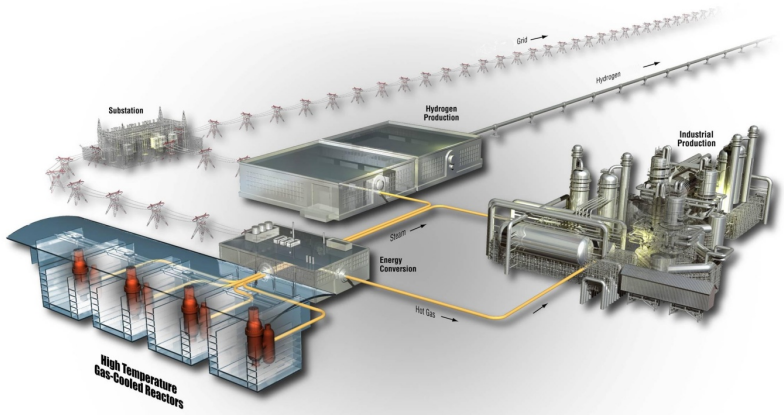
Document ID: PDD-172
Revision ID: 3
Effective Date:05/19/2011

## Program Description Document

# Next Generation Nuclear Plant Quality Assurance Program Description

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## EXECUTIVE SUMMARY

The objective Next Generation Nuclear Plant (NGNP) Project is to sufficiently develop the technology necessary to obtain an NRC license to build and operate the NGNP, a high temperature gas-cooled reactor (HTGR) capable of producing electricity and process heat for industrial applications. The NGNP will be licensed by the Nuclear Regulatory Commission (NRC) and provide the basis for commercialization of a new generation of advanced energy plants that utilize HTGR technology. The general scope of the project is to design, construct, and operate a full-scale prototype HTGR plant, thus establishing the technological basis for expanded commercial applications and infrastructure for the commercialization of this new generation of advanced nuclear plants.

This Quality Assurance Program Description (QAPD) establishes the quality assurance (QA) policy for the NGNP and assigns major functional responsibilities for NGNP activities conducted by or for the NGNP Project. It describes the methods and establishes QA and administrative control requirements that meet 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

These QA requirements are based on Regulatory Guide 1.28, Rev. 4, June 2010, "Quality Assurance Requirements (Design and Construction)" and on Regulatory Guide 1.33, Rev. 2, February 1978, "Quality Assurance Program Requirements (Operation)." Regulatory Guide 1.28, Rev. 4 states that Part I and Part II requirements of NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications" provide an adequate basis for complying with the requirements of 10 CFR Part 50, Appendix B, subject to the additions and modifications identified therein. This QAPD is based on the requirements and guidance of ASME NQA-1-2008, 1a-2009, Parts I and II, with specific reference to selected sections of Parts III and IV as identified in this document. This QAPD addresses additions and modifications to the regulatory positions included in Regulatory Guide 1.28, Rev. 4 and NEI 11-XX DRAFT, "Nuclear Generation Quality Assurance Program Description (NG-QAPD)." Regulatory Guide 1.33, Rev. 2 addresses an older set of standards. Appendix 1 of NG-QAPD provides a roadmap for identifying how Regulatory Guide 1.33, Rev. 2 requirements are addressed by NQA-1-2008, NQA-1a-2009.

This QAPD is applied to NGNP Project activities beginning with technology development and continuing through the design, licensing, operation, construction, preoperation, operation, and decommissioning phases. It includes all planned and systematic activities necessary to provide adequate confidence that safety-related SSCs will perform satisfactorily in service. It may also be applied to certain equipment and activities that are not safety-related, support safe plant operations, or where DOE and/or NRC requirements or guidance result in the establishment of additional program requirements.

Throughout this QAPD, the responsibility for establishing and implementing QAP requirements is assigned to the NGNP organization. As the project advances to design, licensing, startup testing and operations, the QAPD will be revised to reflect the transfer of responsibilities to other organizations (e.g., Nuclear Heat Supply System (NHSS) supplier, AE, operating utility).

## POLICY STATEMENT

The Next Generation Nuclear Plant (NGNP) Project shall develop technology, design, procure, construct, and operate the NGNP in a manner that ensures public and worker health and safety. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations, applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable state and local government laws and regulations.

The NGNP Quality Assurance Program (QAP) is governed by this QAPD and applicable Program Requirements Documents (PRDs) and their associated implementing documents. Together, these documents control NGNP Project activities that affect the quality of technology development activities, safety-related nuclear plant structures, systems, and components (SSCs) and include all the planned and systematic activities necessary to provide adequate confidence that safety-related SSCs will perform satisfactorily in service. This QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where DOE and/or NRC requirements or guidance result in the establishment of additional program requirements.

This QAPD is the policy document that establishes the NGNP Project's overall philosophy and manner 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. Senior management establishes overall expectations for effective QAP implementation and is responsible for obtaining the desired end result. Compliance with this QAPD and its implementing documents is mandatory for personnel directly or indirectly associated with implementing the NGNP QAP.

Signed

*Greg Gibbs*

*Project Director, Next Generation Nuclear Plant Project*

**Idaho National Laboratory**

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|---|---|---|

## Signatures

| Signature | Signature Code | Date | Organization/Discipline |
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| for Jim Kinsey | R&C | 5/18/2011 | NGNP Regulatory Affairs Director |
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| Greg Gibbs | A | 5/18/11 | NGNP Project Director |

R&C – Review and Concurrence
R – Review
A – Approval

## REVISION LOG

| Rev. | Date | Affected Pages | Revision Description |
|---|---|---|---|
| 0 | 10/1/10 | All | New issue. See eCR 583091.<br>This NGNP Quality Assurance Program Description is approved for phased implementation to begin on 10/1/10. This deferred implementation date allows for creation of and training workers to new and revised implementing procedures and instructions. Details of the phased implementation within NGNP, INL organizations outside NGNP, and suppliers outside INL will be detailed in an implementation plan. |
| 1 | 04/15/2011 | All | Revision See eCR 591467<br>Revised to: 1) add an executive summary, 2) clarify the graded approach for technology development activities, 3) update to the newest NEI template, NEI 11-XX DRAFT, including NQA-1 commitments and exceptions, and 4) Add commitment to Reg. Guide 1.33, Rev. 2. |
| 2 | 05/11/2011 | <br>1<br>14<br>20<br><br>22-25 | Revision See eCR 592493<br>Changed Author to Donald Prigel<br>Updated Figure 2 to reflect missing dotted line.<br>Para. 2.1.6, Clarified QA director's ability to take QA disagreements to INL Director for resolution.<br>Fix numbering sequence 2.7 to 2.1.7. This changed remaining paragraph numbers in section 2.1. |
| 3 | 05/19/2011 | Executive Summary | See eCR 593005 Deleted the last nine words from paragraph 3. |
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# 1. PART I – INTRODUCTION

## 1.1 General

The NGNP will be licensed by the U.S. Nuclear Regulatory Commission (NRC) and provide the basis for commercialization of a new generation of advanced energy plants that utilize high temperature gas-cooled reactor (HTGR) technology. The general project scope is to design, construct, and operate a full-scale prototype HTGR plant, thus establishing the technological basis for expanded commercial applications and infrastructure for the commercialization of this new generation of advanced nuclear plants. The NGNP Project is established under the Idaho National Laboratory (INL) Management and Operations contract between the Department of Energy (DOE) and Battelle Energy Alliance, LLC (BEA).

This Quality Assurance Program Description(QAPD) and associated Program Requirements Documents (PRDs) establish the NGNP Project quality assurance (QA) requirements based on Regulatory Guide 1.28, Rev. 4, "Quality Assurance Program Requirements (Design and Construction)," and on Regulatory Guide 1.33, Rev. 2, "Quality Assurance Program Requirements (Operation)." Regulatory Guide 1.28, Rev. 4 states that Part I and Part II requirements included in NQA-1-2008 and the 1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications" are acceptable to the Nuclear Regulatory Commission (NRC) staff and provide an adequate basis for complying with the requirements of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," subject to the additions and modifications of NQA-1-2008 and the 1a-2009 Addenda identified therein. This QAPD is based on the requirements and guidance of ASME NQA-1-2008, 1a-2009, Parts I and II, with specific reference to selected sections in Parts III and IV as identified in this document. This QAPD addresses additions and modifications to the regulatory positions included in Regulatory Guide 1.28, Rev. 4, and NEI 11-XX DRAFT, "Nuclear Generation Quality Assurance Program Description (NG-QAPD)." Regulatory Guide 1.33, Rev. 2 addresses an older set of standards and also describes a method acceptable to NRC staff for complying with the Commission's regulations during the operations phase of nuclear power plants. Appendix 1 of the NG-QAPD provides a roadmap for identifying how Regulatory Guide 1.33, Rev. 2 requirements are addressed by NQA-1-2008, NQA-1a-2009, and/or through the NG-QAPD to this QAPD.

The Quality Assurance Program (QAP) is defined by the NRC approved regulatory document that describes the QA elements (the QAPD), along with its

associated implementing documents. Procedures and instructions that control NGNP activities will be developed prior to commencement of those activities. Procedures establish practices for certain activities that are common to all NGNP organizations performing those activities so 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.

Because the NGNP Project is established under the INL Management and Operations contract with DOE, this QAPD also describes the methods and administrative control requirements to comply with 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements," and DOE Order 414.1C, "Quality Assurance."

The NGNP QAP is integrated with other INL management systems, including the Integrated Safety Management System, Environmental Management System, and Integrated Safeguards and Security Management System. All of these management systems function collectively to ensure safe, secure, and compliant work that meets or exceeds customer requirements and expectations.

The QAPD is applied to NGNP Project activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and includes all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD will also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where DOE and/or NRC requirements or guidance result in the establishment of additional program requirements. Implementing documents establish program element applicability.

Functional responsibilities and levels of authority are identified in roles, responsibilities, accountabilities, and authorities documents (R2A2s), which are developed for each management position. Specific responsibilities for implementing NGNP QAP requirements are identified in the associated implementing procedures.

In many instances, INL procedures are used to implement NGNP QAP requirements. When INL procedures lack specific requirements and rigor to implement NGNP QAP requirements, NGNP specific procedures are established.

## 1.2 Scope/Applicability

This QAPD applies to technology development (integrating research and development [R&D], engineering, and design) necessary to obtain an NRC

license to build and operate an HTGR, obtain an Early Site Permit (ESP) and Combined License (COL) and perform construction, preoperation, operations, and decommissioning activities that may affect the quality and performance of safety-related SSCs, including but not limited to:

- R&D
- Engineering
- Designing
- Safety related analysis and evaluation
- Siting
- Software V&V
- Procuring
- Fabricating
- Cleaning
- Handling
- Shipping
- Receiving
- Storing
- Constructing
- Erecting
- Installing
- Inspecting
- Preoperational activities (including ITAAC[a])
- Testing
- Startup
- Operating
- Maintaining
- Repairing
- Modifying
- Refueling
- Training
- Decommissioning

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

The NGNP QAP assures a high degree of quality and reliability of the nuclear plant while ensuring the health and safety of its workers and the public. To this end, selected elements of this 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 DOE and/or NRC requirements or guidance result in the establishment of additional QA requirements. Implementing documents establish program element applicability.

The definitions provided in ASME NQA-1–2008, 1a-2009, Part I, Section 400 apply to select terms as used in this document.

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a. ITAACs are those inspections, tests, analyses and acceptance criteria (ITAACs) the applicant must satisfy as determined by the commission in accordance with 10 CFR Part 52.

## 1.3 Source Documents

### 1.3.1 Requirements

The NGNP QAP implements the requirements of:

- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."
- 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements" (QA Rule). The QA Rule requires DOE contractors who conduct activities or provide items or services that affect, or may affect, the safety of DOE nuclear facilities to develop and maintain a QAP that implements 10 criteria specified in the rule.
- DOE Order 414.1C, "Quality Assurance" (QA Order). The QA Order requires all DOE contractors to develop and maintain a QAP, which implements 10 criteria specified in the order. The criteria are the same as those specified in the QA Rule.

### 1.3.2 Standards

Both the QA Rule and the QA Order require that the QAP use appropriate voluntary consensus standards, where practicable, and are consistent with contractual and regulatory requirements. The NGNP QAP uses the following standards:

A. NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," Part I and Part II, "Requirements for Quality Assurance Programs for Nuclear Facilities."

B. ASNT-SNT-TC-1A, "The American Society of Nondestructive Testing Recommended Practice." This standard is used for nondestructive examination activities in accordance with NQA-1-2008, 1a-2009.

C. ANSI/NCSL Z540-1, "American National Standard for Calibration-Calibration Laboratories and Measuring and Test Equipment-General Requirements," and ISO-17025, "General Requirements for the Competence of Testing and Calibration Laboratories," for calibration of nonradiological instrumentation.

### 1.3.3 Guides

DOE Order 414.1.c also requires that appropriate *guidance* (see def.) be considered in developing the QAP. The following guidance was used in developing the NGNP QAP implementing processes and documents:

A. DOE Guide 414.1-1A, "Management Assessment and Independent Assessment"

B. DOE Guide 414.1-2A, "Quality Assurance Management System"

C. DOE Guide 414.1-3, "Suspect/Counterfeit Items"

D. DOE Guide 414.1-4, "Safety Software."

## 1.4 Program Documents

For work performed at the INL, the NGNP QAP is described and implemented through a tiered document structure that includes *Program Description Documents* (PDDs; see def.), *Program Requirements Documents* (PRDs; see def.), *Laboratory Wide Procedures* (LWPs; see def.), *Management Control Procedures* (MCPs; see def.), *Technical Procedures* (TPRs; see def.), *Laboratory Instructions* (LIs), *Standards* (STDs; see def.), *Guides* (GDEs; see def.), *Plans* (PLNs), and *Lists* (LSTs; see def.).

At the highest level (Tier 1), this QAPD provides an overall description of the QAP, and how it is implemented, to facilitate understanding of the program scope and structure.

At the next level (Tier 2), PRDs identify the requirements by program elements that are contained in the external requirements documents listed in Section 1.3 above.

At Tier 3, MCPs, STDs, GDEs, LSTs, LIs ,TPRs, and other site-specific procedures are used to implement the QAP at the *organizational* (see def.), *functional support area* (see def.), or *facility levels* (see def).

# 2. PART II – QAPD DETAILS

## 2.1 Organization

This section describes the NGNP organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes the INL Organization under which the NGNP is presently organized and the NGNP Project

Organization responsible to establish and implement the NGNP QAP. This QAPD will be modified as the NGNP evolves from the INL NGNP Project to future organizational structures. The current organizational structure includes current functions for the NGNP Project, including interface responsibilities for multiple organizations that perform quality-related functions, but does not fully address the functional responsibilities of the evolving NGNP organization. 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.

INL is led by the Laboratory Director who is assisted by the Deputy Laboratory Director for Operations. Organizations reporting to the Laboratory Director include line organizations led by Associate Laboratory Directors (ALDs) and support organizations led by Support Directors. Within the support organizations are functional areas led by directors or managers. The NGNP Project Director (at the ALD level) reports directly to the INL Laboratory Director.

The NGNP Project Director assisted by the Deputy Project Director is responsible for the overall management of NGNP activities, which include establishing and executing the NGNP QAPD. The NGNP Project Director is responsible for establishing overall expectations for effective implementation of the QAPD and for obtaining the desired end result. The NGNP Project Director will staff the QA organization commensurate with the duties and responsibilities assigned.

The NGNP QA Director reports administratively (home organization) to the NGNP Project Director and is responsible for maintaining and monitoring the implementation of the overall NGNP QAPD. The NGNP QA Director has sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to assure that an appropriate QAP has been established and to verify activities affecting quality.

During the R&D, conceptual design, final design, and licensing phases of the NGNP Project, the quality affecting activities are performed by INL staff or contracted to qualified suppliers. The Very High Temperature Reactor (VHTR) Technology Development Office (TDO) performs the required R&D in support of NGNP. The VHTR TDO is established under the INL Nuclear Science and Technology ALD. Selected R&D work is subcontracted to other national laboratories, universities, and commercial companies. NGNP QAP requirements are rolled down to the VHTR TDO. The VHTR TDO rolls down NGNP quality requirements through the use of subcontracts, memorandum purchase orders, specifications, and statements of work. INL support services and infrastructure are used to support the NGNP Project for most all activities during the R&D phase, conceptual design, final design, and licensing phases. NGNP QAP requirements

are imposed for these services by NGNP implementing documents specified for each individual activity. NGNP QAP implementing procedures include both INL and NGNP specific procedures. An implementation matrix will identify the correct implementing procedure for NGNP QAP requirements. The following subsections describe additional roles, responsibilities, authorities, and accountabilities for individuals performing NGNP Project quality affecting activities.

The NGNP organization chart depicted in Figure 2 is a general representation of how the NGNP Project implements the applicable organizational requirements of NQA-1-2008, 1a-2009.

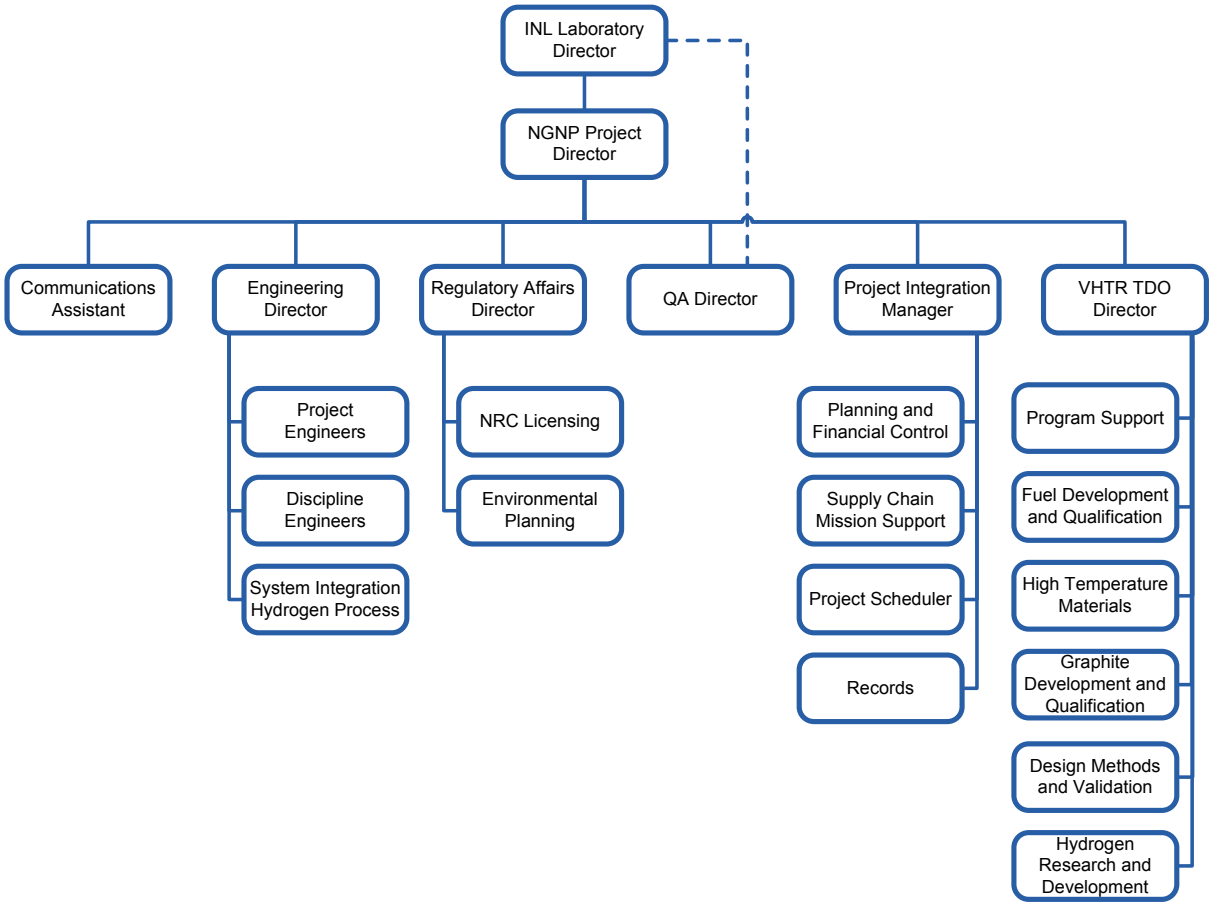


Figure 2. NGNP organization.

### 2.1.1 NGNP Project Director

#### 2.1.1.1 Roles and Responsibilities

A. Establishes overall expectations for effective implementation of the NGNP QAP and is responsible for obtaining the desired end result.

B. Provides overall management for the execution of the NGNP Project.

C. Leads the cross-functional group of project team members assembled to successfully execute the project objectives established jointly with the customer, INL Program Manager, Deputy for Projects Nuclear Support and Production, and INL Laboratory Director. The Deputy Project Director must ensure that the project objectives safely meet the NGNP Project requirements and are fulfilled within cost and schedule. These responsibilities span the definition and execution of R&D, design, licensing, construction, testing, operation, and maintenance for the life of the project organization.

D. Provides overall management direction, defines roles and responsibilities, delegates authorities, and enforces accountabilities for the organization.

E. Ensures that the appropriate process controls are formally defined for the execution of project work.

F. Develops and maintains cost and schedule contingencies that are commensurate with acceptable risk levels for the project.

G. Provides the focal point for both internal and external communication on the project. Responsible for formal correspondence to licensing and regulatory authorities for the NGNP project.

#### 2.1.1.2 Accountabilities and Authorities

A. Accountable to the sponsor and the INL Laboratory Director for the overall execution of the NGNP

Project within schedule, cost, and quality requirements.

B. Accountable to provide the NGNP Project organization with leadership and direction.

C. Authorizes the expenditure of project funds up to the approved authority limit.

D. Establishes and approves proposed changes to technical, cost, and schedule baselines within authority limits as defined in project management documents, and endorses other changes affecting the cost, schedule, and technical parameters within the formal project baselines.

E. Submits formal correspondence to licensing and regulatory authorities for the NGNP Project.

F. Approves the assignment and reassignment of key project team members.

G. Manages the project schedule to maximize project efficiency and performance.

H. Enforces accountability from the NGNP Project organization and the Project Team.

### 2.1.2 NGNP Deputy Project Director

#### 2.1.2.1 Roles and Responsibilities

A. Supports the Project Director in successfully fulfilling the Director's R2A2s.

B. Assumes the R2A2s of the NGNP Project Director in the absence of the Director. This assumption of the Project Director's R2A2s have been formally established by project policy to ensure clear lines of accountability and communication of expectations within the project organization and the project team.

### 2.1.3 NGNP Engineering Director

#### 2.1.3.1 Roles and Responsibilities

A. Establishes, in coordination with the NGNP Project Director, the structure, processes, and responsibilities of NGNP Engineering, which includes developing and executing work packages to complete NGNP project milestones.

B. Responsible for subcontract and direct NGNP Engineering work.

C. Supports development of and maintains, in coordination with NGNP Project management and R&D and licensing organizations, the NGNP Project system technical requirements (e.g., preparation of functional and operational requirements and safety research modification).

D. Provides technical direction, coordination, problem resolution, and oversight of NGNP Project design and regulatory activities to ensure that the approach, scope, and outcomes of these activities are consistent with the technical requirements (e.g., functional and operational requirements) of the NGNP Project.

E. Supports the development of the licensing and regulatory strategies.

F. Ensures that NGNP subcontractor design work is consistent with the project system requirements and licensing strategy.

G. Provides direct technical oversight of subcontractor activities during the design and engineering activities for the project. This technical oversight includes supporting review and evaluation of original subcontractor proposals to perform design work, and, during the development of the design, performing technical review of deliverables, conducting integrated design reviews, and supporting evaluation of earned value against budget and schedule.

H. Provides technical support to licensing as required in the interface with the NRC.

#### 2.1.3.2 Accountabilities and Authorities

A. Accountable to the NGNP Project Director for:

- Developing and supervising NGNP Engineering
- Defining NGNP technical requirements and coordinating and overseeing technical activities within the NGNP project to ensure these activities are consistent with the NGNP technical requirements
- Compliance with QA, procurement, and intellectual property protection requirements as they apply to the NGNP Project.

B. Coordinates and oversees the schedule and budget for NGNP Engineering activities.

C. Coordinates and oversees allocated budget.

D. Coordinates and oversees activities of NGNP Engineering personnel in support of the NGNP Project (e.g., making assignments, reviewing work, and evaluating performance).

E. Revises Engineering organization responsibilities with NGNP Project Director concurrence.

### 2.1.4 NGNP Project Integration Manager

#### 2.1.4.1 Roles and Responsibilities

A. Establishes and maintains an integrated schedule and cost control process for the project's entire work scope.

B. Provides the overall administrative structure for execution of the project, in coordination with the other directors.

C. Acts as a liaison between the project and other organizations.

D. Manages planning and financial control's resources for the development and maintenance of an integrated schedule and cost control process.

E. Ensures proper cost and accounting management of funded work scope.

#### 2.1.4.2 Accountabilities and Authorities

A. Accountable to the project organization as the primary point of contact for procurement activities.

B. Accountable to the INL Director of Business Management to ensure that Project activities are performed in accordance with INL processes and practices.

C. Obtains and assigns personnel, as required, to fulfill responsibilities within the authorized budget.

D. Approves purchase requisitions and other procurement actions within authority limits.

E. Serves as the control account manager of work packages covering assigned scope of responsibilities.

### 2.1.5 NGNP Regulatory Affairs Director

#### 2.1.5.1 Roles and Responsibilities

A. Coordinates all technical and licensing interfaces with the NRC and environmental/state regulatory agencies.

B. Establishes requirements for conduct of work within the NGNP Project organization and its subcontractors necessary to fulfill licensing and regulatory requirements.

C. Coordinates with NGNP management to ensure that the licensing strategy is consistent with the technical

requirements and that R&D activity is sufficient to support that strategy.

D. Coordinates with environmental experts and NRC Licensing personnel to ensure that site characterization activities are completed on schedule to support the NRC licensing strategy.

#### 2.1.5.2 Accountabilities and Authorities

A. Accountable to the NGNP Project Director to successfully develop and implement the licensing and regulatory strategy for the NGNP prototype and to establish the requirements for the associated work activities within the project, including R&D, design, construction, testing, and operations.

B. Accountable (authority delegated from the Project Director) as the licensing contact with the NRC and regulatory agencies.

C. Coordinates and oversees the allocated budget.

### 2.1.6 NGNP QA Director

The NGNP QA Director is sufficiently independent from other NGNP Project priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding NGNP Project activities. If the NGNP QA Director disagrees with any actions taken by the NGNP organization and is unable to obtain resolution, the NGNP QA Director shall inform the NGNP Project Director and the disagreement may be elevated to the INL Laboratory Director for final resolution.

#### 2.1.6.1 Roles and Responsibilities

A. Verifies the development and implementation of this QAPD.

B. Assures compliance with regulatory requirements and procedures by: audits; monitoring technical reviews and organization processes to ensure conformance to commitments and licensing document requirements; and ensuring that vendors who provide quality services, parts, and materials to

NGNP are meeting the requirements of 10 CFR 50, Appendix B through NUPIC or NGNP vendor audits.

C. Serves as QA Director to provide leadership and direction and to integrate and manage the QAPD for the NGNP Project.

D. Assists in identifying and interpreting the QA requirements and standards that apply to NGNP activities.

E. Verifies that QA processes and systems are developed, implemented, and updated as necessary to support NGNP program needs.

F. Assists the NGNP Project Director in developing and maintaining QAPD documentation, including implementing procedures.

G. Provides ongoing, timely, and candid communications with NGNP management, participants, and regulating agencies as appropriate.

H. Assesses implementation of NGNP processes and systems and assists in resolving identified issues. The QA Director may make recommendations to the NGNP Project management regarding improving the quality of work processes.

I. Assists the NGNP Project Director in coordinating outside audits, and ensures identified issues are entered into the INL issues tracking system.

J. Measures, analyzes, and reports QA performance to NGNP Project management.

K. Provides and encourages appropriate training, professional development, and leadership opportunities for QA staff.

#### 2.1.6.2 Accountabilities and Authorities

A. Accountable to provide NGNP Project management with leadership and stewardship to achieve success in the NGNP Project's mission.

B. Accountable to provide QA staff with leadership, mentoring, training, and necessary resources.

C. Obtains and assigns QA staff to support NGNP Project needs.

D. Holds the QA staff accountable for performance.

E. Resolves quality issues with NGNP management.

### 2.1.7 VHTR TDO Director

#### 2.1.7.1 Roles and Responsibilities

A. Establish, in coordination with the NGNP Director, the structure, processes, and responsibilities of the VHTR TDO, including the development of work packages to complete NGNP R&D project milestones

B. Oversee the development of technical requirements related to R&D activities

C. Provide technical direction, coordination, and oversight of TDO R&D activities to ensure that the approach, scope, and outcome of these activities are consistent with technical requirements

D. Work closely with the NGNP Project Director, Licensing Director and NGNP Engineering Director in the development, assessment, change, and interpretation of technical requirements as specifically addressed by planned and ongoing R&D activities in support of the NGNP

#### 2.1.7.2 Accountabilities

A. Accountable to the NGNP Director for:

- Development and supervision of the VHTR TDO organization
- Implementation, coordination and oversight of technical requirements with R&D activities in support of the project
- Performance and assessment of assigned Performance Evaluation
- Measurement Plan (PEMP) measures, laboratory strategy objectives, and stewardship assignments
- Compliance with laboratory policies, standards, and procedures
- Compliance with QA, procurement, and intellectual property protection requirements, as they apply to the VHTR TDO activities
- Coordination and oversight of the allocated VHTR TDO budget.

#### 2.1.7.3 Authorities:

A. Oversee and approve key personnel assignments

B. Hold staff and management accountable for performance

### 2.1.8 Project Support Personnel

#### 2.1.8.1 Roles and Responsibilities

A. Provide support functions for daily operations of NGNP.

B. *Financial support personnel*: Assist program, project, control account, and work package managers in developing and implementing direct or indirect project baselines.

C. Assist in developing resource-loaded schedules, establishing work breakdown structures as necessary, opening and closing charge number

structures, and establishing the appropriate earned value criteria. Provides guidance in the implementation of applicable company processes and procedures as they relate to project controls.

D. *Records and document control personnel*: Serve as the NGNP Project representative and direct lead for all document and records management functions.

E. Ensure that documents specifying quality requirements or prescribing activities affecting quality are controlled during preparation, issue, and change such that correct documents are being employed.

#### 2.1.8.2 Accountabilities and Authorities

A. Accountable to the NGNP Project Director for:

- Fulfilling all assigned responsibilities
- Ensuring that all identified resources are appropriately costed using the correct company rates
- Ensuring that quality affecting documents and records are managed and stored properly such that configuration control is maintained for the project.

### 2.1.9 R2A2s

Functional responsibilities and levels of authority are identified in roles, responsibilities, accountabilities, and authorities developed for each management position Specific responsibilities for implementing NGNP QAP requirements are identified in each implementing procedure.

### 2.1.10 Authority to Stop Work

QA and inspection personnel have the responsibility and authority to stop work in progress if it is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to offsite work performed by suppliers that furnish safety-related materials and services to NGNP. All NGNP personnel have the authority to initiate a timeout to resolve a condition that is potentially unsafe or

adverse to quality, and to declare a stop work action if the condition is not readily fixable.

### 2.1.11 QA Organizational Independence

Independence shall be maintained between the organization(s) performing the checking (QA and quality control) functions and the organizations performing the functions. This provision does not apply to design review/verification.

### 2.1.12 NQA-1 Commitment

In establishing its organizational structure, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 1.

## 2.2 Quality Assurance Program

NGNP has established the necessary measures and governing procedures to implement the QAP as described in this QAPD. NGNP is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plant as described and to the extent delineated in this QAPD. This QAPD shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, NGNP 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. NGNP Project and DOE Senior management are regularly apprised of the adequacy of implementation of this QAPD through the audit functions described in Section 2.18.

The objectives of this QAPD are to assure that NGNP technology development activities result in defensible data and records, and that the NGNP is designed, constructed, and operated in accordance with governing regulations and license requirements. The NGNP QAP is based on the requirements of ASME NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document.

The applicability of NQA-1-2008, 1a-2009 requirements to technology development is determined using a technology life-cycle approach identified in NQA-1-2008, 1a-2009, Part IV, Subpart 4.2, "Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development." The rigor with which the applicable QAP requirements are applied is then determined through a formal risk-based process that considers probability and consequence of failure. To ensure defensible data and records used in design and licensing of the NGNP, technology development resulting in data used in safety-related design and licensing activities is subject to all applicable NQA-1-2008, 1a-2009

requirements as defined in Parts I and II of this QAPD and the risk-based process used.

This QAP applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Once safety-related SSCs are determined, applicable NQA-1-2008, 1a-2009, Part I and Part II requirements as defined in this QAPD are applied. 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 will be maintained at the appropriate facility. The design information in the COL application will be used as the basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAP when opposed to safety function considerations.

As described in Part III, specific QAP controls are applied to nonsafety-related SSCs for which 10 CFR Part 50, Appendix B requirements do not apply. As these SSCs are significant contributors to plant safety, NGNP QAP controls are applied to those items in a selected manner, targeting 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 principal contractor has been approved as a supplier in accordance with this QAPD. Periodic audits and assessments of supplier QAPs are performed to assure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

The QAPD applies to those NGNP activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In addition, this QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

Detailed engineering specifications and construction procedures will be developed to implement this QAPD and Nuclear (NHSS) supplier QAPs prior to commencement of preconstruction (ESP) and COL activities. Examples of Limited Work Authorization activities that could impact safety-related SSCs during construction of the plant include the interface between nonsafety-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 INL implementing procedures, NGNP Project implementing procedures, or supplier implementing procedures governed by a supplier QAP.

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 of 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. Audit schedules are based on the month in which the audit starts.

### 2.2.1 Responsibilities

Personnel who work directly or indirectly for the NGNP Project are responsible for achieving acceptable quality in the work covered by this QAPD. This includes the activities delineated in Part I, Section 1.2. NGNP personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by this QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and its 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 NGNP QA Director is responsible to verify that processes and procedures comply with the QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

### 2.2.2 Delegation of Work

NGNP retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Part II, Section 2.1, 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.

### 2.2.3 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 QA measures are applied.

### 2.2.4 Periodic Review of the QA Program

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

### 2.2.5 Issuance and Revision to QA Program

Administrative control of this QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a). Changes to this QAPD are evaluated by the NGNP QA Director to ensure that such changes do not degrade safety for previously approved QA controls specified herein. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the ESP and COL application development process. New revisions to this document will be reviewed, at a minimum, by the NGNP QA Director and approved by the NGNP Project Director.

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 10 CFR 50, Appendix B will be satisfied. In order to comply with this requirement, the FSAR references the NGNP QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to this document.

### 2.2.6 Personnel Training and Qualifications

Personnel assigned to implement elements of this QAPD shall be capable of performing their assigned tasks. To this end, NGNP establishes and maintains formal indoctrination, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of this QAPD to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. The

indoctrination, training and qualification programs are commensurate with scope, complexity, and importance of the activities and include or address the following, as appropriate:

A. Education, experience, and proficiency of the personnel receiving training

B. General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and QAP requirements

C. On-the-job training, if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Minimum qualification requirements for plant and support staff are as delineated in the plant Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications (applicable to plant operations only). Project specific qualification requirements for research and support staff are established in the INL computer-based training and qualification system, TRAIN. These qualification requirements will be consistent with those delineated by the INL R&D organization to support work activities that produce data to support safety-related design and licensing activities.

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 NGNP procedures (applicable to plant operations only). Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the elements of this QAPD 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 NGNP QA Director are that he/she holds an engineering or related science degree and a minimum of 4 years of related experience including 2 years of nuclear power plant experience, 1 year of supervisory or management experience, and 1 year of the experience in performing quality verification activities. Special requirements shall include management and supervisory skills and

experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing, and maintaining the programs for the NGNP 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.

### 2.2.7 NQA Commitment/Exceptions

In establishing qualification and training programs, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 2 with the following clarifications and exceptions:

A. For Section 302, "Inspection and Test," NGNP will either adopt nonmandatory Appendix 2A-1 as if it were part of the requirement by following Option 1 below and/or take exception to 2A-1 following Option 2. This determination will be made at a later date, and a different option may be applied during different project phases.

**Option 1**

Requirement 2 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Requirement. When applying Option 1, either or both of the following two alternatives may be applied to the implementation of this requirement and appendix:

- In lieu of being certified as Level I, II, or III in accordance with NQA-1-2008, 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 (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.

- 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 5 years engineering work experience with at least 2 years of this experience related to nuclear facilities.

**Option 2**

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

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

- When selecting Option 2, the following alternative may be applied to the implementation of Requirement 2. Inspections, examinations, or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work

involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b, and c are not met, inspections, examinations or tests are carried out by individuals certified in accordance with Section 300. Individuals performing visual inspections required by the ASME Boiler and Pressure Vessel Code are qualified and certified according to Code requirements.

B. NGNP shall follow Section 301 for qualification of nondestructive examination personnel, except NGNP 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 the NGNP site for the scope of activities governed by these cited standards.

C. As an alternative to the Section 303.3 requirement that prospective Lead Auditors have participated in a minimum of five audits in the previous 3 years the following may be used for qualification of experienced individuals: “A Prospective Lead Auditor that has related industry experience and previously demonstrated ability to properly implement the audit process shall participate in one nuclear QA audit within the year prior to qualification.”

D. Section 400(a)(8) requires the date of certification expiration be included on the qualification record. NGNP considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

## 2.3 Design Control

NGNP 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 set points) of items that are subject to the provisions of this QAPD. The design process includes provisions to control design inputs, outputs, design changes, interfaces, records, and organizational interfaces within NGNP and 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 contains or references appropriate acceptance criteria that can be related to the design input in sufficient detail to permit verification by inspection

and test, as required. Design change processes and the division of responsibilities for design-related activities are detailed in NGNP and supplier procedures. Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities are justified and subject to design control measures commensurate with those applied to the original design. 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 NGNP design organization or by other organizations so authorized by NGNP.

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

### 2.3.1 Design Verification

NGNP design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application and 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 or computer program 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 ensure 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 the item's intended use.

NGNP 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.

### 2.3.2 Design Records

NGNP 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 a 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.

### 2.3.3 Computer Application and Digital Equipment Software

The QAPD governs the development, procurement, testing, maintenance, control, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Computer program acceptability is pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. NGNP 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. This QAPD also applies 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.

### 2.3.4 Set-Point Control

Instrument and equipment set points that could affect nuclear safety are controlled in accordance with written instructions. As a minimum, these written instructions:

A. Identify responsibilities and processes for reviewing, approving, and revising set points and set-point changes originally supplied by the NHSS supplier, the A/E, and the plant's technical staff

B. Ensure that set points and set-point changes are consistent with design and accident analysis requirements and assumptions

C. Provide for documentation of set points, including those determined operationally

D. Provide for access to necessary set point 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.

### 2.3.5 NQA-1 Commitment

In establishing its program for design control and verification, the NGNP Project commits to compliance with NQA-1-2008, 1a-2009, Requirement 3, the subsurface investigation requirements in Subpart 2.20, and the standards for computer software in Subpart 2.7

## 2.4 Procurement Document Control

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

A. Where original technical or QA 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.

B. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, and 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 QAP that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements, or the supplier may work under the NGNP approved QAP.

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.

### 2.4.1 NQA-1 Commitment/Exceptions

In establishing controls for procurement, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 4 with the following clarifications and exceptions:

A. Section 203 requires the purchaser to specify the QA requirements in the procurement documents. To meet this requirement, NGNP 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.

B. With regard to service performed by a supplier, NGNP procurement documents may allow the supplier to work under the NGNP QAP, including implementing procedures, in lieu of the supplier having its own QAP.

C. Section 300 and 400 of Requirement 4 requires the review of technical and QAP requirements of procurement documents prior to award of a contract and for procurement document changes. NGNP may satisfy this requirement through the review of the procurement specification, when the specification contains the technical and QA requirements of the procurement.

D. Procurement documents for commercial grade items that will be procured by NGNP for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

## 2.5 Instructions, Procedures, and Drawings

NGNP 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 this QAPD as described herein. Such documents are prepared and controlled according to Part II, Section 2.6, "Document Control." 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.

### 2.5.1 Procedure Adherence

NGNP'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 2.6. 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.

### 2.5.2 Procedure Content

The established measures address the applicable content of procedures as described in the Introduction to Part II of NQA-1-2008, 1a-2009. In addition, procedures governing tests, inspections, operational activities, and maintenance will include, as applicable, initial conditions and prerequisites for the performance of the activity.

### 2.5.3 NQA-1 Commitment

In establishing procedural controls, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 5.

## 2.6 Document Control

NGNP 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 ensure that correct documents are being employed. The following controls (including electronic systems used to make documents available) are applied to documents and changes thereto:

A. Identification of controlled documents

B. Specified distribution of controlled documents for use at the appropriate location

C. A method to identify the correct document (including revision) to be used and control of superseded documents

D. Identification of individuals responsible for preparation, review, approval, and distribution of controlled documents

E. Review of controlled documents for adequacy, completeness, and approval prior to distribution

F. A method for providing feedback from users to improve procedures and work instructions

G. Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

A. Drawings such as design, construction, installation, and as-built drawings

B. Engineering calculations

C. Design specifications

D. Purchase orders and related documents

E. Vendor-supplied documents

F. Audit, surveillance, and quality verification/inspection procedures

G. Inspection and test reports

H. Instructions and procedures for activities covered by this QAPD, including R&D activities, design, construction, installation, operation (including normal and emergency operations), maintenance, calibration, and routine testing

I. Technical specifications

J. Nonconformance 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.

### 2.6.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the ESP or construction phase, procedures for design, construction, and installation are also reviewed by the organization responsible for quality verification to ensure QA measures have been appropriately applied. The documented review signifies concurrence.

During the operations phase, documents affecting the configuration or operation of the nuclear station as described in the SAR are screened to identify those that require review by the Independent Review Committee (IRC) prior to implementation as described in Part V, Section 5.2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary based on one or more of 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

E. Results of QA audits conducted in accordance with, Part II, Section 2.18.

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.

### 2.6.2 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.

### 2.6.3 NQA-1 Commitment

In establishing provisions for document control, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 6.

## 2.7 Control of Purchased Material, Equipment, and Services

NGNP 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/or examination of items or services.

### 2.7.1 Acceptance of Item or Service

NGNP 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:

A. Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.

B. Prospective suppliers of safety-related items and services are evaluated to ensure 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. NGNP may utilize audits conducted by outside organizations for supplier qualification, provided the scope and adequacy of the audits meet NGNP 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.

C. 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.

D. 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 ensure they will perform satisfactorily in service in safety-related applications. When commercial grade items or services are used, the requirements of ASME NQA-1-2008, 1a-2009, Part II, Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services" are applied as an acceptable alternative to Part I, Requirement 7, Sections 200 through 600, except that supplier evaluation and selection, where determined necessary, shall be in accordance with Section 200.

E. If there is insufficient evidence of implementation of a QAP, the initial evaluation is of the existence of a QAP 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 QAP.

### 2.7.2 NQA-1 Commitment/Exceptions

In establishing procurement verification controls, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 7, with the following clarifications and exceptions:

A. NGNP considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other state and federal agencies, which may provide items or services to the NGNP, are not required to be evaluated or audited.

B. 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:

- The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the NGNP QAP and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report identify the laboratory equipment/standard used.

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

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

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

    A. National Voluntary Laboratory Accreditation Program, administered by the National Institute of Standards and Technology

    B. American Association for Laboratory Accreditation

    C. ACLASS Accreditation Services

    D. International Accreditation Service

    E. Laboratory Accreditation Bureau

    F. Other NRC-approved laboratory accrediting body.

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

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

- For Section 501, NGNP considers documents that may be stored in approved electronic media under NGNP or vendor control, not physically located on the plant site but 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 NGNP to support operations. The NGNP records management system will provide for timely retrieval of necessary records.

- In establishing commercial grade item requirements, NGNP commits to compliance with NQA-1a-2009, Section 700 and Subpart 2.14, with the following clarification:

  A. For commercial grade items, quality verification requirements are established and described in NGNP documents to provide the necessary assurance an item will perform satisfactorily in service. NGNP 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.

  B. NGNP will assume 10 CFR 21 reporting responsibility for all items that NGNP dedicates as safety-related.

## 2.8 Identification and Control of Materials, Parts, and Components

NGNP 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 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.

### 2.8.1 NQA-1 Commitment

In establishing provisions for identification and control of items, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 8.

## 2.9 Control of Special Processes

NGNP has established the necessary measures and governing procedures to assure that special processes requiring 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.

### 2.9.1 NQA-1 Commitment

In establishing measures for the control of special processes, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 9.

## 2.10 Inspection

NGNP 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, and 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.

### 2.10.1 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 operations 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.

### 2.10.2 Inspector Qualification

NGNP has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2.2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

### 2.10.3 NQA-1 Commitment/Exceptions

In establishing inspection requirements, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 10, and Subpart 2.4, with the following clarification. In addition, NGNP commits to compliance with the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.

Subpart 2.4 commits NGNP 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. NGNP 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 2.12.

## 2.11 Test Control

NGNP 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, preoperational 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 tests, (2) the use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

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

Tests other than computer program testing 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 2.2.

### 2.11.1 NQA-1 Commitment for Computer Program Testing

NGNP establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected output is obtained and

configuration control is maintained. To this end, NGNP commits to compliance with the requirements of NQA-1-2008, 1a-2009, Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, 1a-2009, Requirement 3.

### 2.11.2 NQA-1 Commitment

In establishing provisions for testing, NGNP commits to compliance with NQA-1-2008, 1a-2009 Requirement 11.

## 2.12 Control of Measuring and Test Equipment

NGNP has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria is met or 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 2.7.1.

### 2.12.1 Installed Instrument and Control Devices

For the operations phase of the facilities, NGNP 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.

### 2.12.2 NQA-1 Commitment/Exceptions

In establishing provisions for control of measuring and test equipment, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 12, with the following clarification and exception:

- The out of calibration conditions described in Section 303.2 refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.

- Measuring and test equipment are not required to be marked with the calibration status, as described in section 303.6, 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-1-2008, 1a-2009, Subpart 2.4 (See Section 7/2/1 of ANSI/IEEE Std. 336-1985).

## 2.13 Handling, Storage, and Shipping

NGNP 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 in accordance with procedures at specified time intervals or prior to use.

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

### 2.13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of SSCs 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.

### 2.13.2 NQA-1 Commitment/Exceptions

In establishing provisions for handling, storage, and shipping, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 13. NGNP also commits, during the construction and preoperational phase of the plant, to comply with the requirements of NQA-1-2008, 1a-2009, and Subpart 2.1, Subpart 2.2, and Subpart 3.2, Appendix 2.1, with the following clarifications:

**NQA-1a-2009, Subpart 2.1**

A. Subpart 2.1, Section 301 and 302 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, NGNP may establish cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. NGNP establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. An optional clarification/alternative to QA requirements applies only to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.

**NQA-1a-2009, Subpart 2.2**

A. Subpart 2.2, Section 202 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, NGNP may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure

that no damage or deterioration exists which could affect their function. An optional clarification/alternative to QA requirements that applies only to operational programs. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.

B. As an alternative to Subpart 2.2, Section 405, "Shipments from Countries Outside the United States," NGNP may elect to establish special requirements that address the appropriate quality requirements and applicable United States Customs and Border Protection/Department of Homeland Security requirements.

C. Subpart 2.2, Section 606, "Storage Records," requires written records be prepared containing information on personnel access. As an alternative to this requirement, NGNP 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 NGNP.

D. Subpart 2.2, Section 701 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 NGNP during construction.

**NQA-1-2008, Subpart 2.3**

A. Subpart 2.3, Section 202 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, NGNP bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. This clarification/alternative was approved for the NMC submittal discussed in the NRC SE, reference ADAMS Accession number ML050700416.

**NQA-1-2008, Part III, Subpart 3.2**

**A.** Subpart 3.2, Appendix 2.1, Section 300, "Cleaning Recommendations and 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.

## 2.14 Inspection, Test, and Operating Status

NGNP 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 that the inspection, test, or operating status be verified before release, fabrication, receipt, installation, testing, 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.

### 2.14.1 NQA-1 Commitment

In establishing measures for control of inspection, test, and operating status, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 14.

## 2.15 Nonconforming Materials, Parts, or Components

NGNP 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. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 2.16. 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 SSCs to ensure 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 NGNP procedures, regulatory requirements, and industry standards.

### 2.15.1 Interface with the Reporting Program

NGNP has appropriate interfaces between the QAP for identifying and controlling nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55, and/or 10 CFR 21 during ESP/COL design and construction, and 10 CFR 21 during operations.

### 2.15.2 NQA-1 Commitment

In establishing measures for nonconforming materials, parts, or components, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 15.

## 2.16 Corrective Action

NGNP has established the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. NGNP 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. NGNP 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, NGNP 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, NGNP may delegate specific responsibilities for corrective actions but NGNP maintains responsibility for the effectiveness of corrective action measures.

### 2.16.1 Interface with the Reporting Program

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

### 2.16.2 NQA-1 Commitment

In establishing provisions for corrective action, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 16.

## 2.17 Quality Assurance Records

NGNP 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 NGNP and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

### 2.17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for R&D, design, engineering, procurement, manufacturing, construction, inspection and testing, installation, preoperation, 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.1.a (3) of Regulatory Guide 1.28, Rev. 4 for design, construction, and initial startup. Retention times for operations phase records are based on construction records that are similar in nature.

NGNP uses ASME NQA-1-2008, 1a-2009, Nonmandatory Appendix 17-A1, “Guidance on Quality Assurance Record,” Paragraph 200, “List of

Lifetime Records," which lists typical lifetime records containing information meeting Requirement 17 of Part 1.

In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met. *(Regulatory Guide 1.28, Rev. 4, 2010)*

### 2.17.2 Electronic Records

When using electronic records storage and retrieval systems, NGNP complies with NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks."

NGNP 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, TG 15-1998, TG 16-1998, and TG 21-1998. *(Regulatory Guide 1.28, Rev. 4, June 2010)*

### 2.17.3 NQA-1 Commitment/Exceptions

In establishing provisions for records, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 17 and with the regulatory positions stated in Regulatory Guide 1.28, Rev. 4, June 2010 with the following clarifications and exceptions:

**Regulatory Guide 1.28, Rev. 4**

In establishing the provisions for a list of records, NGNP commits to compliance with regulatory position C.1.a.(3) as stated in Regulatory Guide 1.28, Rev. 4, June 2010 with the following clarifications by adopting Option 1 or Option 2, as may be appropriate during various project phases:

A. *Option 1*: NGNP commits to develop a list of typical lifetime records based on NQA-1-2008, Part III, "Nonmandatory," Appendix 17A-1, Section 200. NGNP recognizes that the nomenclature of these records may vary and the list may not be all-inclusive. For records not listed in Appendix 17A-1, the type of record that most nearly describes the record in question will be followed with respect to its retention classification. The NGNP commits to maintain sufficient records to furnish evidence of activities affecting quality.

B. *Option 2*: NGNP commits to develop a list of lifetime records and to maintain sufficient records to furnish evidence of activities affecting quality.

## 2.18 Audits

NGNP 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 established requirements and performance criteria are met. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

### 2.18.1 Performance of Audits

Internal audits of selected aspects of NGNP activities, 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 NGNP Project activities, audits will focus on areas, including but not limited to R&D, site investigation, procurement, and corrective action. Functional areas of an organization's QAP for auditing include verification of compliance and effectiveness of implementation of internal rules and procedures, which include but are not limited to: operations, design, procurement, maintenance, modification, refueling, surveillance, testing, 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 and performance of operating, refueling, maintenance, and modification activities, including associated record keeping.

Audits are formally preplanned and scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Quality Director, responsible for the day-to-day program as documented in Section 2.1.

NGNP 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 QAP and are issued to the management of the audited organization and applicable NGNP management.

The results of each audit are reported in writing to the NGNP QA Director or designee, as appropriate. Additional internal distribution is made to other concerned management levels and to managers of the internal audited organizations or activities as per approved procedures.

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

Audits of suppliers of safety-related components and/or services are conducted as described in Section 2.7.1.

### 2.18.2 Internal Audits

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, shall be performed in a manner that ensures all applicable QAP elements are audited for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. (*Regulatory Guide 1.28, Rev. 4, June 2010)*

Internal audits of activities, conducted after placing the facility in operation, should be performed in a manner that assures an audit of all applicable QAP elements is completed for each functional area within a period of two years. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above 2-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based on applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

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

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

B. The performance, training, and qualifications of the NGNP staff.

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

D. The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit are conducted utilizing either a qualified offsite licensed fire protection engineer or an outside qualified fire protection consultant.

E. Other activities and documents considered appropriate by the NGNP Project Director.

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.

### 2.18.3 NQA-1 Commitment/Exceptions

In establishing the independent audit program, NGNP commits to compliance with NQA-1-2008, 1a-2009, Requirement 18, and with the regulatory positions stated in Regulatory Guide 1.28, Rev. 4, June 2010 with the following clarifications and exceptions:

A. Regulatory Guide 1.28, Rev. 4

B. NGNP annual evaluation of the supplier in NRC position C.2.b(4) (a), (b) and (c) shall only be required to consider activities related to NGNP procurement activities.

# 3. PART III – NONSAFETY-RELATED SSC QUALITY ASSURANCE

## 3.1 Nonsafety-Related SSCs – Significant Contributors to Plant Safety

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

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

### 3.1.1 Organization

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

### 3.1.2 QA Program

NGNP QA requirements for nonsafety-related SSCs are established in this QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QAP is not required.

### 3.1.3 Design Control

NGNP 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 that deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer’s work.

### 3.1.4 Procurement Document Control

Procurement documents for items and services obtained by or for NGNP 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.

### 3.1.5 Instructions, Procedures, and Drawings

The NGNP Project provides documents to direct the performance of activities affecting quality that include but are not limited to written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders. The method of instruction employed provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

### 3.1.6 Document Control

The NGNP Project 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.

### 3.1.7 Control of Purchased Items and Services

NGNP 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.

### 3.1.8 Identification and Control of Purchased Items

NGNP 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 these items.

### 3.1.9 Control of Special Processes

NGNP 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.

### 3.1.10 Inspection

NGNP 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.

### 3.1.11 Test Control

NGNP 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.

### 3.1.12 Control M&TE

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

### 3.1.13 Handling, Storage, and Shipping

NGNP 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 markings or labels and the identification of any special storage or handling requirements.

### 3.1.14 Inspection, Test, and Operating Status

NGNP 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.

### 3.1.15 Control of Nonconforming Items

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

### 3.1.16 Corrective Action

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

### 3.1.17 Records

NGNP 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.

### 3.1.18 Audits

NGNP employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective actions. 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 3.2.18).

## 3.2 Nonsafety-Related SSCs Credited for Regulatory Events

NGNP shall provide an evaluation of conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. That evaluation will also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant.

# 4. PART IV – REGULATORY COMMITMENTS

## 4.1 NRC Regulatory Guides and QA Standards

The information is this section of NEI 11–XX DRAFT applies specifically to light water reactors. The appropriate NGNP Regulatory Guides will be identified at the appropriate licensing stage and may be added here if then deemed necessary.

# 5. PART V – ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

The information in Part V is provided as equivalent requirements for meeting regulatory positions of Regulatory Guide 1.33, Rev. 2, as identified in Appendix 1 of NEI 11-XX DRAFT.

NGNP includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operations phase of the plant.

## 5.1 Definitions

NGNP uses the definitions of terms as provided in Section 4 of the Introduction of NQA-1-2008, NQA-1a-2009 in interpreting the requirements of NQA-1 and the other standards to which this QAPD commits. Definitions are provided for the following terms not covered in NQA-1:

**administrative controls** Rules, orders, instructions, procedures, policies, practices and designations of authority and responsibility.

**experiments** Performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known.

**independent review** Review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review).

**nuclear power plant** Any plant using a nuclear reactor to produce electric power, process steam or space heating.

**on-site operating organization** Onsite personnel concerned with the operation, maintenance and certain technical services.

**operating activities** Work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the onsite operating organization.

**operational phase** That period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading, and ends with plant decommissioning.

**review** A deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions.

**supervision** Direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor.

**surveillance testing** Periodic testing to verify that safety related structures, systems, and components continue to function or are in a state of readiness to perform their functions.

**system** An integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function.

## 5.2 Review of Activities Affecting Safe Plant Operation

### 5.2.1 Onsite Operating Organization Review

The NGNP onsite organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of the manager responsible for plant operations. The reviews are part of the normal duties of plant supervisory personnel in order to provide timely and continuing monitoring of operating activities and assist the manager responsible for plant operations in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. The manager responsible for plant operations ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

### 5.2.2 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 reviews the following:

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

B. Proposed tests and experiments not described in the SAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the SAR require a technical specification change or license amendment..

C. 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. 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. Any matter related to nuclear safety that is requested by the NGNP senior official or any IRB/IRC member.

F. Corrective actions for significant conditions adverse to quality.

G. Internal audit reports.

H. The adequacy of the internal audit program every 24 months.

IRB or IRC: NGNP may choose to use either Option I or Option II.

## 5.3 Option I—Independent Review Body

A group may function as an 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.

A. IRB reviews are supplemented as follows:

1. 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.

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

3. 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.

B. 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.

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 years combined managerial and technical support experience. The members of the IRB should have a minimum of five years experience in their own area of responsibility as applicable to the activities being reviewed (a minimum of five years of experience in one of the twelve areas listed below:

- Nuclear power plant operations
- Nuclear engineering
- Chemistry and radiochemistry
- Metallurgy
- Nondestructive testing
- Instrumentation and control
- Radiological safety
- Mechanical engineering
- Electrical engineering
- Administrative control and QA practices
- Training
- Emergency plans and related procedures and equipment.

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

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

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

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

## 5.4 Option II—Independent Review Committee

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

B. The independent review committee reports to a management level above the plant manager as to be described in the organization in Part II, Section 1].

C. The independent review committee is composed of no less than five persons and no more than a minority of members are from the onsite operating organization. For example, at least three of the five members must be from offsite if there are five members on the committee. A minimum of the chairman or alternative chairman and two members must be present for all meetings.

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

E. Results of the meeting are documented and recorded.

F. Consultants and contractors are used for the review of complex problems beyond the expertise of the offsite/onsite independent review committee.

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

**Supervisor or Chairman of the Independent Review Committee**

- Education: baccalaureate in engineering or related science

- Minimum experience: six years combined managerial and technical support.

**Independent Review Committee Members**

- Education: Baccalaureate in engineering or related science for those Independent review personnel who are required to review problems in:

    A. nuclear power plant operations

    B. nuclear engineering

    C. chemistry and radiochemistry

    D. metallurgy

    E. nondestructive testing

    F. instrumentation and control

    G. radiological safety

    H. mechanical engineering, and electrical engineering.

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

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

## 5.5 Operational Phase Procedures

The following is a description of the various types of procedures NGNP will use to govern the design, operation, and maintenance of its nuclear plant. Regulatory Guide 1.33 applies specifically to PWR and BWR light water reactors. As an HTGR, NGNP will follow the applicable guidance of Appendix A to Regulatory Guide 1.33 in identifying the types of activities that should have procedures or

instructions to control the activity. Each procedure will be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.

## 5.6 Format and Content

Procedure format and content may vary from one location to the other, but the procedures will include the following elements, as appropriate, based on the purpose or task to be described:

A. *Title/Status*—Each procedure is given a title descriptive of the work or subject it addresses, and includes a revision number and/or date and an approval status.

B. *Purpose/Statement of Applicability/Scope*—The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes, or conditions to which the procedure applies are also clearly described.

C. *References*—Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

D. *Prerequisites/Initial Conditions*—Prerequisites/initial conditions identify those independent actions or procedures that must be accomplished and plant conditions that must exist prior to performing the procedure. A prerequisite applicable to only a specific portion of a procedure is so identified.

E. *Precautions*—Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

F. *Limitations and actions*—Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

G. *Main body*—The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

H. *Acceptance criteria*—The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.

I. *Checklists*—Complex procedures utilize checklists, which may be included as part of the procedure or appended to it.

## 5.7 Procedure Types

### 5.7.1 Administrative Control Procedures

These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided.

### 5.7.2 Operating Orders/Procedures

Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples where these are applied include, but are not limited to, job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, and shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

### 5.7.3 Special Orders

Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

### 5.7.4 Plant Security and Visitor Control

Procedures or instructions are developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates, and compartments containing sensitive equipment; and provisions for traffic and access control. Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation, and challenging of strangers by operating crews; and a program of pre-employment screening for potential employees are also considered.

### 5.7.5 Temporary Procedures

Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

### 5.7.6 Engineering Procedures

These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

### 5.7.7 Configuration Management Procedures

These documents provide instructions for the responsibility and authority for functions that affect the configuration of the facility including activities such as operations, design, maintenance, construction,

licensing, and procurement. NGNP will establish and document a time or event when configuration management shall be established for the facility.

### 5.7.8 Installation Procedures

These documents provide instructions for installing components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

### 5.7.9 System Procedures

These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for operations of systems related to the safety of the plant. Actions to correct off-normal conditions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure. Separate procedures may be developed for correcting off-normal conditions for those events where system complexity may lead to operator uncertainty. Appropriate procedures will also be developed for the fire protection program.

### 5.7.10 Start-up Procedures

These documents contain instructions for starting the reactor from cold or hot conditions and establishing power operation. This includes documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned, necessary system procedures, tests and calibrations have been completed; and required approvals have been obtained.

### 5.7.11 Shutdown Procedures

These documents contain guidance for operations during controlled shutdown and following reactor trips, including instructions for establishing or maintaining hot shutdown/standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the

plant are specified, including instructions for such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence for activating or deactivating equipment, requirements for prompt analysis for causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal.

### 5.7.12 Power Operation and Load Changing Procedures

These documents contain instructions for steady-state power operation and load changing. They also include provisions for use of control rods, chemical shim, coolant flow control, or any other system available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

### 5.7.13 Process Monitoring Procedures

These documents contain instructions for monitoring performance of plant systems to ensure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

### 5.7.14 Fuel Handling Procedures

These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include: continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for fuel movements in the spent fuel storage areas. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement and fuel cask loading and movement; and status of interlocks, reactor trip circuits, and mode switches. These procedures provide requirements for refueling, including: proper sequence, orientation and seating of fuel and components, rules for minimum operable instrumentation, actions for response to fuel damage, verification of shutdown margin, communications between the control

room and the fuel handling station, independent verification of fuel and component locations, criteria for stopping fuel movements, and documentation of final fuel and component serial numbers (or other unique identifiers) and locations.

### 5.7.15 Maintenance Procedures

These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-2008, Subpart 2.18, Section 202, “Procedures.”

### 5.7.16 Radiation Control Procedures

These documents contain instructions for implementing the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements, and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

### 5.7.17 Calibration and Test Procedures

These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for ensuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

### 5.7.18 Chemical and Radiochemical Control Procedures

These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards when activated. These documents also provide for the control, treatment, and management of radioactive wastes, and control of radioactive calibration sources.

### 5.7.19 Emergency Operating Procedures

These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner's Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.

### 5.7.20 Emergency Plan Implementing Procedures

These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state, and federal agencies, and periodically testing the procedures, communications and alarm systems to ensure they function properly. The format and content of such procedures are such that the requirements of each facility's NRC approved Emergency Plan are met.

### 5.7.21 Test and Inspection Procedures

These documents provide the necessary measures to assure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test

or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to ensure that test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identifying those performing the test or inspection, as-found conditions, corrective actions performed (if any), and as-left conditions, as appropriate for the subject test or inspection.

## 5.8 Control of Systems and Equipment in the Operational Phase

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented. Measures, such as installing tags or locks and releasing stored energy, are used to ensure the safety of personnel and equipment. When entry into a closed system is required, NGNP will use established control measures to prevent entry of extraneous material and to ensure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include: shutdown margin; method of emergency core cooling; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining, and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing, or actions such as returning valves, breakers, and switches to proper startup or operating positions from “test” or “manual” positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.

### 5.9 Plant Maintenance

NGNP will establish controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related SSCs are maintained in a manner that ensures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

In establishing controls for plant maintenance, NGNP commits to compliance with NQA-1-2008, Subpart 2.18, with the following clarifications:

A. Where Subpart 2.18 refers to the requirements of ANS-3.2, it shall be interpreted to mean the applicable standards and requirements established within the NGNP QAPD.

B. Section 203 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the NGNP QAPD, Part II, Section 2.13.2.

## 6. RECORDS

None

## 7. DEFINITIONS

Terms used in the QAPD are defined in Section 5.1 and in LST-649, *NGNP Definitions and Acronyms.*

## 8. REFERENCES

Title 10, Code of Federal Regulations, Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Title 10, Code of Federal Regulations, Part 21, Reporting of Defect and Noncompliance

Title 10, Code of Federal Regulations 830, Nuclear Safety Management, Subpart A, Quality Assurance Requirements

ASME NQA-1-2008, 1a 2009, Quality Assurance Requirements for Nuclear Facility Applications

NEI- 11-XX DRAFT, Nuclear Energy Institute Nuclear Generation Quality Assurance Program Description

NRC Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction), Rev. 4, dated June 2010

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

NRC NUREG 0800, Standard Review Plan, Section 17.5,

NRC Generic Letter 88-18, Plant Record Storage on Optical Disks

IEEE 336-1985, Installation, Inspection and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities

IEEE 498-1985, Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities

IEEE 603-1980, Standard Criteria for Safety Systems for Nuclear Power Generating Stations

National Information and Records Management Association Inc. (NIRMA) Technical Guides (TGs), TG-11-1998, TG-15-1998, TG-16-1998, and TG-21-1998.