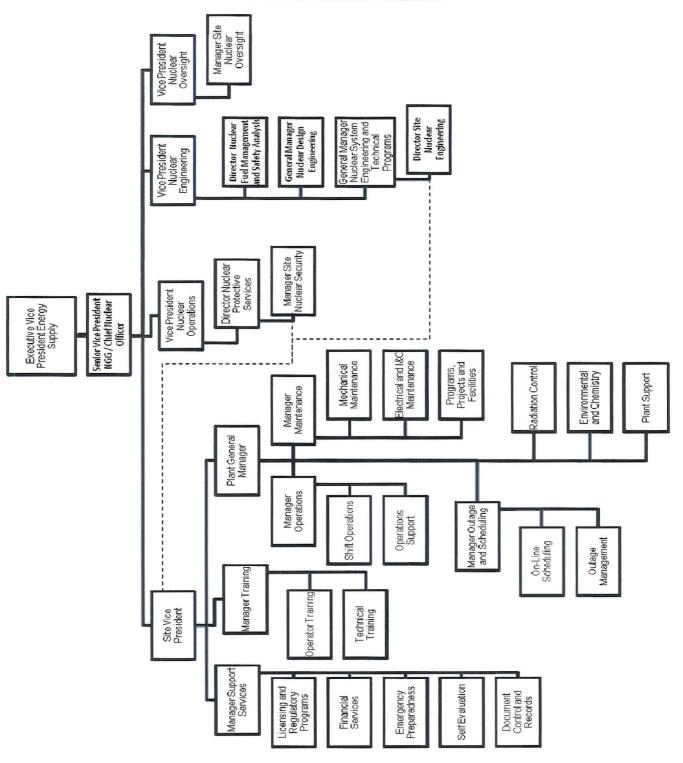


Figure II.1-4

### **Operations Phase Organization**



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#### SECTION 2 QUALITY ASSURANCE PROGRAM

PGN has established the necessary measures and governing procedures to implement the QAPD as described in the QAPD. PGN is committed to implementing the QAP 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, PGN ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAPD through the audit functions described in Part II, Section 18.

The objective of the QAPD is to assure that PGN's 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 (excluding Design Certification activities), fabrication, construction and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Examples of COL program safety-related activities include, but are not limited to, site specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility. The Design Certification Document is used as the basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAPD.

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

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

For the COL applications, the QAPD applies to those New Generation Programs and Projects and Progress Energy Inc. activities that can affect either directly or indirectly the safety related site characteristics or analysis of those characteristics. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of PGN's New Generation Programs and Projects Department. Detailed engineering specifications and construction procedures will be developed to implement the QAPD and the Westinghouse and Shaw Stone and Webster QA programs prior to commencement of construction (COL) activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of new plants, the design interface between

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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 PGN implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

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

#### 2.1 Responsibilities

Personnel who work directly or indirectly for PGN are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. PGN 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 Vice President NOS 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

PGN retains and exercises the responsibility for the scope and implementation of an effective QAPD. Positions identified in Part II, Section 1, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

#### 2.3 Site-specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied.

#### 2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, or portions thereof, assesses the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter.

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#### 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 Vice President NOS 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 COL application development process. New revisions to the document will be reviewed, at a minimum, by the Director Corporate Nuclear Oversight and approved by the Vice President Nuclear Oversight (NOS) and the Vice President New Generation Programs and Projects.

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

#### 2.6 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end PGN establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. 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 PGN 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 Director NPD Quality Assurance and Manager Site NOS at the new nuclear generating plants are that each holds an engineering or related science degree and has a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing and

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

#### 2.7 Independent Review

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

- a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). The Independent Review Body (IRB) also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.
- b. Reviews proposed tests and experiments not described in the SAR. Changes to proposed tests and experiments not described in the SAR that do require a technical specification change must be reviewed by the IRB prior to NRC submittal and implementation.
- c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- d. Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- e. Reviews any matter related to nuclear safety that is requested by the Site Vice President, Plant General 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.

#### Independent Review Body

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

- 1. IRB reviews are supplemented as follows:
  - A 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.

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- b. Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.
- c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.
- 2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.
  - a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities. The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the twelve areas listed below:
    - (1) Nuclear power plant operations
    - (2) Nuclear engineering
    - (3) Chemistry and radiochemistry
    - (4) Metallurgy
    - (5) Nondestructive testing
    - (6) Instrumentation and control
    - (7) Radiological safety
    - (8) Mechanical engineering
    - (9) Electrical engineering
    - (10) Administrative control and quality assurance practices
    - (11) Training
    - (12) Emergency plans and related procedures and equipment).
  - b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.
  - c. Results of the review are documented and reported to responsible management.
  - d. Management periodically considers 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.

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#### 2.8 NQA-1-1994 Commitment / Exceptions

- In establishing qualification and training programs, PGN commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4, with the following clarifications and exceptions:
  - NQA-1-1994, Supplement 2S-1
    - Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement. The following two alternatives may be applied to the implementation of this Supplement and Appendix:
      - (1) In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.
      - (2) A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.
  - NQA-1-1994, Supplement 2S-2
    - In lieu of Supplement 2S-2, for qualification of nondestructive examination personnel, PGN 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 PGN 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 PGN, 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."

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#### SECTION 3 DESIGN CONTROL

PGN has established and implements a process to control the design, design changes and temporary modifications (e.g. temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records and organizational interfaces within PGN 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 PGN 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 PGN design organization or by other organizations so authorized by PGN.

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

#### 3.1 Design Verification

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

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

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

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PGN 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

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

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

#### 3.3 Computer Application and Digital Equipment Software

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

#### 3.4 Setpoint Control

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

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

#### 3.5 NQA-1-1994 Commitment

In establishing its program for design control and verification, PGN commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1, the subsurface investigations requirements in Subpart 2.20, and the standards for computer software contained in Subpart 2.7.

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#### SECTION 4 PROCUREMENT DOCUMENT CONTROL

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

- Where original technical or quality assurance requirements cannot be determined, an
  engineering evaluation is conducted and documented by qualified staff to establish
  appropriate requirements and controls to assure that interfaces, interchangeability, safety,
  fit and function, as applicable, are not adversely affected or contrary to applicable
  regulatory requirements.
- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under PGN's approved QA program).

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

#### 4.1 NQA-1-1994 Commitment / Exceptions

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

- NQA-1-1994, Supplement 4S-1
  - Section 2.3 of this Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, PGN 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, PGN procurement documents may allow the supplier to work under the PGN 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

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

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

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# SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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

#### 5.1 Procedure Adherence

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

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

#### **5.2** Procedure Content

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

#### 5.3 NQA-1-1994 Commitment

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

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#### SECTION 6 DOCUMENT CONTROL

PGN has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

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

The types of documents to be controlled include:

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

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

# 6.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the construction phase, procedures for design, construction, and installation are also

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reviewed by the manager responsible for quality assurance and oversight to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

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

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

- (a) following any modification to a system;
- (b) following an unusual incident, such as an accident, significant operator error, or equipment malfunction;
- (c) when procedure discrepancies are found;
- (d) prior to use if not used in the previous two years; or
- (e) results of QA audits are conducted in accordance with Part II, Section 18.1.

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

### 6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval. Where temporary procedure changes are necessary during the operations phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. 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, PGN commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

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# SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

# 7.1 Acceptance of Item or Service

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

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

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of, or changes the methods or controls for, activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. PGN may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet PGN requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

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- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

## 7.2 NQA-1-1994 Commitment / Exceptions

In establishing procurement verification controls, PGN 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
  - PGN 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 PGN 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 PGN QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.
    - (2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
    - (3) A documented review of the supplier's accreditation will be performed and will include a verification of each of the following:
      - The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):
        - National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology;
        - American Association for Laboratory Accreditation (A2LA);
        - ACLASS Accreditation Services (ACLASS);

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- International Accreditation Services (IAS);
- Laboratory Accreditation Bureau (L-A-B);
- Other NRC approved laboratory accrediting body.
- The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories.
- The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
- For Section 8.1, PGN considers documents that may be stored in approved electronic media under PGN or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to PGN to support operations. The PGN records management system will provide for timely retrieval of necessary records.
- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in PGN documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.
  - For commercial grade items, special quality verification requirements are
    established and described in PGN documents to provide the necessary assurance
    an item will perform satisfactorily in service. The PGN 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.
  - PGN will also use other appropriate approved regulatory means and controls to support PGN commercial grade dedication activities PGN will assume 10 CFR 21 reporting responsibility for all items that PGN dedicates as safety-related.

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

PGN 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, PGN commits to compliance with NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

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# **SECTION 9 CONTROL OF SPECIAL PROCESSES**

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

# 9.1 NQA-1-1994 Commitment

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

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#### **SECTION 10 INSPECTION**

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

### 10.1 Inspection Program

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

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

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

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

#### 10.2 Inspector Qualification

PGN has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

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# 10.3 NQA-1-1994 Commitments / Exceptions

In establishing inspection requirements, PGN commits to compliance with NQA-1-1994, Basic Requirement 10, Supplement 10S-1 and Subpart 2.4, with the following clarification. In addition, PGN commits to compliance with the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.

- Subpart 2.4 commits PGN to IEEE 336-1985. IEEE 336-1985 refers to IEEE 498-1985. Both IEEE 336-1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. PGN commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.
- An additional exception to Subpart 2.4 is addressed in Part II, Section 12.
- Where inspections at the operating facility are performed by persons within the same organization (e.g. Maintenance group), PGN takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to Nuclear Oversight organization while performing those inspections.

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#### **SECTION 11 TEST CONTROL**

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

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

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

#### 11.1 NQA-1-1994 Commitment

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

#### 11.2 NQA-1-1994 Commitment for Computer Program Testing

PGN 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 PGN commits to compliance with the requirements of NQA-1-1994, Supplement 11S-2, and Subpart 2.7 to establish the appropriate provisions.

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# SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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

#### 12.1 Installed Instrument and Control Devices

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

# 12.2 NQA-1-1994 Commitment / Exceptions

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

- The out of calibration conditions described in paragraph 3.2 of Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration.
- Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-1994, Subpart 2.4, Section 7.2.1 (ANSI/IEEE Std. 336-1985).

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# SECTION 13 HANDLING, STORAGE, AND SHIPPING

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

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

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

Operators of special handling and lifting equipment are experienced or trained in the use of the equipment. During the operational phase, PGN 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, PGN complies with applicable hoisting, rigging and transportation regulations and codes.

#### 13.1 Housekeeping

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

# 13.2 NQA-1-1994 Commitment / Exceptions

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

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# NQA-1-1994, Subpart 2.2

- Subpart 2.2, section 6.6, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, PGN documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.
- Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for the nuclear power plants during construction.

# NQA-1-1994, Subpart 3.2

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

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# SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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

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

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

#### 14.1 NQA-1-1994 Commitment

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

# SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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

# 15.1 Interface with the Reporting Program

PGN has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55(e) and/or 10 CFR 21 during COL design and construction and 10 CFR 21 during operations.

#### 15.2 NQA-1-1994 Commitment

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

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## **SECTION 16 CORRECTIVE ACTION**

PGN has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. PGN 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. PGN procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, PGN documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, PGN may delegate specific responsibilities for corrective actions but PGN maintains responsibility for the effectiveness of corrective action measures.

#### 16.1 Interface with the Reporting Program

PGN has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55(e) and or 10 CFR 21 during the COL design and construction, and 10 CFR 21 during operations.

#### 16.2 NQA-1-1994 Commitment

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

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### SECTION 17 QUALITY ASSURANCE RECORDS

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

#### 17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, Revision 3 for design, construction, and initial startup. Retention times for operations phase records are based on construction records that are similar in nature. 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, PGN complies with NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks." PGN will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

#### 17.3 NQA-1-1994 Commitment / Exceptions

In establishing provisions for records, PGN 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 PGN, 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.

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# **SECTION 18 AUDITS**

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

#### **18.1 Performance of Audits**

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

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

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

The results of each audit are reported in writing to the Senior Vice President Nuclear Generation Group / Chief Nuclear Officer and the Senior Vice President Corporate Development and Improvement Group, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

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

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

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#### 18.2 Internal Audits

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

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

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

#### 18.3 NQA-1-1994 Commitment

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

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# PART III NON-SAFETY-RELATED SSC QUALITY CONTROL

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

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

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

# 1.1 Organization

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

# 1.2 QA Program

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

# 1.3 Design Control

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

#### 1.4 Procurement Document Control

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

#### 1.5 Instructions, Procedures, and Drawings

PGN provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed provides an appropriate degree of guidance to the personnel

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performing the activity to achieve acceptable functional performance of the SSC.

#### 1.6 Document Control

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

#### 1.7 Control of Purchased Items and Services

PGN employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

### 1.8 Identification and Control of Purchased Items

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

### 1.9 Control of Special Processes

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

#### 1.10 Inspection

PGN uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

#### 1.11 Test Control

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

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

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

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# 1.13 Handling, Storage, and Shipping

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

# 1.14 Inspection, Test, and Operating Status

PGN employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

# 1.15 Control of Nonconforming Items

PGN employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

#### 1.16 Corrective Action

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

#### 1.17 Records

PGN employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

#### 1.18 Audits

PGN employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

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

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

- PGN implements quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants" as identified in FSAR Chapter 1.
- PGN implements the quality requirements for ATWS equipment in accordance with Part III, Section 1.
- PGN implements quality requirements for SBO equipment in accordance with Part III, Section 1. Regulatory Guide 1.155, is not applicable for the AP1000 design in accordance with the certified design as shown in DCD Appendix 1A. Regulatory Guide 1.155 relates to the availability of safety related functions supported by AC power. Since AC power is not required to support the availability of safety-related functions, the guidance is not applicable.

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# PART IV REGULATORY COMMITMENTS

# **NRC Regulatory Guides and Quality Assurance Standards**

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

# **Regulatory Guides:**

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

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

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

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

Regulatory Guide 1.26 defines classification of systems and components.

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

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

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

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

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

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

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

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

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

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

<u>Regulatory Guide 1.37</u>, Revision 1, March 2007 – Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants.

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

PGN identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

#### Standards:

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

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

<u>Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides</u> (TGs)

PGN commits to NIRMA TGs as described in Part II, Section 17.

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